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Content

The Hemiplegic Shoulder Trilogy: Pain, Subluxation and Orthosis

Restoring functions of an individual to the highest possible level is the primary goal of every rehabilitation service. After stroke rehabilitation, recovery of the upper extremity is less than the lower extremity. Many are able to walk, but not able to use their weak or paralyzed upper extremity. Flaccid paralysis of the shoulder muscles causes shoulder subluxation and shoulder pain which prevent use of the affected upper limb and limit self-care activities. Therefore, one of the most challenging goals to achieve is recovery of the upper extremity functions.

In this issue, there are two interesting articles about shoulder problems. One is a systematic review on management of shoulder pain in patients with stroke and the other is a clinical trial comparing the effect of a newly designed custom-made shoulder subluxation orthosis and a commercial Bobath sling commonly prescribed for patients with shoulder subluxation.

The systematic review shows the use of supportive devices/slings for shoulder subluxation has only moderate evidence and is moderately recommended. A strong recommendation needs not only a good randomized control trial but also a more effective and appropriate shoulder orthosis. The commercial sling may be easily accessible but not effective enough to reduce the occurrence of shoulder subluxation. Perhaps, the custom-made orthosis presented in the other article would be a good alternative shoulder subluxation orthosis; it is relatively low cost and could be made by occupational therapists. However, this new shoulder subluxation orthosis may not help control shoulder pain as the participants recruited in the study had rather low pain intensity. Therefore, future study should consider not only its effect on shoulder subluxation but also shoulder pain and functional recovery of the upper limbs. This could be the potential solution to facilitating upper limbs recovery in people with stroke in the future.

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Editor-in-chief

Impact of COVID-19 on Medical Rehabilitation Services, Education and Research in Thailand

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Introduction

Emerging infectious diseases, like the coronavirus-19 (SAR-CoV-2; COVID-19) virus which is currently a worldwide pandemic, can have several negative impacts around the globe. In early March 2022, globally there were over four hundred million confirmed cases of COVID-19, including about six million deaths.[1] In Thailand, there have been 2,958,162 confirmed cases of COVID-19 with 23,070 deaths,[1] and the number of daily new cases has continued to rise during January-February 2022.[1] Several healthcare strategies, both prevention and treatment, have been implemented in Thailand to control this disease. "DMHTT" (distancing, mask, hand hygiene, temperature testing) has been implemented for prevention while the "Thai chana" mobile application is for tracing persons at risk of contracting the disease. The word "chana" in Thai means "to win, to conquer" giving the expression of positive meaning that all Thais will ultimately overcome this adversity. Another important national strategy has been developing immunity via vaccination. In Thailand, COVID-19 vaccination was first implemented in late 2020. Available vaccines were first offered to health care personnel, patients with underlying diseases (especially respiratory and cardiovascular diseases), people aged over 60 and frontline immigration officers and essential workers. By February 2022, more than one hundred and twenty million vaccine doses had been administered in Thailand.[1] Guidelines for COVID-19 treatment has been developed and is updated periodically by the Ministry of Public Health (MOPH).[2,3] The latest guideline, dated Nov 2, 2021, suggested about administration of Kariyat which is known in Thai as Far Ta Lai Jone (Andrographis paniculata), a medicinal plant, for the treatment of flu-like symptoms, fever, cough, sore throat, fatigue and muscle pain due to viral infection. The recommended dose for adults is 180 mg/day of andrographolide.[3]

COVID-19 not only causes acute illness but also has long-term consequences. According to the World Health Organization, rehabilitation is an essential part of the health care system which should be integrated into all levels of health system including primary, secondary and tertiary.[4] Since the first case of COVID-19 was detected in Thailand, the roles of physiatrists (rehabilitation physicians) in providing medical rehabilitation services to restore function as well as in providing education and conducting research have been impacted and changed.

Medical rehabilitation services

Early in the COVID-19 pandemic, Thai physiatrists, just as other general practitioners and specialists, were recruited to take part in providing COVID-related medical services and patient care, e.g., screening for the disease and identifying active cases in the community as well as in acute respiratory infection clinics and serving as attending physicians in COVID-19 wards. Some physiatrists voluntarily looked after patients at home and to help with community isolation programs, while some became physicians-in-charge at COVID-19 vaccination service centers.

Rehabilitation services, both at hospitals as well as at the community level, have been affected by both the disease itself and by government policies of lockdown, curfew and travel restrictions. On the 1st of June 2021, the Sirindhorn National Medical Rehabilitation Institute (SNMRI) set up a field hospital for persons with disabilities (PWDs), named the Sirindhorn Science Home Field Hospital, with the cooperation of the Department of Empowerment of Persons with Disabilities and the National Science and Technology Development Agency (NSTDA).[5] This field hospital was established to assist independent asymptomatic and mildly symptomatic COVID-19 PWDs including the physically challenged, the blind and the deaf. Mobile prosthesis services, which normally provide services at least once a year, were temporarily suspended in 2020 to avoid contracting an infection and to prevent disease transmission. The recommended guideline of

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management and immunization program are applied for the PWDs as well.[6]

Rehabilitation programs provided at hospitals or in community had to be changed or adjusted depending on the factors and conditions confronting the healthcare system, e.g., COVID-19 prevalence and virulence, available medical resources including personal protective equipment (PPE), and the state of vaccination of health personnel and the general Thai population. Inpatient rehabilitation services, special rehabilitation investigations and some close contact therapies/ treatments were temporarily discontinued. Manuals for hospital risk management during a pandemic of an emerging infectious disease[7] were developed. Recommendations for provision of medical rehabilitation services during the COVID-19 outbreak were published by a team of physiatrists[8] to ensure proper rehabilitation services and to protect the rehabilitation health personnel from contracting COVID-19 by effective use of PPE. The recommendations included that all rehabilitation programs should be provided in compliance with universal precautions and social distancing policies and that swallowing evaluation as well as swallowing training, speech training and electrodiagnosis should be postponed unless the patient had an exceptional indication and should depend on the judgement of the attending physiatrists and rehabilitation teams.[8,9] At present, testing for COVID-19 by real time polymerase chain reaction (RT-PCR) or using an antigen test kit (ATK) is performed prior to beginning close contact investigations and treatment as mentioned above, including screening before rehabilitation ward admission.

Telemedicine, telerehabilitation and postal medicine delivery are also emphasized.[9] Telerehabilitation services are ignited to replace or to be used concomitant with the usual practices, e.g., patient education, follow-up and monitoring, individual and group exercise, home programs, home visits, speech therapy, and psychological support via phone, video calls and clips, and infographics via various media platforms. Such programs and activities are applied in the case of various medical conditions such as pain, dysphagia, pulmonary and neurological disorders as well as for pediatric patients. The QR codes for COVID-19 and non-COVID-19 patients shown in Figure 1 were produced by rehabilitation departments in Thailand.[10-14] These telerehabilitation services are useful and are compatible with policies such as social distancing and travel restriction.

In the acute phase of COVID-19, patient rehabilitation is mainly performed by distance instruction via brochures and social media, e.g., demonstration video clips. Asymptomatic patients and those with mild symptoms are suggested to receive video clips as part of the patient education service. Breathing exercises are emphasized and monitored by video calls. In patients with severe acute respiratory distress syndrome (ARDS), prone positioning is advised to facilitate re-expansion of a collapsed lung parenchyma, to lessen ventilation-perfusion mismatch, to improve gas exchange and oxygenation and thus to decrease mortality.[8] Experience has taught that some COVID-19 patients hospitalized in the intensive care unit (ICU) may develop post-intensive care syndrome (PICS), and at least a third of moderate to severe COVID-19 survivors suffer from neurological sequelae.[15] In the post COVID-19 phase, some may have post-COVID-19 syndrome or "long COVID", with symptoms including fatigability, shortness of breath, difficulty breathing, and poor endurance.[16] These individuals need rehabilitation programs, including pulmonary rehabilitation, graded reconditioning exercise programs and neurological rehabilitation. Presently, some of the media addressing long COVID-19 rehabilitation are available for Thais in the Thai language (Figure 2).[17,18]

Exercise and physical activity are important tools for rehabilitation. Exercises prescribed for infected patients vary depending on clinical findings. Asymptomatic patients and patients with mild symptoms and without major risk factors can perform light to moderate intensity aerobic and strengthening exercises.[8] A simple sit-to-stand test is recommended for screening for exercise-induced desaturation in COVID-19

Figure 1. QR codes of rehabilitation programs available for COVID and non-COVID patients. A: muscle stretching, B: swallowing training, C: pediatric chest physiotherapy, D: COVID-19 rehabilitation 1 and E: COVID-19 rehabilitation[2]

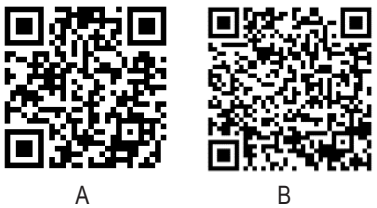

Figure 2. Long COVID. A: media for rehabilitation and B: guidelines for post COVID-19 syndrome

patients who do not have resting hypoxemia. Positive deoxygenation or 3% or more decrease of oxygen saturation (SpO_2) suggests that a patient may develop COVID-19 pneumonia and should be transferred from home or from a community isolation facility, a hospitel (a hostel serving as a hospital) to a hospital for increased safety.[19-21] During recovery from a COVID-19 infection, it is recommended that the individual gradually begin exercising, starting with light intensity aerobic exercise first, then gradually increasing the intensity. Non-infected persons should stay active with aerobic activity such as brisk walking and dancing or with outdoor activities such as walking, bicycling and gardening. Exercise at moderate intensity for 150 minutes per week is recommended. Physical distancing, at least 2 meters from others, is suggested. Individuals at high risk for SARS-CoV-2 exposure should refrain from exhaustive exercise and overtraining.[22]

Rehabilitation medicine education

The Rehabilitation Medicine Residency Training Program has been disturbed by the COVID-19 pandemic. Teaching and learning activities have had to be changed under the prevention scheme for infection control. Certain academic activities and events have been either cancelled or postponed. Nevertheless, during the crisis there has been great opportunity for online versions of those activities, e.g., classroom sessions, academic meetings and scientific conferences. However, hands-on and skill training has been negatively impacted due to a reduction in the number of patients available. Resource material has been reduced by travel restrictions and limitations on the number of inpatient beds for non-COVID-19 patients. This situation has unquestionably decreased the training capacity of medical academic institutes. Elective activities and rotations to other training institutes have been affected from time to time during the country lock down periods following a very high daily infection rate. The Medical Council, the University Hospital Network, MOPH, the Royal College of Physicians of Thailand and the Infection Disease Association of Thailand have established guidelines on safe conditions (environment, vaccination and active surveillance). All training institutes have to follow those guidelines to help ensure the safety of the residents in training.[23] In addition to changes in the learning experience, the Royal College of Physiatrists of Thailand conducted an online oral examination, in-house examination instead of an examination at a central examination facility and has placed emphasis on workplace-based assessment (WPBA) instead of the usual face-to-face exit examinations. The WPBA of the Rehabilitation Medicine Residency Training Curriculum established before the pandemic was revised in 2021 to ensure the appropriateness and completeness of evaluations during training.[24] Advantages of the online oral examination and the evaluation based on WPBA include time saving, cost saving, no travel expense, and minimized risk of both examinees and examiners contracting disease. Disadvantages of the online examination include dependence on the quality of the internet signal and system and limited opportunity to observe the body language and manner of the examinees.

Research in rehabilitation medicine

Research projects conducted by physiatrists and in-training residents have been similarly interrupted during the COVID-19 pandemic due to difficulty in recruiting subjects, more patients lost to follow-up, protocol deviations and drop outs. Methodology modifications and amendments to protocol, e.g., changing from an onsite follow-up to a phone or VDO call, were instituted to allow research work to continue to completion. New research projects conducted by residents in training during this pandemic period are mostly questionnaire-based and/or based on retrospection. However, there is opportunity for case reports,[25] telerehabilitation, and COVID-19-related research.

Conclusions

The COVID-19 pandemic has impacted on rehabilitation services, residency training programs and research. The Royal College of Physiatrists of Thailand, the Sirindhorn National Medical Rehabilitation Institute, and the Rehabilitation Medicine training institutes and their members have had to change their roles and adjust their services, training programs, and research projects so that service recipients, including rehabilitation patients and in-training residents, could receive optimal rehabilitation and educational services. Telerehabilitation and online teaching have partly replaced the traditional face-to-face services and learning experience. Moreover, the DMHTT strategy, the use of PPE, COVID-19 screening policies, and national vaccination policies have been essential means in helping ensure workplace safety and disease prevention. Online learning and evaluation, as well as workplace-based assessment, has been implemented to overcome the interruption of training programs. Research in rehabilitation has also been similarly affected by the pandemic. However, the pandemic situation does allow opportunity for case reports as well as for research on telerehabilitation and for COVID-19 related research.

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Review Article

A Systematic Review of Clinical Practice Guidelines for the Management of Shoulder Pain in Patients with Stroke

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ABSTRACT

Objectives: To assess the quality, scope, and consistency of relevant clinical practice guidelines (CPGs) recommendations for hemiplegic shoulder pain (HSP) management among stroke patients.

Study design: A systematic review of CPGs.

Setting: Publishing regions were North America, Europe, Asia, and Oceania.

Subjects: Adult (≥ 18 years) stroke patients who had HSP.

Methods: Seven databases were used to search for CPGs. A total of 267 articles were screened; 8 guidelines met the inclusion criteria. The Appraisal of Guideline for Research and Evaluation (AGREE-II) was used for evaluating the quality of the selected CPGs.

Results: The recommendations of 5 high-quality guidelines for post-stroke HSP management were synthesized and 5 scopes of consistent recommendations were found comprising assessment, prevention, medical treatment, physical therapy treatment, and management of shoulder subluxation.

Conclusions: The key recommendations proposed that the assessment should evaluate muscle tone and pain level; advice and education be provided to family members and caregivers on how to handle and position the shoulder correctly, and avoid exercises involving overhead pulleys to prevent HSP; medical treatment should consider the administration of analgesics, high doses of botulinum toxin injections, subacromial corticosteroid injections, and suprascapular nerve blocks; and that physical therapy approaches should employ active exercises, taping or strapping, and the management of shoulder subluxation via slings and electrical stimulation. Future up-to-date guidelines should consider all domains of AGREE-II in order to improve their quality.

Keywords: assessment, guideline, hemiplegic shoulder pain, rehabilitation, stroke

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Introduction

Although the current incidence of stroke is declining in most regions worldwide,[1] stroke still remains a serious global health problem, which is a major cause of mortality, morbidity, and disability.[1,2] Stroke is a leading cause of long-term disability;[3,4] between 15.0% and 30.0%[3,5] of stroke survivors have severe and often permanent disabilities, while 40.0% have a moderate disability.[3] As a consequence, many stroke survivors experience difficulties when performing activities of daily living (ADLs) and have a reduced quality of life,[6,7] which may result in secondary complications.[8] Hemiplegic shoulder pain (HSP) is a complex and intense complication following a stroke.[9,10] The incidence of HSP is high;[11] however, it varies between 5.0% and 84.0% depending on the definition of shoulder pain, type, severity, and timing of evaluation.[6,9,11-18] HSP affects the stroke survivors' physical and mental well-being.[13] Persons with HSP experience intense pain[15] resulting in a limited range of motion (ROM),[13] impaired upper limb movement,[14,19] and restricted ability to perform ADLs,[13,17,20,21] which lead to a worsening of their functional status.[20] Moreover, these problems contribute to sleep disorders and depression.[15,17,19,21] This results in poor functional recovery,[12, 3,15,19,21] decreased participation in social activities,[13,17] and a lower quality of life.[12-17,19,21,22]

The precise causes of HSP are still unclear,[10,15,23] but it is hypothesized that multiple factors play a role in its development.[6,11,15,17,18,24] The diverse mechanisms and contributing factors that cause HSP can be present irrespective of recovery stage.[15] Such factors include (1) motor control impairment (e.g., muscle weakness, flaccidity, or limited ROM),[10,15,17,18] (2) soft-tissue lesions (e.g.,shoulder subluxation,adhesive capsulitis,or rotator cuff tear),[10,11,14,15,17,20,25] (3) muscle tone changes (e.g.,spasticity)[10,11,14,17,25] (4) other peripheral and central nervous system dysfunctions (e.g., complex regional pain syndrome (CRPS), brachial plexus injury, peripheral

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nerve entrapment, somatosensory abnormalities, and central post-stroke pain),[10,11,14,15,17,18,20] and (5) psychological factors (e.g., anxiety and depression).[15] These presentations may occur either alone or in combination.[15] Given the fact that HSP has multifactorial causes,and our understanding of its pathogenesis is still unclear,the treatment of stroke patients with HSP is challenging. Even though,various treatment approaches have been advocated,no specific treatment has been shown to be superior.[9,11,14,17,20]

However, the provision of care should be based on clinical practice guidelines (CPGs). Such guidelines are systematically developed based on the current best scientific evidence to assist members of multidisciplinary care teams in various settings. Therefore, educating and encouraging care providers to follow the recommendations of CPG can increase the knowledge of care team members, enhance patient care, reduce practice variance, increase care efficiency, and ultimately improve treatment outcomes for stroke patients.[26,27] Different countries employ different CPGs depending on the context of the country and the guideline developers, thus they vary in content, scope, and detail. Consequently, some differences exist between guidelines in terms of the level of evidence, strength of recommendations, and details of each recommendation.[26] Hence, the purpose of this study was to assess the quality, scope, and consistency of different guideline recommendations using a systematic review of CPGs for HSP management among stroke patients.

Methods

This systematic review was approved by the Human Research Ethics Committee of the Faculty of Medicine, Prince of Songkla University (REC. 64-058-30-2). This study followed the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).

Identification and selection of guidelines and their recommendations

Guideline eligibility was based on the Population and Clinical Areas, Interventions, Comparators, Attributes of CPGs, and Recommendation characteristics (PICAR) framework[28] (Appendix 1) as well as on some adapted criteria from PEDro.[29] The inclusion criteria consisted of CPGs: (1) developed by a government or private health profession association from North America, Europe, Oceania (Australia and New Zealand), and Asia (China, Japan, Korea, and Thailand); (2) developed based on systematic literature review and containing recommendations, methods, or information to guide decisions related to the appropriate management of shoulder pain in stroke patients; (3) intended for adult stroke patients 18 years of age or older, excluding transient ischemic attack; (4) reporting at least one recommendation regarding the management of shoulder pain in stroke patients; (5) published or reported in English or Thai from 1 January, 2016 to 23 February, 2021; and (6) with the latest version selected in case of successive editions.

Search for guidelines

Literature search strategies used medical subject headings and text words related to guidelines for shoulder pain in persons with stroke. The databases consisted of Medline, Cochrane Library, Physiotherapy Evidence Database, American Physical Therapy Association, The National Institute for Health and Care Excellence, Guidelines International Network, and Google Scholar. In addition, reference lists of selected CPGs were screened for additional eligible guidelines. The keywords used in the search for guidelines comprised “cerebrovascular disease,” “stroke,” “post-stroke,” “shoulder pain,” and “guidelines.” Keywords were combined using the Boolean operators “AND” and “OR.” Two investigators (WY and LK) independently screened potential CPGs based on titles and abstracts. Disagreement on inclusion was resolved through discussion with a third investigator (TS). All decisions were made by consensus, and the reasons for excluding guidelines were recorded. The potential full-text guidelines were evaluated in the same manner.

Appraisal of guidelines

The Appraisal of Guideline for Research and Evaluation (AGREE-II) was used to assess the methodological quality of selected CPGs. It consists of 6 domains: (1) scope and purpose, (2) stakeholder involvement, (3) rigor of development, (4) clarity and presentation, (5) applicability, and (6) editorial independence. The 23-item AGREE-II tool uses a scoring system involving 7 levels from 1 (strongly disagree) to 7 (strongly agree). The higher the scores, the greater the methodological quality of the guideline. In this regard, the guidelines that achieved a score equal to or more than 60% (scores for each domain minus the lowest possible score divided by the highest possible score minus the lowest possible score) in domains 1, 3, and 6 were considered to be of a high quality,[28] and their recommendations for the management of shoulder pain in stroke patients were synthesized. Two investigators (WY and LK) assessed the full text of the selected CPGs independently according to the AGREE-II criteria. Total score discrepancies of more than 10% were discussed and re-assessed independently by a third investigator (TS).[29]

Synthesis of guideline recommendations

Using textual descriptive synthesis, the scope, context, and consistency of the selected CPG recommendations were evaluated. Initially, one author (WY) read each selected CPG in order to familiarize himself with the overall information of its content. Then he coded the CPG with the aim of identifying the scopes covered by the guideline. The initial codes were identified and refined via the constant comparison of recommendations in each CPG as the data collection progressed. Finally, the guideline recommendations were compared across CPGs in order to identify any similarities and/or discrepancies related to each scope.[29]

The level of evidence and the degree of recommendations for each CPG were converted into the same format followed the American Heart Association.[6] This scale allows for comparison between the different recommendations of each CPG. It employs 3 levels of evidence–A (strong), B (moderate), and C (low) (Appendix 2). Four degrees of recommendation were adapted from the Oxford Center for Evidence-based Medicine Levels of Evidence. They consisted of: very recommendable, moderately recommendable, not recommended, and controversial (Appendix 3).[30] The authors (WY and LK) compared the selected guidelines in terms of the different scopes they covered, scope consistency, and congruence related to both their content and recommendations. Finally, the recommendations from the high-quality guidelines based on the 23-item AGREE-II tool were synthesized in order to provide an overview of all the identified recommendations.[29]

Results

Search results

The database search found 324 guidelines in total; after removing irrelevant or duplicate guidelines, 267 relevant guidelines remained. After screening the titles and abstracts when available, 244 guidelines were excluded. Twenty-three full-text guidelines were retrieved and reviewed based on the inclusion criteria. Finally, eight guidelines were included in the study analysis (Figure 1).

Selected guideline characteristics

The 8 selected guidelines were published or reported between 2016 and 2020. Seven of them were applicable to all types of stroke, and 1 guideline was developed for ischemic stroke. Two guidelines (2 organizations) were from the United States,[6,31] another 2 (2 organizations) came from Canada,[19,32] 2 more (1 organization) from Thailand,[33,34] and 1 guideline each was developed in the United Kingdom[23] and Australia[35] (Appendix 4).

Methodology quality

The AGREE-II domain scores for each CPG (n=8) are presented in Table 1. The percentages of the total mean domain scores obtained ranged between 35.99% and 83.51%. The mean scores (range) of each domain were: (1) scope and purpose 79.17% (47.22%–100%); (2) stakeholder involvement 64.19% (8.33%–94.44%); (3) rigor of development 65.99% (17.71%–94.79%); (4) clarity of presentation 90.97% (75%–100%); (5) applicability 27.53% (12.5%–60.42%), and (6) editorial independence 59.15% (0%–100%). Five were high-quality guidelines with a score equal to or more than 60% in domains 1, 3, and 6.

Synthesis of recommendations

Only 5 high-quality guidelines were used in recommendation synthesis and comparison. The guideline recommendations were found to be consistent in 5 scopes: assessment, prevention, medical treatment, physical therapy treatment, and management of shoulder subluxation. In brief,

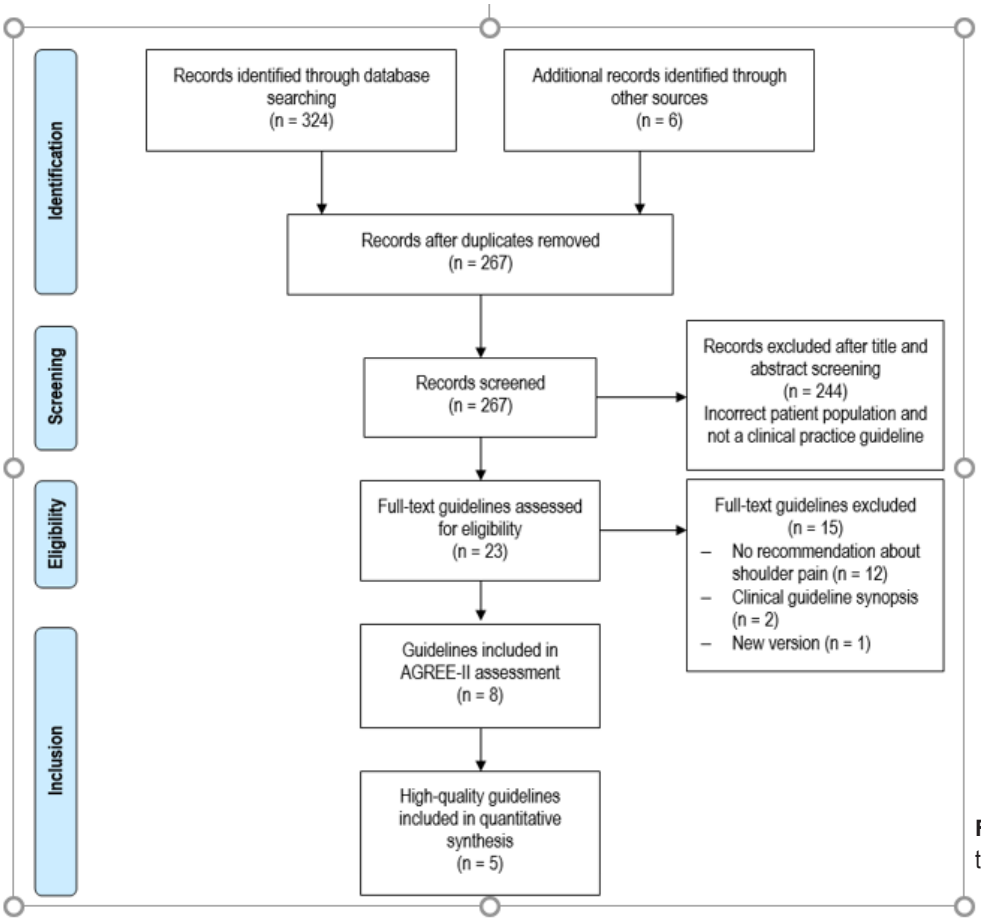

Figure 1. Flow chart of papers through the review

Table 1. Guideline assessment using the AGREE-II instrument (n = 8)

Guideline authors/organization/society	Domain scores (%)						Total mean domain score (%)
	Scope and purpose	Stakeholder involvement	Rigor of development	Clarity and presentation	Applicability	Editorial independence	
USA							
1. U.S. Department of Veterans Affairs and U.S. Department of Defense (VA/DoD)[31]	97.22	94.44	86.46	97.22	16.67	87.5	79.92
2. Winstein CJ, et al.[6] American Heart Association/American Stroke Association	100	52.4	82.1	100	28.6	85.7	74.8
Canada							
3. Teasell R, et al.[19] Heart and Stroke Foundation of Canada	83.33		80.56	78.13	37.5	100	78.07
4. Iruthayarajah J, et al.[32] Heart and Stroke Foundation of Canada and Canadian Partnership for Stroke Recovery	55.56		8.33	64.58	12.5	0	35.99
UK							
5. Rudd AG, et al.[23] Intercollegiate Stroke Working Party	100	86.11	94.79	80.56	39.58	100	83.51
Australia							
6. Stroke Foundation[35]	100	69.44	75	100	60.42	75	79.98
Thailand							
7. Tantiritthisak T, et al. Prasat Neurological Institute, Department of Medical Services, Ministry of Public Health[33]	47.22	55.56	17.71	94.44	12.5	12.5	39.99
8. Masakulpan P, et al. Prasat Neurological Institute, Department of Medical Services, Ministry of Public Health[34]	50	66.67	29.17	91.67	12.5	12.5	43.75

%: Domain scores are calculated by adding all the points of the individual domain items and standardizing the total, as a percentage of the maximum possible score for that domain using the following formula: (Score obtained - Minimum possible score) / (Maximum possible score - Minimum possible score) x 100.

Table 2. Synthesized of high-quality guidelines recommendations for shoulder pain management (n = 5) and their comparison with guidelines from Thailand (n = 2)

Guideline recommendation scopes	1VA/DoD[31]	2Winstein[6]	3Teasell[19]	5Rudd[23]	6Stroke Foundation[35]	7Tantiritthisak[33]	8Masakulpan[34]
1. Assessment							
- Muscle tone		C**	C**				
- Pain level			C**	*		C*	C*
2. Prevention							
- Family or caregivers education; proper protection, positioning, and handling of affected arm			A*	*		C*	C*
- Avoidance of overhead pulley exercises		C*	A*	*		A*	A*
3. Medical treatment							
- Analgesics			C**	*			
- Botulinum toxin		A**	B**		**		
- Subacromial corticosteroid injection		B**	B**	*	**		
- Suprascapular nerve block		B**			**		
4. Physical therapy treatment							
- Active exercise			B*		*	A*	B**
- Taping or strapping			A**		**	A?	
- Patient and family education		C*			*		
5. Shoulder subluxation							
- Positioning		C**			*	C*	C*
- Supportive devices and slings		C**			*	B**	B**
- Electrical stimulation; FES and NMES	**	A**			**	A**	A**

A strong, B modertae, C low, *very recommendable, **moderately recommendable, Xnot recommendable, ?controversial (neither recommended nor disapproved)

FES, functional electrical stimulation; NMES, neuromuscular electrical stimulation.

the synthesized recommendations for the management of shoulder pain in stroke patients are shown in Table 2. A clinical assessment should evaluate muscle tone and level of pain.[6,19,23] The prevention of shoulder pain should focus on the family and caregiver education related to the proper protection,positioning,and handling of the affected arm,for instance,careful positioning and helping to support the affected arm during moves such as transferring the patient and avoiding pulling on the hemiplegic arm. Moreover,patients should avoid overhead pulley exercises.[6,19,23] In terms of medical treatment, patients can be offered analgesics,[19,23] botulinum toxin for those with shoulder pain caused by the spasticity of the muscles surrounding the shoulder joint,[6,19,35] subacromial corticosteroid injections in cases of injury or inflammation in the subacromial region (e.g., rotator cuff or bursa injury),[6,19,23,35] and suprascapular nerve block.[6,35] Physical therapy treatment is recommended via active exercise,[19,35] taping or strapping,[19,35] and patient and family education regarding ROM exercise and positioning is also advised.[6,35] Shoulder subluxation should be treated using advice for proper positioning,[6,35] supportive devices and slings,[6,35] and electrical stimulation (ES) via either functional electrical stimulation (FES) or neuromuscular electrical stimulation (NMES).[6,31,35]

Discussion

The evaluation of the methodology quality of the 8 selected CPGs found that 5 of them were of a high quality and the other 3 had scores less than 60% in AGREE-II domain 1, 3, and 6. Among the selected CPGs, the highest total mean domain score was 83.51% corresponding to the United Kingdom study,[23] meanwhile the study from Canada had the lowest total mean domain score of 35.99%.[32] Clarity and presentation had the highest mean domain score (90.97%), and applicability yielded the lowest one (27.53%). For both Thai CPGs, the total mean domain score was about 40%. There was only 1 domain higher than 60% (clarity and presentation). Therefore, the future Thai CPGs should pay closer attention to the other 5 domains, especially rigor of development, applicability, and editorial independence in order to improve their quality. After synthesizing the contents of the 5 high-quality CPGs, 14 recommendations for the management of shoulder pain in persons with stroke were found consistently between them. Therefore, the adherence to these recommendations by treatment or multidisciplinary teams would constitute a primary quality assurance for the care standard of shoulder pain in stroke patients. In addition, the upcoming Thai guidelines for the management of HSP after stroke should include a recommendation to persistently inquire about shoulder pain in stroke patients with upper limb weakness as well as to perform pain measurement and monitor the severity of the pain using precise instruments. Other treatment approaches that Thai guidelines should consider for the treatment of patients with HSP include analgesics, pain neuromodulation, botulinum toxin, subacromial corticosteroid injections, suprascapular nerve block or surgical tenotomy, and NMES to maximize the potential of achieving the best outcome in these patients.

Assessment

Three of the 5 high-quality guidelines shared the same recommendations for the assessment of shoulder pain; they included muscle tone[6,19] and pain level assessment.[6,23] Moreover, other guidelines recommended that the severity of shoulder pain should be monitored regularly using a validated pain assessment tool, and the impact of pain on physical and psychological health should also be assessed.[19,23] Besides,changes in the length of soft tissues and the alignment of shoulder girdle joints,[19,33,34] active movement,trunk posture,[19] and sensation should be assessed,[6,33,34] and any possible shoulder subluxation should be identified.[6,33,34] In addition,ultrasound may be considered as a diagnostic tool for soft tissue injury in HSP.[6,33,34]

Prevention

Three high-quality guidelines reported the same recommendations regarding the prevention of HSP, i.e., providing relevant education to family members and caregivers and avoiding overhead pulley exercises.[6,19,23] Hence,healthcare staff,patients,family members,and caregivers should be educated adequately on how to properly protect, position,and handle the affected arm—for instance, while transferring the patient from wheelchair to bed and vice versa and the need to avoid pulling on the hemiplegic arm.[19,23,33]

Medical treatment

Four of the 5 high-quality guidelines recommended the use of medical treatment for HSP consisting of analgesics,[19,23] botulinum toxin,[6,19,35] subacromial corticosteroids injections,[6,19,23,35] and suprascapular nerve block.[6,23] Analgesics, such as ibuprofen or narcotics, can be used regularly simply to reduce HSP-related pain without any contraindications.[19,23,26] Botulinum toxin injections are beneficial for pain relief in persons with HSP related to upper extremity spasticity involving muscles such as the pectoralis and subscapularis.[6,19,26,32,35,36] It has been reported that high doses (500U) of botulinum toxin are required to improve pain and ROM.[12] Furthermore, subacromial corticosteroid injections may be used in cases of injury or inflammation of the subacromial area such as the rotator cuff or bursa.[19,23,26,32,35] However, suprascapular nerve block injections, e.g., using methylprednisolone and bupivacaine, may be used as an adjunctive intervention to reduce shoulder pain.[6,12,32,35]

Physical therapy treatment

The recommendations of 3 from the 5 high-quality guidelines consisted of physical therapy treatment involving active exercise,[19,35] taping or strapping,[19,35] and providing advice and education to patients and their family members.[6,35] Active ROM exercises should be implemented gradually, along

with alignment restoration and exercises to strengthen weak muscles around the shoulder girdle in order to improve limb function.[19,26,33-35] Aggressive ROM exercises, such as those involving overhead pulleys, increase HSP compared to those that do not employ pulley exercises.[12,33,34] Therefore, the use of overhead pulley exercises should not to be used in stroke patients.[6,19,23,26,32-34] Moreover, taping or strapping the hemiplegic shoulder can be used to relieve pain[12,19,32,35] and prevent the incidence of shoulder pain.[34] Patient and family education regarding ROM exercises, shoulder positioning, and proper patient transfer,[6,34,35] especially before discharge or transitions in care, is recommended for HSP treatment following a stroke.[6]

Shoulder subluxation

Three of the 5 high-quality guidelines gave consistent recommendations about shoulder subluxation management consisting of positioning,[6,35] supportive devices and slings,[6,35] and ES.[6,31,35] Both positioning and correct manual handling of the hemiplegic shoulder have been identified as strong recommendations to prevent and minimize shoulder subluxation. For example, when the patient is in the upright position such as sitting or standing, hemiplegic arm should be supported with pillows or slings, movements that can cause injury to the affected arm, e.g., excessive ROM, should be avoided, as should shoulder movements of more than 90 degrees during shoulder flexion or abduction, unless the scapula is upwardly rotated and the humeral head is in external rotation, and pulling on the affected arm when transferring the patient.[6,33-35] In addition, a suitable sling can be used to reduce shoulder subluxation[33,34] both at rest[6,12,36] or when standing or walking.[35] Moreover, firm support devices such as a lap-tray may be used for the management of shoulder subluxation.[6,35,36] ES, such as FES or NMES, may be also used to prevent or diminish shoulder subluxation; stimulation at the supraspinatus, posterior deltoid, and long head of biceps muscles is recommendation,[6,31,33-35] particularly in the first six months following a stroke.[35]

There are some limitations to this systematic review. Firstly, the CPGs involved came only from certain countries; thus, the study sample may not cover all the regions around the world. Secondly, AGREE-II is an assessment tool that focuses on the CPG development process, but it does not assess the content of the CPG recommendations.[29]

Conclusions

Five of the 8 selected CPGs were determined to be high-quality guidelines. Five scopes of consistent recommendations for HSP management in stroke patients were identified–assessment, prevention, medical treatment, physical therapy treatment, and management of shoulder subluxation. However, for the development of up-to-date CPGs in the future, all domains of the AGREE-II should be considered in order to improve the quality of guidelines.

Disclosure

The authors declare that they have no conflict of interest regarding the publication of this review article.

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Appendix

Appendix 1. PICAR framework for guideline-specific criteria.

	Guideline-specific criteria
Population and clinical condition	- Adult (≥ 18 years) stroke patients who had shoulder pain, excluding transient ischemic attack
Interventions	- Any interventions
Comparators	- Any comparators
Attributes of eligible CPGs	- Language: Available in English or Thai - Year: Published from 1 January, 2016 to 23 February, 2021 - Publishing region: North America, Europe, Oceania (Australia and New Zealand), and Asia (China, Japan, Korea, and Thailand) - Version: Latest version only - Development: A government or private health profession association - System of rating evidence: Systematic literature review and containing recommendations, methods, or information to guide decisions related to the appropriate management of shoulder pain in stroke patients - Scope: National or international guidelines in the management of shoulder pain in patients with stroke - Recommendations: At least one recommendation regarding the management of shoulder pain in stroke patients - Minimum quality score: A score of ≥60% in AGREE-II domains 1, 3, and 6
Recommendation characteristics	- Any recommendations for the management of shoulder pain in patients with stroke

PICAR, Population and Clinical Areas, Interventions, Comparators, Attributes of CPGs, and Recommendation characteristics

Appendix 2. Level of evidence of guideline recommendations.

Level of Evidence	Type of Study	Level of Confidence
A	Systematic review Meta-analysis	Strong
B	Randomized clinical trial Non-randomized clinical trial	Moderate
C	Case studies Opinion of expert committee	Low

Appendix 3. The degree of guideline recommendations according to the Oxford Center for Evidence-based Medicine Levels of Evidence.

Grade of Recommendation	Meaning
*	Very recommendable
**	Moderately recommendable
X	Not recommended
?	Controversial (neither recommended nor disapproved)

Appendix 4. Characteristics of included guidelines (n = 8)

	Guideline authors/organization/society	Guideline name(s)	Year of publication	Type of stroke
	USA			
1	U.S. Department of Veterans Affairs and U.S. Department of Defense (VA/DoD)[31]	VA/DoD clinical practice guideline for the management of stroke rehabilitation	2019	All
2	Winstein CJ, et al.[6] American Heart Association/American Stroke Association	Guidelines for adult stroke rehabilitation and recovery: a guideline for healthcare professionals from the American Heart Association/American Stroke Association	2016	All
	Canada			
3	Teasell R, et al.[19] Heart and Stroke Foundation of Canada	Canadian stroke best practice recommendations: rehabilitation, recovery, and community participation following stroke. Part one: rehabilitation and recovery following stroke; Updated 2019	2020	All
4	Iruthayarajah J, et al.[32] Heart and Stroke Foundation, Canadian Partnership for Stroke Recovery	Evidence-based review of stroke rehabilitation	2018	All
	UK			
5	Rudd AG, et al.[23] Intercollegiate Stroke Working Party	National clinical guideline for stroke: 5th edition	2016	All
	Australia			
6	Stroke Foundation[35]	Clinical guidelines for stroke management	2017	All
	Thailand			
7	Tantiritthisak T, et al.[33] Prasat Neurological Institute, Department of Medical Services, Ministry of Public Health	Clinical practice guidelines for ischemic stroke	2019	Ischemic stroke
8	Masakunpan P, et al.[34] Prasat Neurological Institute, Department of Medical Services, Ministry of Public Health	Clinical practice guidelines for stroke rehabilitation	2016	All

Original Article

Efficacy of a Newly Designed Custom-Fitted Shoulder Subluxation Orthosis for Stroke Patients: A Single-Blinded Crossover Randomized Controlled Trial

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ABSTRACT

Objectives: To compare the efficacy of a newly designed custom-fitted shoulder subluxation orthosis (SSO) with a commercial Bobath sling for shoulder subluxation in stroke patients.

Study design: A single-blinded crossover randomized controlled trial.

Setting: Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand.

Subjects: Sixteen post-stroke patients with hemiplegia/hemiparesis

Methods: A radiologist measured the acromiohumeral (AH) distance in anterior-posterior view radiographs of normal and affected shoulders of patients in a sitting position when not using any orthosis, when wearing a Bobath sling which supports the proximal humerus only, and when wearing an SSO. Comparison of the AH distance was conducted using the paired t-test.

Results: Without any orthosis, the mean (SD) of the affected and normal shoulders were 47.9 (7.5) and 36.2 (4.6) mm, respectively. The AH distance of the affected shoulder while wearing SSO was reduced to 36.8 (4.7) mm which is not statistically significant different from the normal shoulder distance ($p = 0.49$), whereas the mean AH distance wearing a Bobath sling was only reduced to 44.9 (7.7) mm., statistically significantly greater than the normal shoulders ($p < 0.01$).

Conclusions: The newly designed custom-fitted proximal-distal type shoulder subluxation orthosis for hemiplegia/hemiparesis patients, can reduce the AH distance significantly closer to that of a normal shoulder than a Bobath sling.

Keywords: shoulder subluxation, radiograph, orthosis, stroke, rehabilitation

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Introduction

Stroke is a major health problem in Thailand, with an incidence of up to 250,000 cases per year. It results in approximately 50,000 deaths per year and is the leading cause of death and disability in Thailand.[1]

Shoulder pain is a common stroke complication, found in up to 33.9% of stroke patients.[2,3] Multiple causative factors for shoulder pain have been proposed due to the complex anatomy and biomechanics of the shoulder. Shoulder subluxation is often a suspected cause. In some studies, a higher prevalence of post stroke shoulder pain was found in patients with shoulder subluxation.[4-6] Both the shoulder pain and subluxation interfere with rehabilitation and negatively affect quality of life,[7-11] making prevention of shoulder subluxation and the reduction of shoulder pain and its complications an important goal.

Currently, there are many methods to help prevent and reduce shoulder subluxation in stroke patients, e.g., shoulder orthosis, positioning of shoulder, and neuromuscular electrical stimulation. Shoulder orthosis support methods can be divided into 3 main types according to the point of support. The first type is proximal humeral support (P-S) which supports only proximal part of the upper extremity. The second type is whole arm with elbow flexion support (Wh-S) which supports the entire upper arm and keeps the elbow in the flexed position. The last is the proximal distal support (P-D-S) which supports both the proximal and distal parts of the upper extremity.[11]

A systematic review of published reports found that the shoulder orthoses that provide the greatest shoulder subluxation reduction is the Wh-S, followed by the P-D-S and, finally, the P-S type. Although the P-D-S type reduces subluxation slightly less than the Wh-S type, unlike the Wh-S orthosis, it does not limit elbow motion,[11,12] allowing the elbow to move more naturally. However, the P-D-S type shoulder orthoses are not available in Thailand and imported P-D-S orthoses are expensive.

At our institute, only the Bobath sling (P-S type) is widely available and generally prescribed for stroke patients in spite of its limitations, i.e., according to several studies, the P-S shoulder orthosis is unable to clinically significantly reduce shoulder subluxation.[13] An occupational therapist (BC) on

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our rehabilitation team recently designed a custom-fitted shoulder subluxation orthosis (SSO). The SSO, classified as a P-D-S type, can be made from locally available materials, making it both easily accessible and inexpensive. The objective of this study was to evaluate the efficacy of the SSO and to compare it with the Bobath sling in reducing shoulder subluxation in hemiplegic/hemiparetic stroke patients.

Methods

Study design

This single-blinded crossover randomized controlled trial was approved by the Institutional Review Board, Faculty of Medicine, Ramathibodi Hospital (approval number ID 12-60-02).

Participants

Post-stroke patients at our hospital with the following characteristics were recruited during March to December 2018: shoulder subluxation more than 5 mm as measured by physical examination; able to sit without support for at least 30 minutes and willing to participate in the study, including giving written informed consent. Patients were excluded if they had bilateral hemiplegia, were unable to communicate, had neurological, muscular or bone conditions other than stroke that affected movement of the shoulder, or declined participate in the study. The sample size was calculated with the power of 0.8, 5% type I error and 20% type II error, resulting in total of 16 subjects.

Materials

The newly designed custom-fitted SSO was made using ethylene vinyl acetate (EVA) foam sheet, canvas fabric, cloth straps, elastic bands, 3 oval loop rings, Velcro straps, a tape measure, scissors and a sewing machine. The device is divided into proximal and distal parts (Fig. 1). The proximal part rests on the weak or hemiplegic shoulder and the strap from the posterior crosses under the opposite axilla to the front. The distal part wraps around the forearm and is connected to the proximal part by anterior and posterior straps. The posterior strap also passes behind elbow. All straps are adjustable. The cost is about 400-500 baht and requires about 45-60 minutes to make. A petty patent has been applied for with the Department of Intelletual Property, Ministry of Commerce, Thailand (application number 2103000837 Date March 19th, 2021).

The commercial Bobath slings used in the study are available in 3 sizes, small, medium and large, with the appropriate size is determined based on the circumference of the mid arm.

Intervention

The objectives of the study and the research methods were explained to all participants. Patients were randomly assigned to first apply either the SSO or the Bobath sling to the affected shoulder, then later to apply the other type. Randomization was done using a sealed envelope method. Application of both orthoses was done by the same occupational therapist assistant who had been previously trained by a qualified occupational therapist. The rest time between each orthosis application was 5-10 minutes during which participants sat with their arm hanging at the side of their body.

Four anteroposterior radiographs of both shoulders in sitting position (Fig. 3) were taken, the first and the second without any shoulder orthosis, the third and the fourth with either the SSO or the Bobath sling according to the randomization. The acromiohumeral (AH) distances were measured by a radiologist who was blinded to the type of orthosis used.

Demographic data, including age, gender and medical history, were collected. Participants assessed their level of pain using a visual analog scale (VAS), and the researcher (PP), a physiatrist, assessed shoulder range of motion (ROM), muscle tone using modified Ashworth Scale (MAS) and the muscle strength of the deltoid muscle.

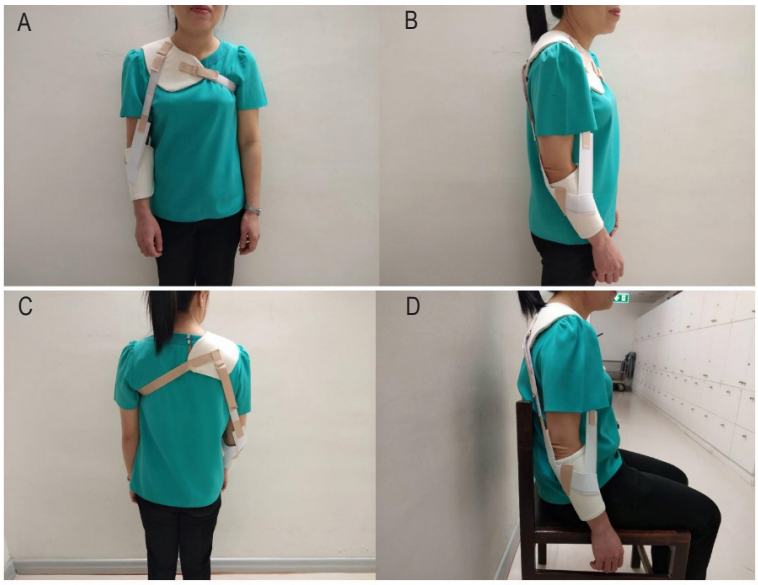

Figure 1. The newly designed shoulder subluxation orthosis in anterior (A), lateral (B) and posterior view (C), and sitting position for radiographs (D)

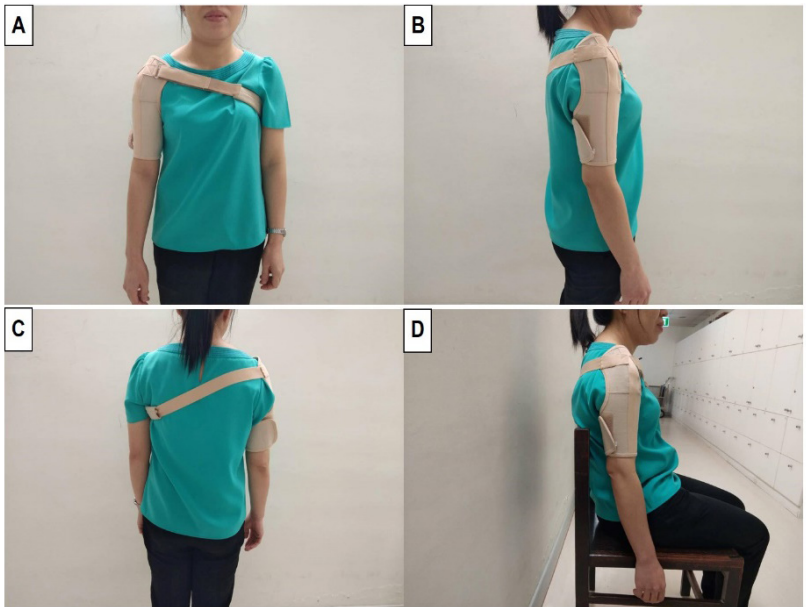

Figure 2. The Bobath sling in anterior (A), lateral (B) and posterior view (C), and sitting position for radiographs (D)

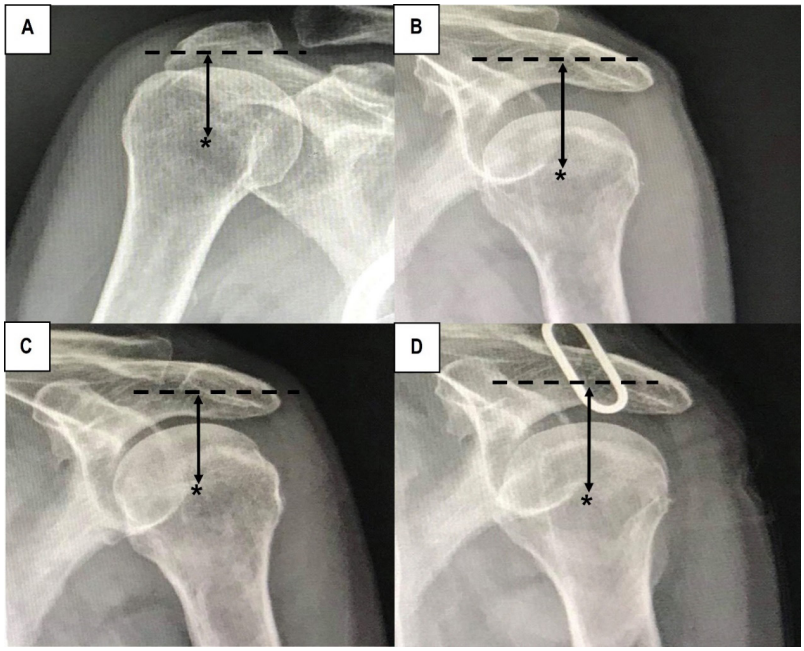

Figure 3. The acromiohumeral (AH) distance measurement in anteroposterior view of a shoulder radiograph: (A) normal shoulder, (B) affected shoulder without orthosis, (C) affected shoulder wearing a shoulder subluxation orthosis (SSO), (D) affected shoulder wearing a Bobath sling. In the figures, an asterisk * marks the center of the humeral head, a double arrow line represents the AH distance, and a horizontal dotted line shows the most inferolateral level of the acromioclavicular joint.

Outcome measurements

The primary outcome of this study was the AH distance, the vertical distance from the most inferolateral surface of acromioclavicular joint to the center of humeral head (Fig. 3).[16]

Statistical analysis

SPSS version 21 was used for data analysis. The demographic data were defined using descriptive statistics, i.e., frequency, mean and standard deviation (SD). The AH distance between the normal and affected shoulders, the AH distance of the affected shoulder without a shoulder orthosis and wearing each type of shoulder orthosis, and the difference in AH distance between the two orthoses was analyzed using the paired t-test. The statistical significance level was set at a $p < 0.05$.

Results

Table 1 shows the demographic characteristics and clinical findings of the 16 stroke participants.

The normal and the affected shoulders had a mean AH distance (SD) of 36.2 (4.6) and 47.9 (7.5) mm, respectively. Table 2 shows the AH distance while wearing the different orthoses. The AH distance of the affected shoulder was reduced significantly when wearing both orthoses; however, the AH distance with the SSO approached that of the normal shoulder ($p = 0.49$), but not with the Bobath sling ($p < 0.01$). The mean distance reduction was significantly greater with the SSO than with the Bobath sling (11.1 vs 3.0 mm, $p < 0.01$).

Discussion

In this study, the efficacy of the SSO, our newly designed custom-fitted P-D-S shoulder orthosis, was evaluated and

Table 1. Demographic data (n = 16)

Characteristics	
Age (years)[1]	61.5 (12.1) [37.0-77.0]
Sex (male : female)[2]	10 : 6
Affected side (right : left)[2]	4 : 12
Shoulder pain VAS score[3]	2.7 (2.2)
Etiology of stroke (ischemic : hemorrhagic)[2]	12 : 4
Affected shoulder ROM[3]	
Flexion : abduction	137.5 (31.7) : 140.6 (31.3)
Internal rotation : external rotation	65.0 (24.2) : 71.9 (28.2)
Affected shoulder spasticity[2]	
MAS 0-1	8
MAS 1+	8
Manual muscle test of deltoid muscle[2]	
Grade 0-1	5
Grade 2	11
Time since diagnosis (months)[3]	5.8 (3.8)

[1]Mean (SD) [range], [2]number, [3]mean (SD)

MAS, modified Ashworth scale; ROM, range of motion; SD, standard deviation; VAS, visual analog scale

Table 2. Acromiohumeral (AH) distance in millimeters (mm) of the normal and affected shoulders and AH distance reduction while wearing the shoulder subluxation orthosis (SSO) and the Bobath sling

AH distance (mm)				AH distance reduction (mm)	
Normal shoulder	Affected shoulder			Affected shoulder	
	Without orthosis	With SSO	With Bobath sling	With SSO	With Bobath sling
36.2 (4.6)	47.9 (7.5)	36.8 (4.7)[a,b] $p < 0.01$[a] $p = 0.49$[b]	44.9 (7.7)[a,b] $p < 0.01$[a] $p < 0.01$[b]	11.1 (5.2)[c] $p < 0.01$[c]	3.0 (2.4)

Mean (SD)

Paired t-test statistical significance level < 0.05, [a]comparison between with and without orthosis, [b]between the affected and normal shoulders, and [c]between using the SSO and the Bobath sling

compared to the Bobath sling which is a P-S type. We found that both types of shoulder orthoses could reduce shoulder subluxation in stroke patients. However, support from the SSO could reduce the AH distance much more than the Bobath sling, approaching the distance of the normal shoulder. The results of this study are in congruence with a previous systemic review study which reported that application of P-D-S and Wh-S shoulder orthoses for the hemiplegic shoulders can help in reducing shoulder subluxation better than P-S type orthoses.[11,12]

In our study, the Bobath sling was shown to reduce shoulder subluxation statistically significantly, but not clinically significantly, which is in line with a previous study.[13] The upward force to support the upper extremity relies only on the proximal support wrapped around the arm. The arm is cylindrical in shape and is composed predominantly of soft tissue. As a consequence, the upward force is not transferred to the bone effectively. This is probably the cause of the lower efficacy of the Bobath sling compared to the P-D-S type.

To the best of our knowledge, two designs of P-D-S are available, GivMohr® sling and OmoNeurexa, both of which have been studied for their efficacy. The GivMohr® sling can decrease shoulder subluxation better than the Rolyan humeral cuff, a P-S type, which cannot significantly reduce shoulder subluxation. The GivMohr® sling is also able to reduce the AH distance closer to that of the normal shoulder side.[17,18] The other P-D-S type shoulder support, OmoNeurexa, can also reduce shoulder subluxation by approximately 8 mm, statistically significantly more than the Bobath sling.[11,15,17]

The other type of shoulder orthosis, the Wh-S type, includes the Harris Hemi Sling and the ordinary triangular bandage. A systematic review showed that the Wh-S type can provide the greatest reduction in shoulder subluxation among the three types, but it restricts the elbow to the bent position which probably increases spasticity and may even cause elbow flexion contracture.[11,12,17] In contrast, the P-D-S and P-S types allow the elbow to move freely, thus permitting the upper extremity to swing naturally during ambulation. As a result, application of Wh-S is limited. Overall, the P-D-S shoulder orthosis seems to be the best for subluxation in hemiplegic shoulders. However, the GivMohr® sling and OmoNeurexa are not generally available in Thailand and the cost of importing these items is high. Our rehabilitation team designed a new P-D-S orthosis, the SSO, which provides good efficacy and can be custom made for each patient in less than an hour from available materials and at an affordable cost.

The probable mechanisms behind the superior efficacy of the SSO may include the following. The distal support grabs the forearm well because there is less soft tissue around the forearm bones so. That, together with the anterior and posterior straps connected to the proximal part providing upward force, transfers more of the orthosis support to the bone. The posterior strap, which passes behind elbow, pushes the elbow into extension, transferring the upward force to the shoulder more effectively. The upshot is that the shoulder joint is adequately supported and subluxation is reduced.

The SSO and the P-D-S type shoulder orthoses, GivMohr® sling and OmoNeurexa, both utilize a similar mechanism. The SSO is similar to the OmoNeurexa, but there are differences in the designs. The proximal and distal support of both types of orthoses have a large contact surface area, and hence provide good force distribution. However, the OmoNeurexa requires more adjustment to fit the device to the individual patient, thus making it potentially more problematic to put on. The GivMohr® sling, unlike the SSO, provides proximal support from the shoulder harness and distal support at hand. However, the proximal and distal support of GivMohr® sling both have less contact surface area and thus less distribution of force which may negatively affect wearer comfort. Each of these 3 P-D-S type shoulder orthoses are different in design, proximal and distal support, and points of adjustment. Only the SSO can be custom-made for each patient, making it fit more comfortably, even for patients with extremely small or large body size, and allowing easier adjustment during donning.

This research demonstrated only the immediate effects of the SSO. Previous studies of long-term effects of shoulder orthosis wear by stroke patients has revealed that wearing an appropriate shoulder orthosis continuously for more than 4 weeks can improve gait pattern by normalizing muscle activation and allowing more symmetrical walking.[11,15,19] Further research on the long-term efficacy of the SSO, including not only reduction of shoulder subluxation and pain, but also evaluation of patients' walking and balance, level of satisfaction, convenience in donning and doffing, and compliance with long term use recommendations as well as durability of the orthotic itself are suggested.

Conclusions

The newly designed custom-fitted shoulder subluxation orthosis, which is classified as a proximal-distal-support type, can significantly reduce shoulder subluxation both statistically and clinically more than the Bobath sling, a proximal-support type. The SSO can effectively support the affected upper extremity and can reduce the acromiohumeral distance close to that of the normal, unaffected shoulder.

Disclosure

The authors declare no conflict of interest of any kind.

Acknowledgements

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Original Article

Clinical Outcomes between Using Prefabricated Toe Sleeve versus Toe Separator in Patients with Painful Hallux Valgus: A Single-Blinded Randomized Control Trial

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ABSTRACT

Objectives: To compare clinical outcomes between using a prefabricated foot-toe orthosis, a toe sleeve and a toe separator in treating painful hallux valgus/bunion.

Study design: A single-blinded randomized controlled trial.

Setting: Ramathibodi Hospital, Bangkok, Thailand.

Subjects: Patients with painful hallux valgus/bunion aged between 25 and 70 years old

Methods: Patients were randomly divided into two groups: a toe separator and a toe sleeve group, both received the same treatment protocols. Primary outcomes were pain using a visual analog scale (VAS) and functions using visual analog scale-foot and ankle (VAS-FA) at one- and three-month follow-ups, and patient compliance with adherence to daily use of the orthosis as a secondary outcome.

Results: Compared with the baseline, the mean VAS at one- and three-month follow-ups statistically significantly decreased in both groups [the toe sleeve group: 55.72, 21.72 and 19.33 (p < 0.01); the toe separator group: 66.00, 42.67 and 42.17 (p < 0.01) respectively]. The mean VAS-FA at both follow-ups statistically significantly increased in both groups [the former toe sleeve group:75.89, 88.67 and 83.83 (p = 0.01), the toe separator group: 53.72, 65.33 and 71.17 (p < 0.01), respectively]. The toe sleeve group showed significantly lower VAS scores than the toe separator group at both follow-ups, whereas the VAS-FA did not differ.

Conclusions: The toe sleeve significantly reduced pain better than the toe separator did in patients with hallux valgus at 1 and 3 months after usage. The VAS-FA also significantly improved in both groups without a significant inter-group difference. Both, a toe sleeve and a toe separator, improved functions.

Keywords*:* bunion, foot orthoses, hallux valgus, pain

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Introduction

Hallux valgus represents the most common forefoot deformity. The prevalence of this disease is 23-35 percent in the population aged over 18 years old.[1] The overall deformities of hallux valgus are a valgus deviation of the big toe, a pronation of the big toe, and a prominent medial aspect of the first metatarsophalangeal joint formed by a pronation of the first metatarsal bone with imbalanced intrinsic-extrinsic foot muscles and a ligamentous structure of the first ray.[2] The etiology of this disease is still not fully understood, but the predisposing factors of the disease include types of footwear, occupations, history of trauma, pes planus, and ligamentous laxity.[2] Hallux valgus can be both symptomatic and asymptomatic. Up to 75% of symptomatic patients complain about bunion pain or pain on the medial prominent of the first metatarsophalangeal joint.

The first-line treatments of hallux valgus/bunion are conservative methods,[3-5] such as modification of footwear, a specific hallux night splint,[6] a toe separator,[6-8] kinesiotaping,[9-10] manipulative therapy,[11] and a toe sleeve. A toe separator helps reduce the abduction of the big toe with a less prominent bunion. A custom-molded toe separator and a combined toe separator with a custom-molded insole are reported to help reduce pain and improve patients' abilities.[6,8] A toe sleeve is a silicone tube expanded to cover the bunion area and acts as a bumper between the bunion and the footwear.[12] Combined with the footwear modification, the toe sleeve can reduce compression and attrition between the footwear and the bunion, alleviating bunion pain as a result.[12]

Nowadays, there are many prefabricated foot-toe orthoses for treatment of hallux valgus or painful bunion available. People can buy at drug stores without need of doctor's prescription. Based on our observation, the toe sleeve might reduce the pain at the bunion better than the toe separator

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due to direct reduction of attrition between bunion and shoe. However, there have been no studies comparing between the use of a prefabricated toe sleeve and a prefabricated toe separator. This study aimed to compare clinical outcomes between the above-mentioned foot-toe orthoses.

Methods

We conducted a single-blinded randomized controlled trial at Ramathibodi Hospital, Thailand, between 2015-2017. After approved by the Institute Review Board of Ramathibodi Hospital, and the trial was registered in the Thai Clinical Trials Registry with the ID TCTR20200506003.

Participants

We enrolled patients with hallux valgus. The diagnosis of hallux valgus was confirmed by the weightbearing foot radiograph demonstrating either an intermetatarsal angle over 9 degrees or hallux valgus angle over 15 degrees.[12] The inclusion criteria were age between 25 and 70 years old, and a complaint of bunion pain. We excluded patients with osteoarthritic changes of the first metatarsophalangeal joint, a history of significant foot injury that affected their normal abilities, neuromuscular disorders, inflammatory joint disease, post infection of the first metatarsophalangeal joint, and allergies to non-steroidal anti-inflammatory drug (NSAIDs) acetaminophen and silicone. Drop out criteria were the patient who did not use foot-toe orthoses or not come to follow-up as schedule.

The sample size was calculated by using the mean visual analog scale (VAS) score from a study of Tehraninasr et al.[6] with alpha = 0.05 and beta = 0.10. The calculated sample size was 18 participants per group.

Randomization

The randomization was done by using a block size of four, generated by STATA 11.0 and concealed by an opaque envelope.

Intervention

The recruited patients were divided into two groups: a toe sleeve and a toe separator group. All participants were instructed to use the prescribed orthosis for at least 7 hours a day, 5 days a week, especially while doing physical activities, such as walking, running, or standing for a long period of time, and record the duration of usage in the logbook. Both groups were advised to wear shoes of one size larger to prevent overstuffing of the foot-toe orthosis and instructed to take either 500 mg of acetaminophen orally every 6 hours or 250 mg of naproxen twice a day after every meal for severe pain and record in a logbook.

The participants' baseline characteristics were recorded. The participants were followed up at one- and three- month for assessment of VAS and visual analog scale-foot and ankle (VAS-FA) after using the prescribed orthosis.

Materials

In the toe separator group, the participants were instructed to wear a prefabricated toe separator, a standard size firm curve silicone rubber (e-life orthopedic, Taiwan) (Figure 1 A).

In the toe sleeve group, the participants were instructed to wear a soft, stretchable fabric fully coated with proprietary polymer gel and one-sided recess to cover the bunion area, size L/XL (SILIPOS, USA) (Figure 1 B). Both foot-toe orthoses were approved by the Thai-FDA.

Outcomes

VAS and the Thai version of VAS-FA were the primary outcomes of the study. VAS was rated by the participants to quantify bunion pain, ranged from 0 (no pain) to 100 (extreme pain). The Thai version of VAS-FA is a validated functional scale which consists of 20 questions about pain (4 questions), functions/abilities (11 questions) and other complaint (5 questions).[13] The total point for entire scaling system is 2,000 points which is then divided by 20, resulting in score ranging 0 (extreme pain and limited function) to 100 (no pain and normal functions).[13]

In addition, patient adherence to the instruction of using the prescribed orthosis, the daily usage (hours), was recorded by participants in a provided logbook.

Statistical methods

The means of both VAS and VAS-FA at baseline were compared by student's t-test. The mean adherence in terms of usage hour was compared by student's t-test. Comparison the mean of VAS and VAS-FA in each group at baseline, and 1 and 3 months after treatment was done using repeated ANOVA. Comparison the mean of VAS and VAS-FA between the toe sleeve and the toe separator groups was done using ANCOVA, taking into account the significant difference at baseline of VAS-FA and possible confounding effects by

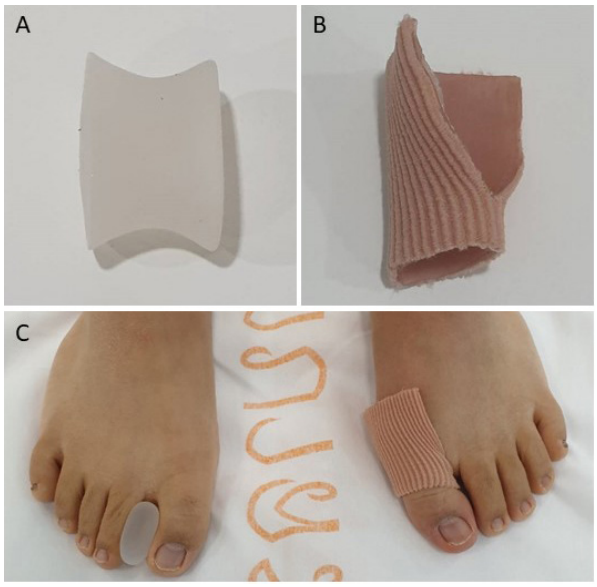

Figure 1. Two types of foot-toe orthoses used in this study: (A) a toe separator, (B) a toe sleeve and (C) showing how the orthoses are used

adherence to treatment. All statistical analyses were done by SPSS version 15 with statistical significance defined as $p < 0.05$. The participants were analyzed based on the intention-to-treat principle.

Results

Thirty-six participants were included in this study. All were female except one male participant in the toe separator group. There was no significant difference in the mean values of the baseline characteristics, hallux valgus angle, intermetatarsal angle, and VAS as shown in Table 1. The ranges of VAS were 13 to 84 in the toe sleeve group and 21 to 91 in the toe separator group. The baseline VAS-FA was, however, significantly different between the two groups, with the means of 53.72 and 75.89 ($p < 0.01$) in the group treated with a toe separator and the group treated with a toe sleeve, respectively (Table 1). There was no participant dropout during the study (Figure 2).

Within group analysis

The mean VAS-FA of both groups increased significantly at both follow-ups (Table 2). respectively. When using repeated-measure ANOVA, both groups were significantly different across the three time points. Post-hoc analysis shown a significant increase of VAS-FA at 1-month follow-up compared to baseline in the toe sleeve group whereas in the toe separator group VAS-FA was increased significantly at 3 months follow-up (Table 3).

Comparison between groups

By using ANCOVA, mean VAS was significant difference between the two groups at 1-month ($p = 0.01$) and 3-month follow-up ($p < 0.01$) (Table 4).

When comparing the mean VAS-FA between two groups at 1-month and 3-month follow-ups (Table 4), no significant difference was observed between the two groups at both time points ($p = 0.10$ and 0.59).

Table 1. Baseline characteristics, baseline disease profile and adherence: mean and standard deviation.

	Toe-sleeve (N = 18)	Toe-separator (N = 18)	*p*-value
Age (years)	51.50 (12.00)	48.00 (12.00)	0.38
Body mass index (Kg/m^2)	21.44 (2.06)	20.61 (2.09)	0.23
IMA (degree)	14.50 (2.40)	14.11 (1.50)	0.56
HVA (degree)	28.11 (5.00)	28.22 (4.00)	0.94
VAS (mm)	55.72 (20.86)	66.00 (14.68)	0.09
VAS-FA (mm)	75.89 (14.01)	53.72 (10.65)	< 0.01*

IMA, intermetatarsal angle; HVA, hallux valgus angle; VAS, Visual analoque scale; VAS-FA. visual analogue scale-Foot and ankle (Thai)
p-value comparing the mean between two groups.

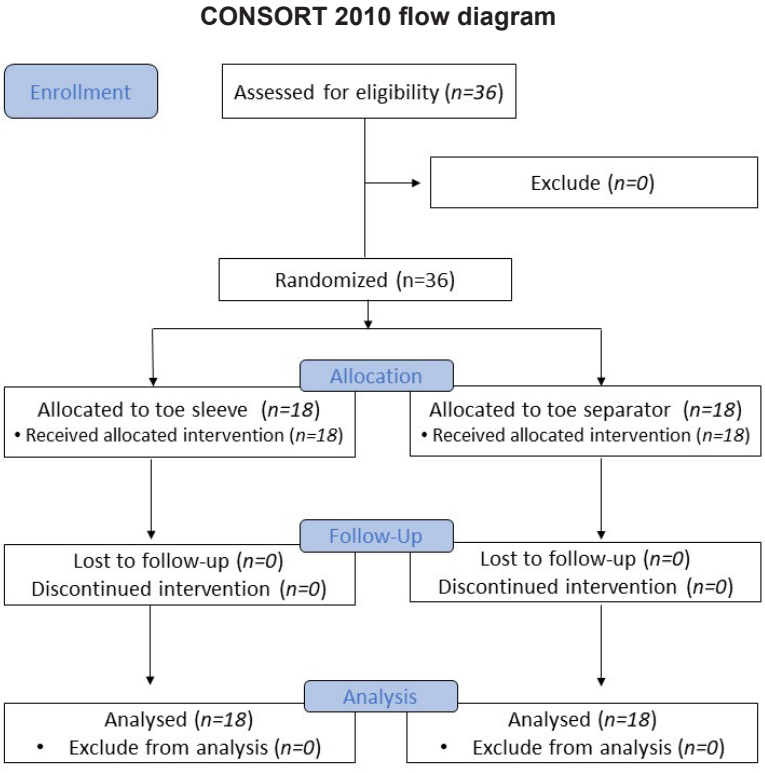

Figure 2. Flowchart of the trial

Table 2. Comparison of VAS and VAS-FA in each group: mean and standard deviation

	Toe sleeve group		Toe separator group	
	VAS	VAS-FA	VAS	VAS-FA
Baseline[1]	55.72 (20.86)	75.89 (14.01)	66.00 (14.68)	53.72 (10.65)
at 1-month FU	21.72 (11.64)	88.67 (12.03)	42.67 (25.72)	65.33 (18.11)
at 3-month FU	19.33 (9.61)	83.83 (11.78)	42.17 (24.58)	71.17 (12.65)
p-value*	< 0.01	0.01	< 0.01	< 0.01

VAS, visual analog scale; VAS-FA, visual analog scale-foot and ankle; FU, follow-up
p-value comparing the same device at different times

Table 3. Post-hoc analysis (pairwise comparisons)

	Toe sleeve group		Toe separator group	
	Mean difference (95% CI)	*p*-value	Mean difference (95% CI)	*p*-value
VAS				
Baseline - 1-month FU	34 (20.33-47.67)	< 0.01	23.33 (9.41-37.25)	< 0.01*
Baseline - 3-month FU	36 (22.94-49.83)	< 0.01	23.83 (10.67-37.00)	< 0.01*
1-month FU - 3-month FU	2.39 (-1.39-6.17)	0.33	0.50 (-37.00- -10.67)	1.00
VAS-FA				
1-month FU - baseline	12.78 (7.85-17.71)	< 0.01	11.61 (-0.23–23.46)	0.55
3-month FU - baseline	7.944 (-0.05–15.93)	0.05	17.44 (9.35–25.54)	< 0.01*
3-month FU - 1-month FU	-4.83 (-11.27–1.60)	0.19	5.83 (1.07-10.59)	0.01*

VAS, visual analog scale; VAS-FA, visual analog scale-foot and ankle; FU, follow-up
Negative mean difference of VAS-FA means worse

Table 4. Comparison of VAS and VAS-FA between the toe sleeve and the toe separator groups: mean and standard deviation

	Toe sleeve group	Toe separator group	*p*-value
VAS			
at 1-month FU	21.72 (11.64)	42.67 (25.72)	0.01*
at 3-month FU	19.33 (9.61)	42.17 (24.58)	< 0.01*
VAS-FA			
at 1-month FU	88.67 (12.03)	65.33 (18.11)	0.10
at 3-month FU	83.83 (11.78)	71.17 (12.65)	0.59

p-value compared between devices at the same period; FU, follow-up

Patient adherence and use of pain medication

In terms of patient adherence to the instruction of using a toe sleeve/toe separator and taking pain medication, there was no significant difference between the two groups with the mean foot-toe orthosis usage of 38.17 (19.65) hours per week in the toe separator group and 36.63 (22.56) hours per week in the toe sleeve group (p = 0.83). There was no reported use of pain medication nor any problems e.g. discomfort from the foot-toe orthoses during the study.

Discussion

In theory, toe sleeve could reduce the pressure on the bunion by padding that covers the bunion and toe separator could reduce the pressure by reduced the deformities of the hallux valgus.[6,12] Here, our study compared the usage of foot-toe orthoses between a toe sleeve and a toe separator using the pain VAS for self-rating painful bunion and the Thai version of VAS-FA for self-assessment of foot and ankle functions. We found that both orthoses could reduce pain and improve function after using them for a month. A comparison between the two orthoses revealed that the toe sleeve had superior outcomes in terms of VAS and VAS-FA over the toe separator, although the baseline VAS-FA of the toe sleeve treatment group was better than that of the toe separator treatment group.

Tehraninasr et al. concluded that a toe separator could reduce pain after three months of follow-up from baseline.[6] The foot-toe orthoses in their study was custom fabricated and used with semi-rigid insole but our study used prefabricated foot-toe orthoses but still can relieved pain and improved functions of patients.

The data show that there were no differences in the VAS and VAS-FA scores when comparing between at one-month and at three-month follow-ups in both groups. The patients still had pain but less, improved functions but still had some limitation. This might be because the foot-toe orthoses could help relieved the pain from the deformities but not totally corrected them so the pain and limitation of functions were not totally resolved.

In terms of the adherence and pain relievers, we found no significant difference in both outcomes between the two groups. Both could treat hallux valgus patients without any reported problems. The foot-toe orthoses in our study were prefabricated and easy to wear. The mean usage hours per week of both foot-toe orthoses were closed to the report by Chadchavalpanichaya et al. in the 3-month follow-up but after 3 months the adherence from their study was decrease.[8] Our study may need more follow-up time to evaluate the adherence in long term.

Our study is a randomized controlled trial with a specific attention to only painful bunion in hallux valgus patients who completed the protocol. The outcomes of our study were measured in reference to the patients' pain and functions. Our limitations were that the majority of the study participants had mild to moderate degrees of hallux valgus, and could not be extrapolated to the patients with severe hallux valgus. Type of footwear of each patient was not evaluated as a baseline characteristic. The follow-up period was only 3 months. A longer period of follow-up, evaluation the type of footwear and inclusion of more types of prefabricated foot-toe orthoses may need to be studied in the future.

In conclusion, daily use of a prefabricated toe separator or a toe sleeve significantly decreased pain and improved the functional mobility of patients with mild to moderate degree of hallux valgus patients and bunion pain. The toe sleeve better relieved pain than the toe separator did in patients with hallux valgus after one month of usage and the pain reduction was maintained at three months.

Disclosure

The authors declare no related activity with or benefits from companies producing the foot-toe orthoses used in the study.

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Original Article

Urological Management and Long-Term Complications in Patients with Spinal Cord Injury and Neurogenic Lower Urinary Tract Dysfunction in Thailand: A Retrospective Study

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ABSTRACT

Objectives: To describe urological assessment, management and long-term complications in patients with spinal cord injury (SCI) and neurogenic lower urinary tract dysfunction (NLUTD) in Thailand.

Study design: Retrospective study.

Setting: Two university hospitals and three A-level hospitals in Thailand.

Subjects: Patients with SCI and NLUTD.

Methods: Medical records of patients with traumatic and non-traumatic SCI and NLUTD from five tertiary/A-level hospitals were obtained and manually reviewed to evaluate urological assessment, management and related complications. Descriptive statistics were used for the evaluation.

Results: Among the 5,822 medical records retrieved, 1,066 cases had been diagnosed with SCI and NLUTD. In the initial NLUTD assessment, it was found that 51.9% of the patients had undergone urodynamic study (UDS). The last bladder emptying techniques included indwelling transurethral catheter (38%), reflex voiding (30.1%), and self-catheterization (clean intermittent catherization) (20.3%). Approximately 40% of patients had had no regular urological follow-up. Among the 760 patients who had undergone imaging, 36.9% had upper urinary tract complications. There were significant differences between the university hospitals and the Ministry of Public Health hospitals in terms of urological assessment, management and follow-up protocol.

Conclusions: There were differences in methods of initial assessment, management, and surveillance follow-up protocol for SCI and NLUTD patients in university hospitals and those in MOPH hospitals in Thailand. Among the patients who underwent surveillance and investigation, a substantial number were found to have upper urinary tract complications.

Keywords: neurogenic lower urinary tract dysfunction, neurogenic bladder, spinal cord injury, rehabilitation, complications

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Introduction

Neurogenic lower urinary tract dysfunction (NLUTD) or neurogenic bladder is a secondary condition found in various neurological diseases. The condition affects a significant number of people with traumatic and non-traumatic spinal cord injury (SCI), myelomeningocele, and multiple sclerosis.[1,2] Neurogenic detrusor overactivity and detrusor external sphincter dyssynergia can cause upper urinary tract complications, e.g., vesicoureteral reflux (VUR), hydronephrosis, and renal failure.[3,4] Surveillance follow-up to monitor upper urinary tract condition is therefore necessary.[2,5,6]

There are many guidelines offering proposals for the management of NLUTD for specific diseases.[2,5-8] The recommendations can be categorized into the initial evaluation, management (which varies based on the results of the evaluation), and long-term follow-up protocol. Most guidelines agree on the need for early assessment of both upper and lower urinary tract anatomy and function, including renal ultrasonography, intravenous pyelography (IVP), renal scans, creatinine clearance, urodynamic studies, voiding cystourethrography (VCUG), and cystoscopy. One guideline also suggests urine analysis and culture to identify infections.[6] Long-term annual surveillance of detrusor and renal function including potential complications of NLUTD, such as bladder cancer, hydronephrosis, and stones, is also recommended. In summary, there are areas of general agreement regarding the assessment of urinary tract structures and functions, both in the initial phase and the surveillance follow-up protocol; there are, however, minor differences such as the rationale for and recommended frequency of urine analysis and culture.[5,6]

Some studies investigated the NLUTD management practices of physicians in high-income countries.[9-12] In 2004, a study by Bycroft et al. found that the practices in spinal units in the United Kingdom and Ireland, were quite varied; however, long-term annual follow-up was usually scheduled,

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including ultrasonography and urodynamic study.[10] A decade after that study, however, practices of these spinal units tended to be limited to annually upper tract imaging with ultrasonography without routine urodynamics.[12] Surveys among urologists in the Netherlands and the United States found a variety of practices in assessment and surveillance investigations; however, the frequency of follow-up was usually every 6 to 12 months.[9,11] In summary, there have been several proposals regarding the management of NLUTD; the actual practices of physicians, however, are even more varied.

In Thailand, there is no general consensus regarding NLUTD management and surveillance follow-up guidelines. Few studies have been conducted in the country to identify problems related to NLUTD. Studies from a rehabilitation department at a university hospital in the Northeastern region revealed a high prevalence of vesicoureteral reflux (VUR) in SCI and myelomeningocele patients of approximately 20% and 40%, respectively.[13,14] A study of a specialized SCI rehabilitation ward at a university hospital in the Northern region found abnormalities in KUB ultrasonography in 30% of males with SCI who were using a reusable silicone catheter for clean intermittent self-catheterization (CISC).[15] In another study, the prevalence of UTI in SCI patients performing CISC was 15.4%.[16] A study of chronic SCI in Thailand revealed 62% of patients still used CISC as their preferred bladder emptying method.[17]

It is difficult to get an accurate estimate of the magnitude of the urological problems in SCI patients including the number with NLUTD, the treatments received, and post-treatment complications. This study aimed to extensively explore the urological management and long-term complications in SCI patients with NLUTD in Thailand by retrospectively reviewing medical records of five tertiary hospitals in different regions of the country. This review study was designed to reflect the current NLUTD management situation and to offer a portrait of the long-term condition of NLUTD patients in Thailand which could pave the way for the development of a national guideline.

Methods

This research was a part of a three-part research project, 'Access to proper urological care in persons with NLUTD,' which is comprised of three distinct sections: 1) quantitative research on the utilization and urological management in hospitals (the focus of the present project), 2) mixed method research on the availability of urological care resources in hospitals, 3) qualitative research on the perspective of persons with SCI related to accessing urological-related care in a hospital. The same study sites were selected for all three projects. The selection process included the following. First, three to five provinces in each of the five regions; northern, northeastern, central and eastern, southern, and Bangkok and perimeter area; with the highest total number of persons with disabilities were selected and disabled people organizations (DPO) in each of those areas were contacted. One province in each of the five regions with a strong and cooperative disabled people organization was selected to serve as the base for contacting persons with SCI in the community for the third project. The five provinces are Lampang, Khon Kaen, Chonburi, Surat Thani, and Bangkok. Next, the tertiary hospitals, their network hospitals, and medical schools in these five provinces were then invited to participate in the second project. Each of the selected tertiary and medical school hospitals had all professionals necessary to care for persons with SCI, i.e., orthopedists, physiatrists, and urologists. Finally, three of the five locations were purposively selected for a medical record review based on the willingness to cooperate of the provincial coordinator. The three locations are Khon Kaen, Surat Thani, and Bangkok. The researchers in this study then recruited five tertiary/A-level hospitals in these three provinces, including two university hospitals (Srinagarind Hospital and Ramathibodi Hospital) and three Ministry of Public Health (MOPH) hospitals (Khon Kaen Hospital, Surat Thani Hospital, and Rajavithi Hospital), for a medical record review to explore details of the medical services received by patients with SCI and NLUTD.

Search strategy

After receiving approval from the research ethics committee of each hospital, the hospital coordinator was asked to retrieve medical records of patients with the following criteria: patients who had paid a visit to the hospital between October 1st 2015 and September 30th 2016 and whose medical records had one or more of the following ICD-10 codes for diagnoses: neuromuscular dysfunction of bladder (N31.0-9), potential causes of NLUTD, e.g., SCI (S14.0, S14.1, S24.0, S24.1, S34.0, S34.1, T09.3); sequelae of spinal cord injury (T91.3); other diseases of the spinal cord (G95.0-9); paraplegia or tetraplegia (G82.0-5); spina bifida (Q05.0-9); other congenital malformation of spinal cord (Q06.0-9); transverse myelitis (G37.3); neoplasm of the spinal cord (C72.0-1); cauda equina syndrome (G83.4); and multiple sclerosis (G35).

Inclusion-exclusion criteria

The researchers (DS, physiatrist; PW, registered nurse; PS; registered nurse) screened the medical records. Only records with one of the following types of evidence of NLUTD problems were included: 1) diagnosis of NLUTD/neurogenic bladder by a physician, 2) signs/symptoms of voiding dysfunction, e.g., incontinence or inability to void, or 3) use of long-term bladder emptying assistance techniques, e.g., clean intermittent self-catheterization (CISC), indwelling transurethral catheter, using external collecting devices or, 4) having investigations related to NLUTD such as urodynamic study or cystometry. Exclusion criteria were medical records of patients who were referred to other medical facilities at the first visit of diagnosing NLUTD, patients who were denied treatment, and patients who had died.

Data extraction

The researchers created a checklist for NLUTD assessment by combining key features of the two guidelines for urological management prepared by SCI experts in the United Kingdom and in Taiwan.[5,6] Initial NLUTD assessments were categorized into six groups: 1) bladder diary or post-void residual urine (PVR), 2) urine analysis, 3) urine culture, 4) serum creatinine, 5) ultrasonography or intravenous pyelography (IVP) or voiding cystourethrography (VCUG), and 6) cystometry or urodynamic studies (UDS).[5,6] The time from onset to each assessment investigation was recorded. In addition, long-term surveillance investigations, urological complications, the most recent bladder emptying technique used, and medication received for treatment of NLUTD were also recorded. This data, as well as the patients' demographic and clinical characteristics, were extracted and recorded by the researchers (DS, PW, and PS)

Surveillance/follow-up investigations for the five years following initial onset were recorded, including whether there were appointments with physicians as well as any check-ups on upper and lower urinary tract function using serum creatinine, ultrasonography or IVP or VCUG, and cystometry or UDS. The frequency of each type of surveillance investigation was also recorded.

Statistical analysis

The retrieved data were analyzed to identify 1) the type of initial urological assessment and the date of that assessment, 2) what proportion of SCI patients had cystometry or UDS done to diagnose NLUTD and how soon after reporting symptoms the diagnosis was done, 3) the latest bladder emptying techniques used, 4) the types of medications for NLUTD prescribed and how frequently they were used, 5) the prevalence of upper urinary tract complications, 6) the types and frequently of investigations done for urological follow-up surveillance during the first 5 years, and 7) whether there were differences in urological management and outcomes of NLUTD between university hospitals and MOPH hospitals. Descriptive statistics are reported as numbers and percentages; inferential statistics were used to compare MOPH hospitals and university hospitals using chi-square for categorical data and the Mann-Whitney U test for non-parametric nominal data.

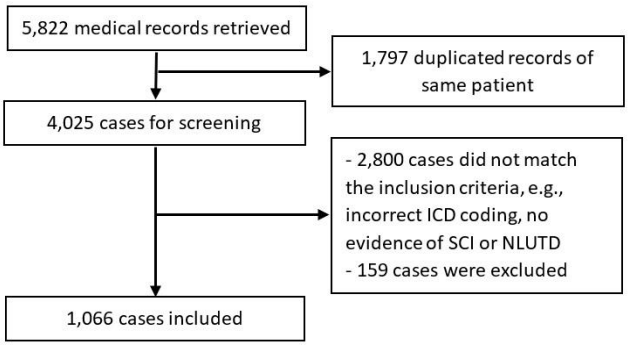

Figure 1. Flow of evaluation of the medical records of recruited cases

Results

Among the 5,822 cases retrieved, 1,066 cases were included in the study (Figure 1). Table 1 shows demographic and clinical characteristics of the included patients. The majority were male (62.6%) and the average age of all patients was 44.9 years.

Table 2 shows the six categories of initial NLUTD assessment. The most frequent was checking serum creatinine (85.9%), followed by urine analysis (75%), USG or IVP or VCUG (71.3%), UDS (51.9%) and bladder diary or PVR (49.1%). There was a statistically significant difference ($p < 0.001$) in the percentage of all categories of the initial NLUTD assessments between the university hospitals and MOPH hospitals. Overall, only 23.8% of patients received all six categories of assessment as part of the initial evaluation. Table

Table 1. Demographic and clinical characteristics of the recruited cases

	Overall (n = 1066)	University hospitals (n = 643)	MOPH hospitals (n = 423)
Demographics			
Gender, male[1]	667 (62.6)	378 (58.8)	289 (68.3)
Age (years)[2]	44.9 (21.5)	42.3 (22.6)	49.3 (18.5)
SCI characteristics			
Cause of SCI[1]			
Traumatic	380 (35.6)	231 (35.9)	149 (35.2)
Non-traumatic			
Congenital diseases	150 (14.1)	124 (19.3)	26 (6.1)
Acquired abnormalities	112 (10.5)	47 (7.3)	65 (15.4)
Neoplastic	123 (11.5)	83 (12.9)	40 (9.5)
Infection	84 (7.9)	58 (9)	26 (6.1)
Unspecified	217 (20.4)	100 (15.6)	117 (27.7)
Severity, paraplegia[1]	646 (60)	461 (71.7)	185 (43.7)
Duration of NLUTD (months)[2]	98.1 (101.3)	111.6 (102.7)	76.8 (95.3)
Duration of NLUTD (months) [3]	62 (27-132)	82 (39-156)	35 (21-88.5)

[1]Number (%), [2]mean (SD), [3]median (IQR)

MOPH, Ministry of Public Health; SCI, spinal cord injury; NLUTD, neurogenic lower urinary tract dysfunction

Table 2. Comparison of initial NLUTD assessments performed at university and MOPH hospitals

Assessment	Overall (n = 1066)	University hospitals (n = 643)	MOPH hospitals (n = 423)	*p*-value*
Bladder diary or PVR	529 (49.6)	440 (68.4)	89 (21.0)	< 0.001
Urine analysis	800 (75.0)	521 (81.0)	279 (65.9)	< 0.001
Urine culture	487 (45.7)	322 (50.0)	165 (39.0)	< 0.001
Serum creatinine	916 (85.9)	587 (91.3)	329 (77.8)	< 0.001
USG or IVP or VCUG	760 (71.3)	577 (89.7)	183 (43.3)	< 0.001
Cystometry or UDS	554 (51.9)	513 (79.8)	41 (9.7)	< 0.001

Number (%); *statistically significant ($p < 0.05$)

IVP, intravenous pyelography; MOPH, Ministry of Public Health; NLUTD, neurogenic lower urinary tract dysfunction; PVR, post-void residual urine; UDS, urodynamic study; USG, ultrasonography; VCUG, voiding cystourethrography

Table 3. Comparison of time since the diagnosis to first urological assessment at university hospitals and at MOPH hospitals (months)

	Months from onset of symptoms to first assessment [mean (range)]			
	Overall	University hospitals	MOPH hospitals	*p*-value*
Bladder diary or PVR assessment	10 (2-40)	10 (2-39.25)	8 (3.5-48)	0.294
Urine analysis	12 (2-50)	15 (3-56)	6 (1-36)	< 0.001
Urine culture	15.5 (3-59)	18 (5-53)	9 (1-71.25)	0.053
Serum creatinine	13 (2-58.5)	17 (4.25-68.75)	5 (1-42)	< 0.001
USG or IVP or VCUG	14 (4.25-60)	13 (4-49)	17 (6-80)	0.019
Cystometry or UDS	16 (4.75-63.25)	16 (4-61.75)	18.5 (7-190.25)	0.032

Median (IQR), *Mann-Whitney U test statistical significance $p < 0.05$

IQR, interquartile range; MOPH, Ministry of Public Health; NLUTD, neurogenic lower urinary tract dysfunction; PVR, post-void residual urine; IVP, intravenous pyelography; VCUG, voiding cystourethrography; UDS, urodynamic studies, USG, ultrasonography

Table 4. Comparison of urological follow-up management during the first five years after onset

	Overall (n = 1,066)	University hospitals (n = 643)	MOPH hospitals (n = 423)	*p*-value*
Complied with annual follow-up	632 (59.3)	461 (71.7)	171 (40.4)	
No appointment given for follow-up	196 (18.4)	59 (9.2)	137 (32.4)	< 0.001
Referred to other hospitals	29 (2.7)	11 (1.7)	18 (4.3)	
Lost to follow-up	209 (19.6)	112 (17.4)	97 (22.9)	

Number (%); *Chi-square statistically significant ($p < 0.05$)

MOPH, Ministry of Public Health

3 shows the time from onset to the initial NLUTD assessment. The median time to UDS/cystometry was 16 months (IQR: 4.75-63.25).

The combined frequency of the most recent bladder emptying techniques used in both types of hospitals were indwelling transurethral catheter (38%), reflex voiding (30.1%), CISC (20.3%), clean intermittent catheterization (CIC) (6.3%), suprapubic cystostomy (2.1%), and others (2.7%). The overall percentage of those who were trained to perform CIC/CISC was 47%. A total of 262 patients (24.6%) experienced urinary incontinence which required the use of external collecting devices. Of these patients, 48% managed their bladder with reflex voiding, 38.9% used CIC, and 8% used an indwelling transurethral catheter.

Of the 1,066 patients, 56.7% had never received an anti-muscarinic agent for detrusor overactivity. Of the 42.5% who had received an agent, only 32.8% still used the medication at their latest visit. Among the 350 patients who still received medication, 90% were followed up at university hospitals. The median duration from onset to the first prescription of an anti-muscarinic agent was 24 months (IQR 8-69.25).

Table 4 compares urological follow-up management during the first five years after the onset of disease. Approximately 60% of patients complied with a regular appointment for urological follow-up, 19.6% were lost to follow-up, and 18.4% did not receive a follow-up appointment. There was a statistically significant difference in the follow-up appointment scheduling and patient compliance between the university and the MOPH's hospitals.

In the analysis of patients with the time from the initial diagnosis of at least 5 years, 574 patients were excluded, leaving 492. Table 5 shows the frequency with which patients received long-term urological follow-up for investigation of upper urinary tract functions and structures. The frequency of annual follow-ups was 49.8% for serum creatinine, 46.7% for USG/IVP/VCUG, and 34.1% for UDS/cystometry. Only 98 patients (19.9%) received all categories of NLUTD assessment annually, all of whom were followed up at a university

Table 5. The frequency of urological investigations during the first 5 years of follow-up

	Frequency of investigations	Overall (n = 492)	University hospitals (n = 360)	MOPH hospitals (n = 132)	*p*-value*
Serum Creatinine	Annually	245 (49.8)	190 (52.8)	55 (41.7)	< 0.001
	2 times in 5 years	123 (25.0)	95 (26.4)	28 (21.2)	
	1 time in 5 years	38 (7.7)	27 (7.5)	11 (8.3)	
	Never received	86 (17.5)	48 (13.3)	38 (28.8)	
USG or IVP or VCUG	Annually	230 (46.7)	201 (55.8)	29 (22.0)	< 0.001
	2 times in 5 years	111 (22.6)	93 (25.8)	18 (13.6)	
	1 time in 5 years	23 (4.7)	19 (5.3)	4 (3.0)	
	Never received	128 (26.0)	47 (13.0)	81 (61.4)	
UDS or cystometry	Annually	168 (34.1)	167 (46.4)	1 (0.8)	< 0.001
	2 times in 5 years	82 (16.7)	80 (22.2)	2 (1.5)	
	1 time in 5 years	22 (4.5)	18 (5.0)	4 (3.0)	
	Never received	220 (44.7)	95 (26.4)	125 (94.7)	

Number (%); *$p < 0.05$

IVP, Intravenous pyelography; MOPH, Ministry of Public Health; VCUG, voiding cystourethrography; UDS, urodynamic study; USG, ultrasonography

Table 6. Incidence of upper urinary tract complications (n = 760)

Upper urinary tract complications	
Vesicoureteral reflux grade 1-3	47 (6.2)
Vesicoureteral reflux with hydronephrosis	192 (25.3)
Chronic kidney disease	28 (3.7)
Chronic kidney disease with renal replacement therapy	9 (1.2)
Other upper urinary tract complications	5 (0.7)
Total	281 (36.9)
No Upper urinary tract complications reported	479 (63.1)

Number (%)

hospital. The significant disparity in the long-term surveillance investigations between the university and the MOPH hospitals is shown in Table 5.

Of the 760 patients that received at least one USG or IVP or VCUG, 3.2% had urinary tract calculi and 36.9% had upper urinary tract complications of different degrees as shown in Table 6.

Discussion

The first urological assessment for NLUTD determined that about half the patients had either a UDS or cystometry which was performed late, about 1-2 years post-onset of injury/post-diagnosis of the primary disease and only one-fourth of the patients had a complete urological assessment. The incidence of complete assessment and UDS was higher in the university hospitals than in the MOPH hospitals, with less than 10% of UDS or cystometry tests performed in MOPH hospitals. This difference could be due to limited resource availability, e.g., only one of the three MOPH hospitals had a urodynamic machine.

The management of NLUTD in Thailand differs from that in high-income countries. For example, the United Kingdom offers an initial urological assessment to all SCI patients at 3-6 months post onset.[5] In addition, SCI units in the UK mandate the evaluation of kidney-ureter-bladder imaging together with urodynamics as part of the initial assessment, with more than 80% of all units using video-urodynamics in the assessment process.[12] In comparison, only half of the patients in our study received UDS/cystometry as a part of the first assessment, even though one-channel simple cystometry is an alternative and safe technique of assessing detrusor functions[18] and has been one of the procedural skills taught in the rehabilitation medicine residency training program in Thailand.[19] The low percentage of UDS/cystometry found in this study suggests that all rehabilitation medicine training institutes should increase emphasis on simple cystometry and provide more opportunity to practice during the training program so that every physiatrist could master this competency. Additionally, assessment of bladder diaries and PVR helps physiatrists/urologists to evaluate the effectiveness and appropriateness of bladder-emptying techniques. However, they were performed in less than one-third of patients during the first assessment.

Two-third of the patients in our study used urinary catheters to empty the bladder, more used indwelling catheters, and about one-third used reflex voiding. These findings are not congruent with the recommendations of the existing guidelines.[2,5,7] Reflex voiding should be used only when UDS shows that the bladder situation is safe and an adequate follow-up is guaranteed. Indwelling catheters are not recommended for long-term use because of the risk of urinary complications.[2,6,7,20] According to the available evidence, bladder emptying techniques used by a patient can be changed over time. El-Masri followed SCI patients for 8-12 years and discovered that 84% learned to used CIC, 67% were using CIC at the time of SCI rehabilitation unit discharge, but only 18% still used CIC at 8-12 years.[21] In Taiwan, long-term follow-up in NLUTD patients similarly showed a decreasing number of patients using CIC over time.[22] Our study findings were similar, with about half the patients who were trained still continuing to perform CIC/CISC at their latest visit. According to a previous study in Thailand, the main reason that chronic SCI

patients choose indwelling catheters is convenience; however, the quality of life of those performing CISC/CIC and those with indwelling catheters are not different.[17]

One-fourth of the patients in this study reported urinary incontinence which is far lower than another study which reported 52.3% urinary incontinence in SCI patients.[23] This difference could, at least in part, be due to the inadequate medical recording as well as to the retrospective nature of the present study. Improper management of incontinence may prompt patients using CIC/CISC to shift back to using indwelling catheters. According to an economic evaluation study in Thailand, the cost of using external collecting devices is a significant burden for people with physical impairment.[24] That added burden could influence patients' choice of bladder management. However, some of the patients using indwelling catheters in our study also had urinary incontinence which might be due to lack of or inadequate anti-muscarinic medications and/or improper care of long-term indwelling catheter usage which can cause bladder neck and urethral erosion.[20]

All NLUTD guidelines recommend controlling detrusor pressure for patients with detrusor activity in order to prevent upper tract damage as well as recommending an annual urological follow-up.[2,5-7,25] To effectively control detrusor pressure, anti-muscarinic mediations are needed,[20] but more than half the patients in our study had never received such medications. For those who did receive it, the medication was received late, about 2 years after the onset of the injury/diagnosis, and only one-third were still taking the medications at the time of their latest visit. Lack or delay in providing anti-muscarinic medication prescriptions and inadequate regular urological follow-up might be two main reasons why one-third of patients in our study had developed upper urinary tract complications.

The upper urinary tract complications rate in our study was 36.9%, higher than rates reported in other countries.[21,26] The proportion of patients with VUR and hydronephrosis in the current study was 31.5%, higher than the 20% in Thongchim's study in Thailand.[13] This difference is probably due to the latter study having been conducted in a single university hospital which has SCI specialists who conducted regular urological follow-ups, whereas some of the patients' records in our study were obtained from MOPH hospitals where NLUTD services are limited. Another recent study conducted in a MOPH tertiary hospital in Thailand found a comparable percentage of hydronephrosis in patients with NLUTD, and reported a high percentage of patients using indwelling catheterization (66.5%) and reflex voiding (16.5%). That study also reported that the bladder emptying method is a strong predictor of hydronephrosis and/or VUR.[27] It is crucial to note that the number of complications in our study could be higher than reported in the medical record as one-third of the patients never had USG, IVP, or VCUG. Five percent of patients in this study had experienced chronic kidney disease (CKD) which could also be an underestimate as the number of CKD patients in the general Thai population is as high as 17.5% and given that NLUTD patients are a high-risk group for CKD.[28] There is also a prediction based on estimated glomerular filtration rate (eGFR) that up to one-third of SCI patients experience some level of CKD but with no diagnosis in their medical record.[29]

Most guidelines suggest at least an annual surveillance check-up for NLUTD patients.[2,5-7] This study explored the period during the first five years of follow-up. About one-third of those who had at least 5 years of follow-up had received UDS/cystometry. In contrast, at the 8-year follow-up in the United Kingdom, up to 64% of patients still received a regular annual check-up.[21] One vital difference between the medical system in Thailand and that in the UK is that rehabilitation service in the UK is under the management of SCI units where there are 12 units in the country offering holistically long-term SCI care.[12] In contrast, rehabilitation services in Thailand are integrated in an acute hospital setting with very limited resources, resulting in limitations in access to care.[30-32] Our study demonstrates that there are significant differences in the provision of urological assessment and follow-up investigations and in bladder emptying techniques and anti-muscarinic prescriptions between university hospitals and MOPH hospitals. These differences reflect the uneven and insufficient NLUTD management for patients with SCI in Thailand, e.g., presently, specialized SCI rehabilitation facilities, which by far provide better functional outcomes, are located only in university hospitals.[33] The policy makers of the MOPH as well as the National Health Security Office (NHSO) should consider developing at least one SCI-specialized rehabilitation facility in each NHSO region to ensure adequate SCI management in the acute, post-acute and long-term phases of treatment.

There are certain limitations in this study due to the nature of the retrospective method used. First, the data were retrieved from only 5 hospitals, which might not be representative of the situation of all Thai patients with SCI. Second, it was a retrospective review of only available medical records, and some data were missing or hard to interpret. Additionally, many investigations, for example, urine analysis, urine culture, and serum creatinine, could have been performed as part of an assessment of other co-morbidities. Even though the investigations included in the study were counted as part of NLUTD evaluation, it was difficult to interpret the intention of the physician at that time, i.e., whether an investigation was performed specifically for NLUTD care or not. In addition, there was a limitation in determining the actual number of patients receiving a complete initial NLUTD assessment. Due to the lack of a standardized NLUTD protocol in all hospitals, each of the six categories of initial assessment was performed over a wide time interval. If this study had included only cases where a strict protocol had been followed and all assessments were done within the prescribed time frame,

the percentage of patients who received a proper initial assessment would be far lower than the 23.8% reported in this study. Finally, the upper urinary tract complication rates might have been higher if all patients had undergone the appropriate investigations, e.g., USG/IVP/VCUG. To overcome these limitations, a prospective study should be conducted in a larger number of hospitals which would better represent the actual situation.

Conclusions

There is a wide variety in the initial assessment and long-term care provided for patients with SCI and NLUTD in Thailand. The majority of patients receive the first urological assessment more than a year post-onset which could result in inappropriate and/or insufficient management as well as an increase in the number of upper urinary tract complications. The retrospective data in this study was insufficient to develop a strong recommendation; however, the available evidence suggests that there might be problems due to the insufficient availability of services and the limitations in the knowledge of healthcare providers related to NLUTD management, especially in the MOPH hospitals. Development of standardized guidelines for NLUTD management which take into account the context of Thai healthcare system would be highly beneficial for both healthcare providers and for NLUTD patients.

Disclosure

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The authors declare that there is no conflict of interest.

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Original Article

Demographics, Clinical Characteristics and Functional Outcome of Non-Traumatic Spinal Cord Injury Undergoing Inpatient Rehabilitation in University Malaya Medical Centre

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ABSTRACT

Objectives: To describe the demographics and functioning of patients with non-traumatic spinal cord injury (NTSCI) undergoing inpatient rehabilitation.

Study design: Retrospective study.

Setting: A tertiary hospital in Malaysia.

Subjects: Patients (N = 141) with NTSCI who had undergone initial inpatient rehabilitation between 1st January 2015 to 31st December 2019.

Methods: This was a retrospective study design where information was obtained from patients' electronic medical records. The etiology of NTSCI, demographic information, length of stay in rehabilitation, American Spinal Injury Association Impairment Scale (AIS) grade at initial rehabilitation and discharge, and Spinal Cord Injury Independence Measure Version III (SCIM III) score at initial rehabilitation and discharge, were recorded and analyzed.

Results: A total of 141 patients with NTSCI were referred for inpatient rehabilitation. The mean age was 58.1 years (range 20-88), and 59.6% were men. The mean duration of inpatient rehabilitation was 32.3 days (range 7-198). The top three etiology were spine degeneration (34.0%), spine neoplasms (30.5%), and infection (23.4%). The commonest neurological impairment was incomplete paraplegia (52.5%). Most patients were classified as AIS D (n=84, 60.4%); only 14 (10.1%) patients were found to be AIS A. The mean difference of SCIM III score between initial and completion of rehabilitation all NTSCI etiologies achieve clinical significance, with mean score ranges from 12.7 to 21.9 points.

Conclusions: Spine degeneration and spine neoplasm were the most common etiology of NTSCI in this study. Regardless of the etiology of NTSCI, all patients benefited from inpatient rehabilitation program, and had similar functional gain.

Keywords: etiology, demography, functional outcome, spinal cord injury, rehabilitation

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Introduction

Spinal cord injury (SCI) is a chronic condition which affects patients' physical, psychological health and social well-being, as well as causes heavy burden on families, communities, and health care systems.[1] The prevalence of SCI was from 440 to 526 per million people.[1] A recent survey in Malaysia where 298 people with SCI participated, 14.6% were non-traumatic spinal cord injury (NTSCI).[2] The incidence of NTSCI is reported to be higher than traumatic SCI in Australia and Canada.[3,4] The number of people with NTSCI is increasing due to aging populations. Therefore, it is anticipated that the incidence of NTSCI will increase with the aging global population.[3] Patients with NTSCI are older than those with traumatic SCI (TSCI), with the typical median age of 60 to 65 years old[2-5] and could possibly have worse functional outcome.

The common etiology of NTSCI are degenerative spinal conditions, benign or malignant neoplasm, vascular disorders, inflammatory disorders, and infection.[2,5,6] NTSCI in developed countries are commonly caused by degenerative conditions and neoplasms, while in developing countries caused by infections and neoplasms.[7]

Clinical characteristics and functional outcome of NTSCI is less often reported compared to traumatic SCI. When compared to NTSCI, TSCI group had a higher proportional of patients who were male (68-76%), tetraplegic (32.1-60.6%), and complete lesion (23-74%).[8-10] Tetraplegia occurred more commonly in patients with degenerative disorder of the spine, as compared to other etiologies.[5,11] Patients with vertebral infection were more likely to have incomplete paraplegia[6] whilst patients with malignant spinal cord compression had similar age and gender distribution compared to other causes of non-traumatic spinal cord injury.[13] Functioning of patients with NTSCI improved following inpatient rehabilitation, but patients with malignant neoplasm have lesser improvement.[5,11,12] Nevertheless, most patients with malignant neoplasms met their inpatient rehabilitation goals.[13]

There is scarce study on the functional outcome among different etiologies in patients with NTSCI in Malaysia. It is important to understand the characteristics of the different etiologies of NTSCI and their functioning changes following rehabilitation, as it might help to facilitate optimal rehabilitation and anticipated outcome of the patients. Thus, the purpose of this study is to describe the demographics, clinical characteristics and functioning profile of patients with NTSCI according to the etiology.

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Methods

This is a retrospective study of patients with NTSCI who were referred to the SCI rehabilitation team for initial inpatient rehabilitation in University Malaya Medical Centre (UMMC), between 1st January 2015 to 31st December 2019. The study was approved by the UMMC Medical Research Ethics Committee (MREC ID Number: 2020628-8831).

The inclusion criteria were patients with NTSCI, 18 years old and above, and referred for initial rehabilitation after the onset of NTSCI, and had Spinal Cord Independence Measure III (SCIM III) scores before and after rehabilitation were included. Those who were diagnosed as Guillain-Barre´ syndrome, multiple sclerosis, spina bifida, Friedreich ataxia, or a conversion syndrome were excluded. The information was gathered from UMMC electronic medical records. Age, gender, date of onset of SCI, duration of inpatient rehabilitation, etiology of NTSCI, level of spinal cord injury (tetraplegia vs paraplegia), and completeness of injury (complete vs incomplete). American Spinal Cord Injury Association Impairment Scale (AIS) grade and SCIM III score at the start of rehabilitation and discharge were collected.

The etiology of NTSCI was classified according to the classification used in the International Nontraumatic Spinal Cord Injury Data Set.[14] According to this classification system, the etiologies in this study were categorized as degenerative, neoplasms, infection and others. The duration of SCI was the date of onset of SCI to the date of initiation of rehabilitation, and were recorded as acute (≤ 1 day), subacute (> 1 day but ≤ 7 days), prolonged (> 7 days but ≤ 1 month), and lengthy (> 1 month).[14] The duration of rehabilitation stay was defined as the date of initiation of inpatient rehabilitation to the date of discharge.

The SCI Rehabilitation service in UMMC routinely uses SCIM III to document functional outcomes of patients with spinal cord injuries at the start and end of inpatient rehabilitation. The SCIM III covers three major domains: self-care (score 0-20), respiration and sphincter management (score 0-40) and mobility (score 0-40). The total score ranges from 0 to 100, where 0 indicates total dependence and 100 indicates complete independence.[15] SCIM III is a reproducible and valid functional outcome measure in patients with NTSCI.[16] The difference between initial rehabilitation and discharge was documented as the functional gain during the inpatient rehabilitation.

Statistical Package for the Social Sciences (SPSS) version 23 was used for data analysis. The chi square test was used to detect significant differences of demographic (gender and pattern of onset) and characteristics of SCI with etiology. One way ANOVA was used to compare age with etiology while Kruskal-Wallis rank sum test was used to compare duration of rehabilitation stay with etiology. Association between SCIM III score and subdomain SCIM III scores with etiology and characteristic of SCI were also analyzed. Kruskal-Wallis rank sum test and Mann-Whitney test was used because of the skewed distribution of the scores. *P* values of less than 0.05 were considered significant.

Results

A total of 141 patients were referred for rehabilitation during the study period (Table 1). The mean (SD) age was 58.1 (14.2) years old (range 20-88), and majority were men (n = 84, 59.6%). A total of 109 patients were admitted to the rehabilitation ward for rehabilitation, while the rest received rehabilitation in the primary ward. The mean duration of inpatient rehabilitation was 32.3 days (median 27, IQR 18-42, range 7-198). The commonest neurological impairment was incomplete paraplegic (52.5%). The top three etiologies were spine degeneration (n = 48, 34.0%), spine neoplasms (n = 43, 30.5%), and infection (n = 33, 23.4%).

At initial rehabilitation, most patients were classified as AIS D (n = 84, 60.4%), only 14 (10.1%) patients were found to be AIS A. At discharge, 36 (25.9%) patients showed improvement in the AIS classification, 102 (73.4%) remained the same, and one (0.7%) deteriorated.

Table 2 shows the comparison of demographic and characteristics of NTSCI between the etiologies. Patients with spine degeneration had a higher mean age (p = 0.07), were mainly men (p = 0.027), and had incomplete tetraplega (p = 0.00) compared to others. Patients with spine infection had the longest rehabilitation length of stay.

Out of the 141 patients with NTSCI who were referred for rehabilitation, only 65 patients had complete informa-

Table 1. Demographics and clinical characteristics of NTSCI patients (N = 141)

Age (years), mean (SD), range	58.1 (14.2), 20-88
Gender, number (%)	
Men	84 (59.6)
Women	57 (40.4)
Pattern onset, number (%)	
Subacute (> 1 day to ≤ 7 days)	11 (7.8)
Prolonged (> 7 days to ≤ 1 month)	45 (31.9)
Lengthy (> 1 month)	85 (60.3)
Characteristics of SCI, number (%)	
Paraplegia complete	11 (7.8)
Paraplegia incomplete	74 (52.5)
Tetraplegia complete	3 (2.1)
Tetraplegia incomplete	53 (37.6)
Ward, number (%)	
Rehabilitation ward	109 (77.3)
Primary ward	32 (22.7)
Etiology, number (%)	
Spine degeneration	48 (34.0)
Neoplasm - benign	7 (5.0)
Neoplasm - malignant	4 (2.8)
Neoplasm - metastasis	32 (22.7)
Infection - bacterial	19 (13.5)
Infection - tuberculosis	14 (9.9)
Others - inflammation	11 (7.8)
Others - vascular	4 (2.8)
Others - osteoporosis	2 (1.4)
Rehabilitation length of stay (days)	
Mean (SD)	32.3 (23.3)
Median (IQR), range	27 (18-42), 7-198

IQR, interquartile range; NTSCI, non-traumatic spinal cord injury; SCI, spinal cord injury; SD, standard deviation

Table 2. Comparison of demographics, characteristics of NTSCI and rehabilitation by etiology

Characteristics	Degenerative	Neoplasm	Infection	Others	*p*-value
Number (%)	48 (34.0)	43 (30.5)	33 (23.4)	17 (12.1)	
Age (years) mean (SD)	62 (14.2)	56.6 (13.5)	57.3 (13.3)	52.2 (16.2)	0.07[a]
Sex, number (%)					
Men	36 (75)	21 (48.8)	20 (60.6)	7 (41.2)	0.027[b]
Women	12 (25)	22 (51.2)	13 (39.4)	10 (58.8)	
Pattern onset, number (%)					
Subacute (> 1 day, ≤ 7 days)	4 (8.3)	1 (2.3)	3 (9.1)	3 (17.6)	0.016[b]
Prolonged (> 7 days, ≤ 1 month)	8 (16.7)	18 (41.9)	10 (30.3)	9 (52.9)	
Lengthy (> 1 month)	36 (75.0)	24 (55.8)	20 (60.6)	5 (29.4)	
Characteristics of SCI, number (%)					
Paraplegia complete	1 (2.1)	5 (11.6)	3 (9.1)	2 (11.8)	0.000[b]
Paraplegia incomplete	15 (31.2)	30 (69.8)	19 (57.6)	10 (58.8)	
Tetraplegia complete	0 (0.0)	0 (0.0)	2 (5.9)	1 (5.9)	
Tetraplegia incomplete	32 (66.7)	8 (18.6)	9 (27.3)	4 (23.5)	
Ward, number (%)					
Rehabilitation ward	46 (95.8)	33 (76.7)	17 (51.5)	13 (76.5)	0.000[b]
Primary ward	2 (4.2)	10 (23.3)	16 (48.5)	4 (23.5)	
Length of stay (days), median (IQR)	18 (13)	28 (21)	37 (23)	28 (27)	0.000[b]

[a]One way ANOVA, [b]Pearson chi-square test, cKruskal-Wallis rank sum test; level of significance $p < 0.05$
IQR, interquartile range; NTSCI, non-traumatic spinal cord injury

tion on initial rehabilitation and at discharge total SCIM III scores. Meanwhile 59 out of the 65 patients had complete information on the breakdown of scores of the three functioning domains of SCIM III. The demographics of patients who had complete SCIM III scores were similar with total NTSCI patients referred for rehabilitation. Due to small number and heterogenous nature of patients in the 'Others' category, it was excluded from the analysis involving SCIM III total and subdomain score. Thus, the analysis involving total SCIM III scores involved 57 patients whilst analysis involving SCIM III subdomain involved 52 patients.

All etiologies showed almost similar mean SCIM III scores at initial rehabilitation, ranging from 35.9 to 38.2 points (Table 3). SCIM III scores at discharge were higher than the initial score in all etiologies, ranging from 50.5 to 57.8 points. Patients with spinal infection had the highest SCIM III score gain (21.9 points), followed by those with neoplasm (15.7 points) and degenerative diseases (12.6 points). However, there was no significant statistical differences between etiologies and SCIM III score at initial rehabilitation and at discharge.

In the subdomain of SCIM III (self-care score, respiration and sphincter management score, and mobility), there is no difference in score at initial rehabilitation, at discharge, and gain between the different etiologies. Nevertheless, our data showed that patients with spine neoplasms and spine infection had higher self-care score at initial rehabilitation and at discharge. Meanwhile, patients with spine degenerative had higher scores in respiration and sphincter management at initial rehabilitation and discharge. In the mobility domain, patients with spine degeneration and spine neoplasms had lower scores at initial rehabilitation but had higher gain at discharge. Patients with spine infection showed highest gain in self-care and respiration and sphincter management but had the lowest gain in mobility.

As can be seen from Table 4, functional outcome was compared between incomplete paraplegia and incomplete tetraplegia patients. There was no between group differences observed for total SCIM III score at initial rehabilitation, at discharge and gain. As expected, incomplete paraplegic patients compared to incomplete tetraplegia had significantly higher self-care scores at initial rehabilitation and at discharge. There was no significant difference in the initial and discharge SCIM score in the respiration and sphincter management score, and mobility score.

Discussion

This is the first study that provided insight to the demographic and functioning of people with NTSCI in Malaysia. The two common etiologies in this study were spine degeneration and spine neoplasms, which is in line with other studies in the developed countries.[7,11,12,17-20] The current study showed patients with NTSCI had improvement in functioning following inpatient rehabilitation regardless of the etiologies. This includes patients with spinal metastases who formed the majority of patients in the spine neoplasms group. The current study showed that all patients had improvement in their SCIM III score. A study by Sciveletto reported that an improvement of at least 4 points of the total SCIM is needed to obtain a small significant improvement and of 10 points to obtain a substantial improvement.[21] Thus in this study patients with NTSCI, regardless of the etiology, achieved clinically significant change in their functioning following rehabilitation.

Although various outcome measures were used in previous studies, all showed NTSCI patients had improvement in functional outcome with inpatient rehabilitation. Most studies used Functional Independence Measure (FIM)[22-25], in which New et al. reported mean admission FIM motor score of 39.6 and discharge FIM motor score of 58.7.[22] Jolien et al. used

Table 3. Comparing total and subdomains SCIM III score with etiologies of NTSCI

Etiology	N	Mean (SD)	Median	IQR	[a]p-value
SCIM III score					
At initial rehabilitation (0-100)					
Degenerative	24	37.9 (17.8)	36	24.5-47.0	0.947
Neoplasm	22	38.2 (13.7)	31	29.5-53.0	
Infection	11	35.9 (13.2)	34	30.8-49.3	
Total	57	37.9 (15.4)	33	26.5-51.5	
At discharge (0-100)					
Degenerative	24	50.5 (20.7)	45	36.0-75.0	0.470
Neoplasm	22	53.9 (14.8)	48	43.0-63.5	
Infection	11	57.8 (12.9)	57.5	44.5-66.3	
Total	57	53.9 (17.3)	52	43.0-71.5	
Self-care score					
At initial rehabilitation (0-20)					
Degenerative	21	9.1 (5.3)	8	4.5-12.5	0.068
Neoplasm	21	11.8 (3.4)	11	10.0-14.5	
Infection	10	11.1 (2.8)	11	8.8-13.3	
Total	52	10.6 (4.2)	10	8.0-14.0	
At discharge (0-20)					
Degenerative	21	12.1 (6.2)	13	6.0-17.0	0.065
Neoplasm	21	15.3 (2.9)	17	13.5-18.0	
Infection	10	16.9 (2.6)	17.5	14.0-19.3	
Total	52	14.3 (4.8)	16	11.0-18.0	
Respiration and sphincter management score					
At initial rehabilitation (0-40)					
Degenerative	21	21.7 (10.1)	19	13.5-32.0	0.421
Neoplasm	21	19.7 (10.0)	15	10.0-30.0	
Infection	10	17.1 (7.0)	15	10.8-22.0	
Total	52	20.0 (9.5)	17	11.0-29.0	
At discharge (0-40)					
Degenerative	21	27.0 (9.7)	29	17.0-36.0	0.295
Neoplasm	21	23.9 (9.9)	22	16.0-33.5	
Infection	10	28.4 (8.5)	27.5	20.8-36.0	
Total	52	26.1 (9.4)	25	17.0-35.0	
Mobility score					
At initial rehabilitation (0-40)					
Degenerative	21	7.2 (6.5)	6	2.0-11.0	0.294
Neoplasm	21	7.1 (4.2)	6	4.0-10.0	
Infection	10	9.6 (4.4)	9	5.8-14.0	
Total	52	7.4 (5.2)	7	3.0-11.0	
At discharge (0-40)					
Degenerative	21	13.1 (6.6)	13	7.0-20.0	0.465
Neoplasm	21	13.1 (4.7)	14	12.0-15.5	
Infection	10	11.6 (3.5)	11.5	9.5-13.8	
Total	52	13.1 (5.6)	13	10.0-16.0	

[a]Kruskal-Wallis rank sum test.

IQR, interquartile range; NTSCI, non-traumatic spinal cord injury; SCIM Spinal Cord Independence Measures; SD, standard deviation

functional status scale consisting of 5 items (mobility, self-care, bladder management, bowel management, and transfers), reported the median score of 47.5 at admission and 90 at discharge.[11] A study in India reported improved functional status using Barthel Index, with mean scores of 31.3 at admission and 55.6 at discharge.[26]

In contrary to the current study, previous studies reported that malignant neoplasms had lesser neurological recovery and poorer functional outcome as compared to other etiologies.[11-13,17] Although the current study did not differentiate between benign and malignant cases, majority (36/43) of cases in the neoplasm group are malignant. There are two possible reasons for this difference; patients in previous studies were older (mean age ranged from 59 to 69), while the mean age in the current study was 54.5 years. Besides that, UMMC is a tertiary center whereby patients can receive advanced high-efficacy anticancer therapeutic agents and radiotherapy, and therefore could have led to a better outcome.

McKinley et al. reported that the most significant improvements achieved during the rehabilitation stay were noted in wheelchair transfers, upper and lower extremity dressing, and toilet and tub transfers.[27] In this study, patients with spine neoplasm compared to other etiologies had higher self-care score and mobility score at discharge. However, our patients

Table 4. Total and subdomains SCIM III scores with NTSCI at initial rehabilitation and at discharge

Characteristic of NTSCI	N	Mean (SD)	Median	IQR	*p*-value
Total SCIM III score					
At initial rehabilitation (0-100)					
Paraplegia incomplete	35	39.9 (14.6)	34.0	30.0-53.0	0.200
Tetraplegia incomplete	24	36.2 (17.5)	31.0	22.5-50.0	
Total	59	38.4 (15.8)	34.0	26.0-53.0	
At discharge (0-100)					
Paraplegia incomplete	35	57.7 (15.1)	57.0	44.0-73.0	0.092
Tetraplegia incomplete	24	49.1 (20.0)	44.5	30.3-71.5	
Total	59	54.2 (17.7)	52.0	43.0-73.0	
Self-care score					
At initial rehabilitation (0-20)					
Paraplegia incomplete	32	11.6 (3.4)	10.0	9.25-14.75	0.029*
Tetraplegia incomplete	21	8.9 (5.2)	8.0	4.5-11.5	
Total	53	10.5 (4.3)	10.0	8.0-14.0	
At discharge (0-20)					
Paraplegia incomplete	32	15.7 (3.4)	16.5	14.0-18.0	0.012*
Tetraplegia incomplete	21	11.7 (5.7)	13.0	6.0-16.0	
Total	53	14.1 (4.9)	15.0	11.0-18.0	
Respiration and sphincter management score					
At initial rehabilitation (0-40)					
Paraplegia incomplete	35	19.3 (9.4)	15.5	10.0-28.75	0.202
Tetraplegia incomplete	24	22.3 (9.8)	20.0	15.0-32.0	
Total	53	20.5(9.6)	17.0	11.0-30.0	
At discharge (0-40)					
Paraplegia incomplete	32	26.4 (9.3)	25.0	17.0-35.0	0.956
Tetraplegia incomplete	21	26.4 (9.8)	24.0	17.0-37.0	
Total	53	26.4 (9.4)	25.0	17.0-35.0	
Mobility score					
At initial rehabilitation (0-40)					
Paraplegia incomplete	35	8.1 (5.0)	9.0	4.0-10.75	0.278
Tetraplegia incomplete	24	6.7 (6.1)	6.0	1.5-11.0	
Total	53	7.6 (5.5)	8.0	2.5-11.0	
At discharge (0-40)					
Paraplegia incomplete	32	13.7 (4.7)	14.0	12.0-16.75	0.553
Tetraplegia incomplete	21	12.7 (7.1)	12.0	7.0-20.0	
Total	53	13.3 (5.7)	14.0	10.0-17.5	

Mann–Whitney test, *$p < 0.05$

IQR, interquartile range; NTSCI, non-traumatic spinal cord injury; SCIM Spinal Cord Independence Measures; SD, standard deviation

had lower sphincter management scores at discharge. Most of the patients who had spinal metastasis were kept with indwelling catheter for convenience of care, as many are still undergoing active radiotherapy or chemotherapy. This could have contributed to the lower score in this subdomain.

Kennedy et al. and Kay et al. had reported that patients with spine infection had more rehabilitation needs and lower rehabilitation outcome.[6,12] The current study showed the opposite; patients with spine infection had improvement in all domains and had equal functional outcomes with other etiologies. This could be attributed to the fact that there were a higher proportion of patients with complete injury[6], and thoracic level involvement[12] as compared to our patients. Apart from that, another possible reason was our patients had longer stay to complete the antibiotic treatment, which allowed more time for rehabilitation.

There is paucity of studies comparing the functional outcome between the levels of injury in NTSCI patients. Our data had demonstrated that both incomplete paraplegia and incomplete tetraplegia group had similar SCIM III median score at initial rehabilitation, at discharge and gain. There was significant difference in self-care score, and this is self-explanatory as persons with paraplegia has no impairments in their upper limbs. As majority of patients in this study were incomplete motor (AIS D), this explains the similar gain in all other domains. This particular finding indicates that despite the different baseline score between individuals with incomplete paraplegia and tetraplegia, the net gain in SCIM III score remains the same.

There are several limitations in our study. As this is a retrospective study, missing values, and incorrect documentation may exist causing inaccuracies. Besides that, SCIM III score was not done or documented for all NTSCI patients, therefore only a small sample size was available for the analysis of the functional outcome. The second limitation is that there is selection bias as not all NTSCI patients are referred to the rehabilitation team, for example, the patients with minimal impairments, those who are not ready to participate in rehabili-

tation, those who are medically unstable, those who are in an advanced stage, or probably no available beds in the rehabilitation ward. The number of patients included in this study is not adequate to achieve statistical power. Sample size calculation indicated that this study needs 190 patients to achieve 95% confidence interval with 5% margin of error. There are a small number of patients in each etiology, and some etiologies need to be combined into a group to obtain enough for analysis. This might be the reason why some of our data showed a difference in the SCIM III score between groups, but it was not statistically significant. Furthermore, our data might not represent the national population as this is a single center study.

Conclusions

Spine degeneration and spine neoplasms were the most common etiology of NTSCI in this study. All etiologies had functional gain during the inpatient rehabilitation. However, there were no significant differences between etiologies and level of functioning. Therefore, all NTSCI patients should be given equal opportunity to rehabilitation in order to improve functional status. A prospective study involving larger groups of patients are needed to provide better quality evidence on the functional outcome of people with NTSCI.

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Short Communication

An Upper Extremity Self-Exercise Programme Increases Duration of Exercise in an Acute Rehabilitation Unit and Adherence After Discharge

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ABSTRACT

Objectives: To assess the effects of an upper extremity self-exercise programme within an acute inpatient rehabilitation unit on the duration of inpatient exercise and post-discharge treatment adherence.

Study design: Observational study.

Setting: Acute inpatient rehabilitation unit within Changi General Hospital, Singapore.

Subjects: Stroke patients with SAFE (Shoulder Abduction Finger Extension) score not less than 5, admitted to the Inpatient Rehabilitation Unit between July 2019 and March 2020.

Methods: This study was initiated as a quality improvement project. The self-exercise programme was adopted from TRIO (Targeted Rehabilitation Improved Outcomes) Home Programme. It was applied as an adjunct to conventional neurorehabilitation. The duration of daily self-exercise was documented. Patient's feedbacks were obtained before discharge. Post discharge 4-6 weeks, adherence to the programme was followed up via a telephone call.

Results: Two hundred and fifteen stroke patients were screened. Thirty patients participated in the project. While admitted, the median number of days spent in the upper extremity self-exercise programme was 6 days with an average of 25.88 (SD 11.80 minutes) per session. Eighty-three percent of patients gave feedback that the programme was helpful for their recovery. On follow up, 56.7% reported continued adherence after discharge and 36.7% were not contactable.

Conclusions: After the early implementation of an upper extremity self-exercise adopted from the TRIO Home Programme within an acute inpatient rehabilitation unit, the average time spent during admission (25.88 minutes) is approaching the minimum recommendation duration of 30 minute per session and promotes treatment adherence after discharge.

Keywords: stroke, upper extremity, exercise, treatment adherence, rehabilitation

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Introduction

Various stroke guidelines advocate intensive inpatient rehabilitation with a recommended duration of 3 hours per day.[1] According to the National Institute for Health and Care Excellence (NICE) guidelines, it is recommended to initially offer the relevant therapy for at least 45 minutes, 5 days per week.[2] There are various reasons for not providing the amount of therapy according to various stroke guidelines that include time spent on the exchange of information, documentation, and the way work is organized.[3]

Research has also shown that post-stroke rehabilitation can aid patients with stroke in the recovery of function and mobility.[4] Beyond inpatient rehabilitation programmes, rehabilitation extended into the home setting post-discharge has shown to facilitate effective treatment.[5] There has been much research done to analyse factors affecting adherence to home-based exercise programmes. These range from the evaluation of various methods of engagement - usage of smart technology versus paper-based modalities[6] or pictorial versus written instructions and studies to identify barriers to home-based exercise programmes.[7] These include the degree of stroke, patients' motivation, caregiver involvement, and external motivation from family.[8] However, there has been limited research on incorporating home-based exercise programmes in an inpatient setting to promote adherence and thereby maximise the benefits reaped.

At our hospital, admissions correspond to various diagnoses, but approximately 40% of the patients admitted per year were diagnosed with stroke. Generally, most patients are transferred to the acute inpatient rehabilitation unit as early as third day after stroke (median interval of 0 days from stroke unit referral to transfer to inpatient rehabilitation). According to the survey of our inpatients, the average duration of occupational therapy per stroke patient per weekday was 21 minutes. To improve the upper extremity functions, the team utilised the Targeted Rehabilitation Improved Outcomes (TRIO) home

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exercise booklet, developed by Auckland University,[9] as it is readily available, with permission to be used and downloaded from the website.[7] Curating a new programme was thus not necessary.

The TRIO home exercise programme targeted patients with shoulder abduction and finger extension (SAFE)[10] scores of 5 and above and was designed to utilise commonly available items to promote both strength and finger dexterity. The SAFE score[10] was calculated by scoring shoulder abduction and finger extension separately, using the Medical Research Council Muscle Scale.[11] The patient's muscle strength in each of these movements was scored between 0 and 5, whereby 0 reflected a lack of muscle activity and 5 reflected normal strength and range of movement. The TRIO programme was modified for simplicity and higher acceptability by patients. With a smaller range of selected tasks, patients can be more focused in the exercises, resulting in increased number of repetitions and intensity of each exercise. The objective of this project was to assess the effects of an upper extremity self-exercise programme adopted from the TRIO home exercise programme within an acute inpatient rehabilitation unit on the duration of exercise during admission and post-discharge adherence.

Methods

This project was initiated as a quality improvement (QI) project in an acute inpatient rehabilitation unit of Changi General Hospital, Singapore. The institutional review board (IRB) has reviewed and determined that the project does not require further ethical deliberation. (IRB Reference number: 2020/2811).

Participants

Stroke patients admitted between July 2019 and March 2020 were screened by medical officer in charge on admission as per inclusion criteria of age > 18 years, SAFE score ≥ 5, the cognitive functional independence measure (FIM) ≥ 5[12] in each component and verbal consent was given. Exclusion criteria included laceration or abrasion or musculoskeletal issues like joint pain, tendon tear or fracture that prevented effective participation. Patients with cognitive impairment who were unable to follow the instructions were excluded.

Materials

The self-exercise toolbox which was supplied to each enrolled patient included the following (Figure 1): a ball (wooden or plastic), cloth pegs, a writing board with pen, a weight-adjustable dumbbell (a fully filled dumbbell weighs 1 kg), plastic cups and spoon, a deck of cards, and a TRIO exercise booklet downloaded from Auckland university website.[7]

Intervention

The self-exercise toolbox was placed at the patient's bedside for easy access throughout their inpatient stay. In the inpatient setting, the patient was shown how to utilize each of the 5 items in the TRIO box. The patient would demonstrate that they understand by performing the exercises to the team member instructing the patient and was encouraged to engage in the exercise of his/her own volition with a recommended minimal duration of 30 minutes a day. The time spent on self-exercise and adherence was documented by the nurse in charge.

The self-exercise programme was not initiated immediately on the day of transfer to the acute rehabilitation unit (which would be after 2 days following stroke admission) if a patient was transferred in after normal work hours. The programme was terminated one day prior to discharge.

On discharge, one of the team members whether a nurse or a medical officer administered a patient feedback survey and reinforced adherence to the exercise programme at home. The patient was provided with a TRIO booklet and advised to utilize common household items such as canned food, fork and spoon, paper and pen and paper cups as illus-

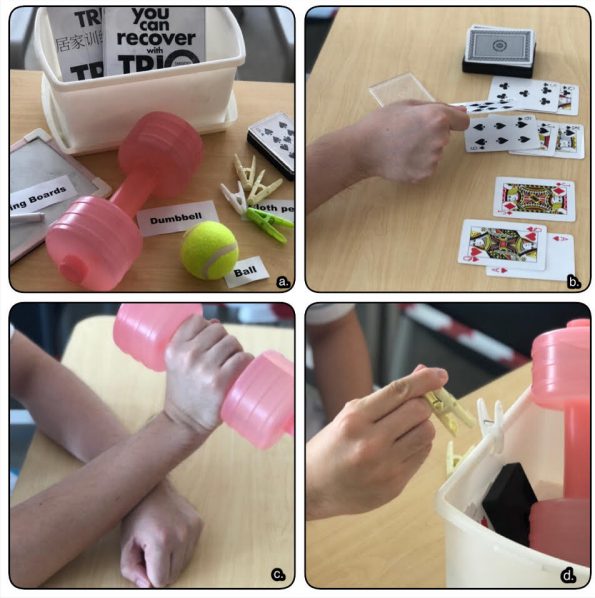

Figure 1. a. Self-Exercise Box: contains TRIO booklet, writing board with pen, water-filled dumbbell, cloth pegs, ball and cards, b. cards sorting, c. wrist extension using water-filled dumbbell, d. cloth pegs clipping onto the box

trated in the booklet for the home exercise programme. The TRIO box was not supplied to the patient on discharge. The patient was advised to perform the exercises for 30 minutes a day. These patients were followed up between four to six weeks post-discharge via a telephone call to enquire if they adhered to the self-exercise programme. In addition, relevant clinical data such as admission Fugl-Meyer score and National Institutes of Health Stroke Scale or NIH Stroke Scale (NIHSS) of the recruited patients were gathered. The SAFE and the NIHSS scores were re-assessed at discharge.

Outcome measurements

The primary outcome measures were the time spent in performing the exercises while being in the inpatient rehabilitation unit and adherence to the programme post discharge. Post discharge, the patient was deemed to be adherent if he/she performed the exercises daily for minimum of 15minutes. Secondary outcome measures were admission and discharge SAFE and NIHSS.

Statistical analysis

Descriptive statistics were used for age, gender and stroke classifications. Continuous data were summarized as mean (standard deviation) or median (interquartile range) for symmetrically distributed and skewed data respectively. Categorical data were summarized by frequency (%). Data analysis was performed using IBM SPSS version 25.0. Pre- and post-data were performed using single-tailed t-test and a p value of < 0.05 was considered statistically significant.

Results

Amongst the 215 patients with stroke screened by the QI team on admission to the inpatient rehabilitation unit between July 2019 and March 2020, 30 patients fulfilled the inclusion criteria for the programme. The baseline demographics and clinical data including the side of the stroke, admission Fugl-Meyer and NIHSS scores, and the rehabilitation length of stay are detailed in Table 1.

During admission, the median duration of the programme was 6 days and the average time spent per day was 25.88 (SD 11.80) minutes. The average SAFE score on admission was 7.9, at discharge score was 8.3, and the average improvement was 0.30 (p = 0.204) after completion of the programme. The average NIHSS score on admission was 5.2, at discharge score was 2.5, and improved by 2.63 (SD 3.94, p = 0.001) in this group of patients.

Twenty-seven (90%) patients gave the feedback regarding the self-exercise programme on the day of discharge, of whom 25 (83.33%) were positive about the programme. They perceived that it was helpful to their recovery, and 24 (80.0%) patients reported that the programme offered them confidence to perform the exercises at home correctly. (Figure 2)

Between four to six weeks post-discharge, 19 (63.33%) patients were contactable for follow-up whereas 11 (36.67%) were not. Seventeen patients (89.47% of the total contactable patients) reported that they continued the exercises according to the TRIO booklet daily. Therefore, 56.67% of all programme participants adhered to the home exercise programme. (Figure 3)

Table 1. Baseline demographics and clinical characteristics of the patients (n = 30)

Demographic information	
Age, mean (SD)	62.26 (12.3)
Gender, n (%)	
Male	23 (76.67)
Lesion characteristic	
Stroke types, n (%)	
Ischaemic	26 (86.67)
Haemorrhagic	4 (13.33)
Stroke sites, n (%)	
Right	17 (56.67)
Left	11 (36.67)
Bilateral	2 (6.67)
Baseline scores	
SAFE score, mean (SD)	7.9 (1.74)
Admission Fugl-Meyer UE motor, median (IQR)	61.5 (48, 64)
Admission Fugl-Meyer UE total, median (IQR)	122 (108.25, 124)
NIHSS, median (IQR)	5 (2, 6)
Length of inpatient rehab stay, median (IQR)	10.5 (7.7, 15)

SAFE, Shoulder Abduction Finger Extension; NIHSS, National Institutes of Health Stroke Scale; UE, upper extremity.

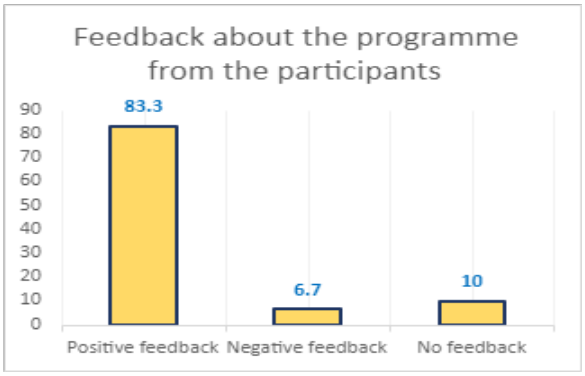

Figure 2. Feedback from the patients participated

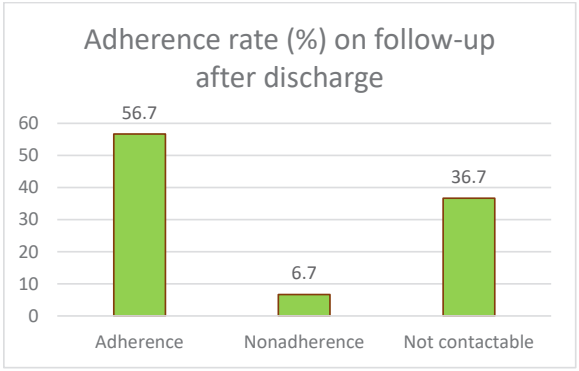

Figure 3. Adherence rate (%) on follow-up

Discussion

Rehabilitation after stroke is not an intervention provided at a single point in time. If we were able to encourage greater patient autonomy and participation at the point of discharge, there could be potential gains later in the journey.[13] Upper extremity impairments are a major contributor to post-stroke functional limitations, which have downstream effects on activities of daily living.[14] In this project of implementing the TRIO home exercise programme within an acute rehabilitation unit, the median duration of the self-exercise programme was 6 days whereas of the rehabilitation length of stay was 10.5 days, and the average time spent per day was 25.88 minutes. According to our previous observation before implementing the TRIO home exercise programme, the average duration of occupational therapy per stroke patient per weekday was 21 minutes. These demonstrate the benefit of early intervention of upper extremity self-exercise programme within an acute rehabilitation phase by promoting more therapy duration during admission.

In addition, majority of the patients gave positive feedback about the programme and the self-reported rates of post-discharge adherence to the programme were 89% in those who were contactable and 56.67% in all patients. These were higher than the adherence rates reported for other home exercise programmes (24.5%).[15] One reason might be that the patients were allowed as integral stakeholders in the rehabilitative process, with some degree of autonomy over therapy duration and time during the rehabilitation admission. They can practice even on weekends when conventional therapy is not available. This shift in their mind-set potentially increased ownership and facilitated greater adherence to the home-based exercise programme post-discharge. Lastly, through the introduction of home-based exercise programmes in an inpatient setting, both patients and their caregivers have a greater length of time being exposed to and familiarising themselves with the exercises. They had many opportunities to clarify any questions concerning the exercises. This may potentially promote greater adherence to post-discharge exercises.

Regarding neurological recovery, the improvement in the SAFE score and NIHSS were modest. The average NIHSS score was improved by 2.63 at discharge. In this study, the rehabilitation length of stay was relatively short and most of the strokes were mild as one of the inclusion criteria was SAFE score at least 5. It was therefore difficult to demonstrate a greater degree of improvement within a short period of time. However, Kerr et al. (2012) found that NIHSS was sensitive to change as early as after 7 days post stroke.[16]

As this study was initiated as a departmental-level QI pilot, the sample size was limited. Furthermore, no pre-intervention data besides baseline duration of occupational therapy (OT) were available. The length of stay was generally short and discharge functional scores such as Fugl-Meyer was not available. Self-reported compliance rates might have been subject to respondents' recall bias, which could potentially over represent adherence rates in this population. In addition, to establish the long-term benefit of early intervention of upper extremity self-exercise programme in patients with acute stroke, it is necessary to follow-up the patients over a period of time. Further collaboration with allied health professionals for assessment of neurological and functional outcomes will strengthen the study. The average time spent in OT was assessed in an earlier cohort of patients. It is assumed that the additional 25.8 minutes which spent in self-exercise would be able to make up to 45 minutes per day of OT per NICE guideline.

Conclusions

Based on the preliminary results, it is possible to initiate and incorporate the TRIO home-based exercise programme as an upper extremity self-exercise programme in an acute inpatient rehabilitation setting to promote post-discharge adherence for patients with mild stroke. This provides patients with greater autonomy in their recovery process and increases the duration of time patients spend exercising their upper extremities every day. This is an innovative way to address two issues with one intervention.

Disclosure

The authors declare no potential conflicts of interest.

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Case Report

A Combined Outpatient and Home-Based Rehabilitation Program for a Patient with an Open Atrial Septal Defect (ASD) and Severe Pulmonary Hypertension: A Case Report

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ABSTRACT

Objectives: This paper presents a rehabilitation intervention for improving functional capacity and physical activity level in a patient with an open atrial septal defect (ASD) with severe pulmonary hypertension contraindicated to ASD closure.

Study design: Case report.

Setting: Hasan Sadikin General Hospital, Bandung, West Java, Indonesia.

Subjects: A-37 year old female, an elementary school teacher, complained of shortness of breath when doing daily activities, walking, and speaking for three years. She was planned for ASD closure but could not be done because of severe pulmonary hypertension. The right heart catheterization showed pulmonary hypertension (mean Pap: 70 mmHg). In addition, the CT-Scan showed cardiomegaly with pulmonary hypertension and pulmonary fibrosis.

Methods: A combined outpatient and home-based comprehensive rehabilitation program including cardiopulmonary endurance exercise with a treadmill, breathing exercises (controlled breathing and deep breathing), and sustained maximum inspiration technique were prescribed to reduce fatigue and dyspnea on exertion.

Results: Eight weeks after following the program, there were improvements in cardiorespiratory fitness (from 2.92 to 5.27 METs), maximum inspiratory volume (from 1,500 to 2,500 ml), the Modified Medical Research Council (MMRC) scale (from 2 to 1), and the Fatigue Severity Scale (FSS) (from 71 % to 45 %).

Conclusions: In a limited inpatient rehabilitation service country like Indonesia, a combined outpatient and home-based rehabilitation program of exercises benefits the functional capacity of a patient with an open ASD with severe pulmonary hypertension and mild pulmonary fibrosis.

Keywords: atrial septal defect, dyspnea, exercise, fatigue, pulmonary hypertension

ASEAN J Rehabil Med. 2022; 32(2): 93-96

Introduction

The second most common congenital heart disease (CHD) is atrial septal defects (ASDs).[1] It accounts for roughly 13% of CHD cases, with a female to male ratio of 2:1.[1,2] Al though most ASDs are benign, left to right shunting can occasionally overwhelm the right heart, resulting in RHF and arrhythmias.[1] In the context of severe shunting and symptoms of RHF, shunt closure is recommended.[1] Closure of ASD is not recommended if irreversible pulmonary arterial hypertension (PAH) develops due to the risk of right ventricular decompensation and death following the operation.[1,3]

Pulmonary hypertension (PH) is a chronic illness that worsens over time. Dyspnea frequently appears gradually in the early stages of PH, delaying diagnosis.[4] Physical activity was thought to negatively affect PH patients since it increased the risk of disease progression, right ventricular decompensation, and sudden cardiac death. As a result, people with PH were advised to limit their physical activity, which worsened their mobility and exercise tolerance.[4] Despite improved medical treatment, most individuals with PH, continue to experience symptoms, decreased exercise capacity, poor quality of life (QoL), and disease progression.[5] In most cases, medication will not be able to completely stop or reverse right ventricular dysfunction, nor will it be able to normalize pulmonary vascular resistance.[5] Exercise training is helpful in various illnesses, including cardiac and pulmonary diseases, and is one of the most essential, safe, and cost-effective therapy alternatives.[5]

Long-term endurance exercise, according to research, increases right ventricle size and improves early diastolic right ventricular function and left ventricular stiffness.[5] As a result, moderate physical activity has been recommended to avoid various cardiovascular problems.[5] Exercise training for patients with left heart failure was given a 1A recommen-

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dation in the most recent guidelines. It has been shown to improve QoL and exercise capacity, as well as lower the risk of heart failure-related hospitalization and morbidity events.[6] However, excessive physical activity, particularly in untrained individuals, can increase the risk of myocardial infarction.[5]

There have been no exercise guidelines for patients with PH. However, in addition to pharmacological therapy, recent guidelines advocate a supervised and thoroughly monitored exercise and respiratory training program in specialized clinics for stable PH patients (class II, level of evidence B).[5] Exercise training for patients with PH, on the other hand, is only frequently reimbursed by insurance programs or government financing in a few high-income countries[5], including phase 2 cardiac rehabilitation in Indonesia.

According to the guidelines, for patients with severe PH who are stable on medical therapy, an inpatient and outpatient program should be used.[5] The majority of rehabilitation programs and services are provided at outpatient clinics in our setting; there are no rehabilitation beds or wards for inpatient treatment. As a result, the goal of presenting this case is to show that employing current guidelines at a limited health/rehabilitation care institution can successfully rehabilitate a patient with an open ASD and severe PH, which causes limitations in daily activities and restrictions in working as a school teacher.

Case presentation

A-37 year old female, an elementary school teacher, came to the rehabilitation clinic with a chief complaint of shortness of breath while doing daily activities such as sweeping and mopping, which started three years ago after giving birth. The symptoms disappeared with resting. However, the symptoms restricted her work as a teacher. She could not teach because of shortness of breath when speaking for more than 10 minutes.

The oxygen saturation was sometimes below 90% if she developed shortness of breath. Later, she also felt easily tired when doing daily activities, walking more than 150 meters, and speaking for more than 10 minutes, and became sedentary because of shortness of breath and fatigue. An atrial septal defect (ASD) closure was planned but could not be done because of severe pulmonary hypertension. For about 10 minutes, the oxygen saturation was reduced during the talk. The maximal inspiratory volume was 1,500 ml with chest expansion at axillary, nipple, and xiphisternum levels of 2 cm, respectively. The trunk alignment was straight (normal posture). Her body weight was 43 kg, her body height was 146 cm, and body impedance analysis revealed 21% visceral fat, 13.7 kg of skeletal muscle mass, and 56.6% of total body water.

The spirometry test was requested and showed mild restrictive. The echocardiography revealed dilated right atrium and ventricle, diastolic dysfunction, and reduced right ventricular contractility with a high probability of pulmonary hypertension. The right heart catheterization showed secundum ASD with balance shunt; pulmonary hypertension (mean pulmonary arterial pressure of 70 mmHg); low flow, high resistance, and nonreactive oxygen test. The CT scan of the thorax with contrast showed: cardiomegaly with pulmonary hypertension; minimal fibrosis spread over the lateral segment of the middle lobe, the anterobasal segment of the inferior lobe of the right lung, and almost the entire segment of the left lung; minimal left pleural thickening; minimal ground-glass opacity in the superior and anterobasal segments of the left inferior lobe of the left lung, compatible with idiopathic pulmonary fibrosis (IPF).

Using the Modified Medical Research Council (MMRS) Scale, the dyspnea scale was 2 (moderate dyspnea). The cardiorespiratory fitness using the treadmill exercise stress test with the “Bruce protocol” showed low cardiorespiratory fitness (METs = 2.92) with desaturation during exercise and the Fatigue Severity Scale (FSS) was 45 (71.43%).

The patient was referred to a rehabilitation physician by a cardiologist at the outpatient clinic. Under the supervision of a rehabilitation physician, the patient got oxygen supplementation 2-3 liters/minutes via nasal cannula while performing cardiopulmonary endurance exercise, which consisted of a 20-minutes session of low-intensity conditioning treadmill exercise with warming-up and cooling-down activities for 5 minutes, 3 days per week. Exercise duration was increased by 5 minutes every 2 weeks as tolerated. The oxygen saturation was maintained at above 88%.

In addition, the patient was trained to perform a home program of sustained maximum inspiration (SMI) using an incentive spirometer for two sessions per day. Each session consisted of 3 sets of 10 repetitions, rest 2-3 minutes between

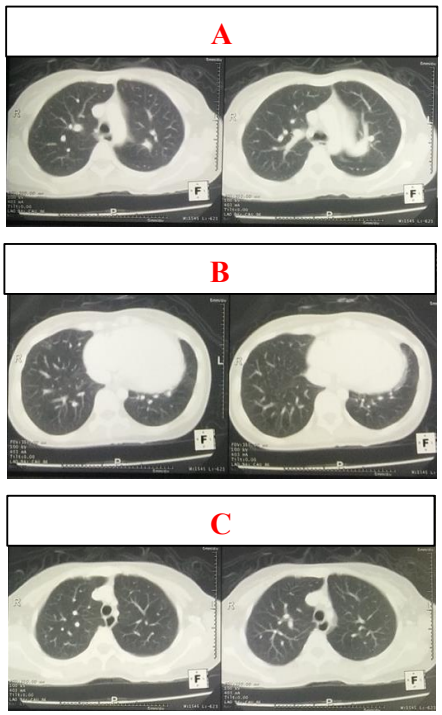

Figure 1. CT scan of thorax with the contrast of this patient showing (A) pulmonary hypertension; (B) cardiomegaly; (C) bilateral pulmonary fibrosis.

Table 1. The results before and after eight weeks of following the comprehensive rehabilitation program

	Before	After
MMRC score	2 (moderate dyspnea)	1 (mild dyspnea)
FSS score (%)	45 (71.4)	30 (47.6)
Maximum inspiratory volume (ml)	1.500	2.500
Chest expansion (cm)	2/2/2	3/3/3
Cardiorespiratory fitness (METs)	2.92	5.27
Oxygen saturation at rest (%)	92-93	95-96

MMRC, Modified Medical Research Council; METs, metabolic equivalents; FSS, fatigue severity scale
Max FSS score is 63; the higher the score, the greater the fatigue severity.[7]
Oxygen saturation during treadmill exercise was 87-91%

sets. The progression was to increase inspiratory volume every week as tolerated, and the target was 2,500 ml. Moreover, the patient was educated about controlled breathing during activity, relaxation techniques, and energy conservation.

The patient could complete the exercise program as planned. However, oxygen saturation was initially low, sometimes falling below 88% during exercise training. Therefore, the patient planned to provide the program for 8 weeks from the beginning.

Eight weeks after the comprehensive rehabilitation program, dyspnea and fatigue decreased while the maximum inspiratory volume, chest expansion, and cardiorespiratory fitness increased, as shown in Table 1. The patient could do daily activities with minimal shortness of breath and fatigue and resumed working as a part-time teacher.

Discussion

We describe a middle-aged female patient whose closure of ASD was contraindicated because of severe PH and the risk of right ventricular decompensation and death after the operation. The patient was referred to a rehabilitation physician (physiatrist) to rehabilitate a case that was not common in our setting. Before planning a comprehensive rehabilitation program for this patient, we were aware of her physical condition. Her respiratory disturbance might be caused by PH and restrictive lung disease due to IPF. This comprehensive exercise program aimed to lessen her symptoms of shortness of breath and dyspnea on exertion. The program consisted of controlled breathing techniques, which are generally used to improve pulmonary function tests, reduce dyspnea, reduce work of breathing, improve ventilator muscle function, facilitate relaxation, and are indicated in patients with obstructive and restrictive pulmonary problems.[8,9]

A home program of SMI with an incentive spirometer seemed like a cost-effective breathing exercise technique. After 8 weeks of SMI, her maximum inspiratory volume reached the target of 2,500 ml. This supports the evidence that SMI can increase chest expansion and lung volume to improve cardiorespiratory fitness for daily activities.[10,11] The target inspiratory volume of 2,500 ml was based on age.[12]

As spirometry showed mild restrictive lung disease in this case, we believe that the most likely cause of oxygen desaturation during exertion was of cardiac origin, rather than pulmonary. Therefore, besides breathing exercises, a cardiore¬spiratory exercise training program was planned at the outpatient rehabilitation clinic to improve her cardiorespiratory endurance. We started with light intensity aerobic exercise for patient safety, appropriate for patients with severe chronic disease or very deconditioned individuals.[13] The exercise duration was increased as tolerated based on recommended dyspnea ratings of between 3 and 6 on the Borg 10 scale.[14] And the exercise program was conducted at outpatient rehabilitation clinics under the supervision of a physiatrist. According to guideline recommendations, frequency is at least 3-5 days per week, and duration is 20-60 minutes per day at low-to-moderate intensities as tolerated.[5] In this case, we chose a session of 20 minutes of treadmill walking exercise as her cardiorespiratory fitness was low, and treadmill walking is generally the preferred method because walking is a functional activity.[15] We are also concerned about oxygen desaturation during exercise and prescribed oxygen supplementation, which is indicated for patients with a PaO_2 ≤ 55 mm Hg or a SaO_2 ≤ 88% while breathing room air,[16] so that SaO_2 is maintained at > 88% as recommended. After 8 weeks of this program, the patient's respiratory functions and cardiorespiratory fitness improved. The patient was advised to continue using the SMI technique at home. The patient was satisfied with the outcome of this rehabilitation program. She could perform her daily activities as usual, and go back to work as a teacher.

Conclusions

An 8-week combined outpatient and home program of cardiopulmonary and breathing exercises provided a beneficial result in improving the functional capacity and resuming work of a patient with an open ASD with severe pulmonary hypertension who is not fit for operation but is expected to reduce the risk of the worsening of pulmonary hypertension.

Disclosure

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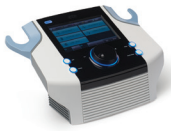

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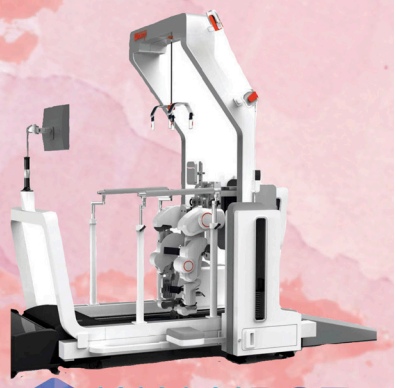

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Content

The Hemiplegic Shoulder Trilogy: Pain, Subluxation and Orthosis

Restoring functions of an individual to the highest possible level is the primary goal of every rehabilitation service. After stroke rehabilitation, recovery of the upper extremity is less than the lower extremity. Many are able to walk, but not able to use their weak or paralyzed upper extremity. Flaccid paralysis of the shoulder muscles causes shoulder subluxation and shoulder pain which prevent use of the affected upper limb and limit self-care activities. Therefore, one of the most challenging goals to achieve is recovery of the upper extremity functions.

In this issue, there are two interesting articles about shoulder problems. One is a systematic review on management of shoulder pain in patients with stroke and the other is a clinical trial comparing the effect of a newly designed custom-made shoulder subluxation orthosis and a commercial Bobath sling commonly prescribed for patients with shoulder subluxation.

The systematic review shows the use of supportive devices/slings for shoulder subluxation has only moderate evidence and is moderately recommended. A strong recommendation needs not only a good randomized control trial but also a more effective and appropriate shoulder orthosis. The commercial sling may be easily accessible but not effective enough to reduce the occurrence of shoulder subluxation. Perhaps, the custom-made orthosis presented in the other article would be a good alternative shoulder subluxation orthosis; it is relatively low cost and could be made by occupational therapists. However, this new shoulder subluxation orthosis may not help control shoulder pain as the participants recruited in the study had rather low pain intensity. Therefore, future study should consider not only its effect on shoulder subluxation but also shoulder pain and functional recovery of the upper limbs. This could be the potential solution to facilitating upper limbs recovery in people with stroke in the future.

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Impact of COVID-19 on Medical Rehabilitation Services, Education and Research in Thailand

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Introduction

Emerging infectious diseases, like the coronavirus-19 (SAR-CoV-2; COVID-19) virus which is currently a worldwide pandemic, can have several negative impacts around the globe. In early March 2022, globally there were over four hundred million confirmed cases of COVID-19, including about six million deaths.[1] In Thailand, there have been 2,958,162 confirmed cases of COVID-19 with 23,070 deaths,[1] and the number of daily new cases has continued to rise during January-February 2022.[1] Several healthcare strategies, both prevention and treatment, have been implemented in Thailand to control this disease. "DMHTT" (distancing, mask, hand hygiene, temperature testing) has been implemented for prevention while the "Thai chana" mobile application is for tracing persons at risk of contracting the disease. The word "chana" in Thai means "to win, to conquer" giving the expression of positive meaning that all Thais will ultimately overcome this adversity. Another important national strategy has been developing immunity via vaccination. In Thailand, COVID-19 vaccination was first implemented in late 2020. Available vaccines were first offered to health care personnel, patients with underlying diseases (especially respiratory and cardiovascular diseases), people aged over 60 and frontline immigration officers and essential workers. By February 2022, more than one hundred and twenty million vaccine doses had been administered in Thailand.[1] Guidelines for COVID-19 treatment has been developed and is updated periodically by the Ministry of Public Health (MOPH).[2,3] The latest guideline, dated Nov 2, 2021, suggested about administration of Kariyat which is known in Thai as Far Ta Lai Jone (Andrographis paniculata), a medicinal plant, for the treatment of flu-like symptoms, fever, cough, sore throat, fatigue and muscle pain due to viral infection. The recommended dose for adults is 180 mg/day of andrographolide.[3]

COVID-19 not only causes acute illness but also has long-term consequences. According to the World Health Organization, rehabilitation is an essential part of the health care system which should be integrated into all levels of health system including primary, secondary and tertiary.[4] Since the first case of COVID-19 was detected in Thailand, the roles of physiatrists (rehabilitation physicians) in providing medical rehabilitation services to restore function as well as in providing education and conducting research have been impacted and changed.

Medical rehabilitation services

Early in the COVID-19 pandemic, Thai physiatrists, just as other general practitioners and specialists, were recruited to take part in providing COVID-related medical services and patient care, e.g., screening for the disease and identifying active cases in the community as well as in acute respiratory infection clinics and serving as attending physicians in COVID-19 wards. Some physiatrists voluntarily looked after patients at home and to help with community isolation programs, while some became physicians-in-charge at COVID-19 vaccination service centers.

Rehabilitation services, both at hospitals as well as at the community level, have been affected by both the disease itself and by government policies of lockdown, curfew and travel restrictions. On the 1st of June 2021, the Sirindhorn National Medical Rehabilitation Institute (SNMRI) set up a field hospital for persons with disabilities (PWDs), named the Sirindhorn Science Home Field Hospital, with the cooperation of the Department of Empowerment of Persons with Disabilities and the National Science and Technology Development Agency (NSTDA).[5] This field hospital was established to assist independent asymptomatic and mildly symptomatic COVID-19 PWDs including the physically challenged, the blind and the deaf. Mobile prosthesis services, which normally provide services at least once a year, were temporarily suspended in 2020 to avoid contracting an infection and to prevent disease transmission. The recommended guideline of

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management and immunization program are applied for the PWDs as well.[6]

Rehabilitation programs provided at hospitals or in community had to be changed or adjusted depending on the factors and conditions confronting the healthcare system, e.g., COVID-19 prevalence and virulence, available medical resources including personal protective equipment (PPE), and the state of vaccination of health personnel and the general Thai population. Inpatient rehabilitation services, special rehabilitation investigations and some close contact therapies/ treatments were temporarily discontinued. Manuals for hospital risk management during a pandemic of an emerging infectious disease[7] were developed. Recommendations for provision of medical rehabilitation services during the COVID-19 outbreak were published by a team of physiatrists[8] to ensure proper rehabilitation services and to protect the rehabilitation health personnel from contracting COVID-19 by effective use of PPE. The recommendations included that all rehabilitation programs should be provided in compliance with universal precautions and social distancing policies and that swallowing evaluation as well as swallowing training, speech training and electrodiagnosis should be postponed unless the patient had an exceptional indication and should depend on the judgement of the attending physiatrists and rehabilitation teams.[8,9] At present, testing for COVID-19 by real time polymerase chain reaction (RT-PCR) or using an antigen test kit (ATK) is performed prior to beginning close contact investigations and treatment as mentioned above, including screening before rehabilitation ward admission.

Telemedicine, telerehabilitation and postal medicine delivery are also emphasized.[9] Telerehabilitation services are ignited to replace or to be used concomitant with the usual practices, e.g., patient education, follow-up and monitoring, individual and group exercise, home programs, home visits, speech therapy, and psychological support via phone, video calls and clips, and infographics via various media platforms. Such programs and activities are applied in the case of various medical conditions such as pain, dysphagia, pulmonary and neurological disorders as well as for pediatric patients. The QR codes for COVID-19 and non-COVID-19 patients shown in Figure 1 were produced by rehabilitation departments in Thailand.[10-14] These telerehabilitation services are useful and are compatible with policies such as social distancing and travel restriction.

In the acute phase of COVID-19, patient rehabilitation is mainly performed by distance instruction via brochures and social media, e.g., demonstration video clips. Asymptomatic patients and those with mild symptoms are suggested to receive video clips as part of the patient education service. Breathing exercises are emphasized and monitored by video calls. In patients with severe acute respiratory distress syndrome (ARDS), prone positioning is advised to facilitate re-expansion of a collapsed lung parenchyma, to lessen ventilation-perfusion mismatch, to improve gas exchange and oxygenation and thus to decrease mortality.[8] Experience has taught that some COVID-19 patients hospitalized in the intensive care unit (ICU) may develop post-intensive care syndrome (PICS), and at least a third of moderate to severe COVID-19 survivors suffer from neurological sequelae.[15] In the post COVID-19 phase, some may have post-COVID-19 syndrome or "long COVID", with symptoms including fatigability, shortness of breath, difficulty breathing, and poor endurance.[16] These individuals need rehabilitation programs, including pulmonary rehabilitation, graded reconditioning exercise programs and neurological rehabilitation. Presently, some of the media addressing long COVID-19 rehabilitation are available for Thais in the Thai language (Figure 2).[17,18]

Exercise and physical activity are important tools for rehabilitation. Exercises prescribed for infected patients vary depending on clinical findings. Asymptomatic patients and patients with mild symptoms and without major risk factors can perform light to moderate intensity aerobic and strengthening exercises.[8] A simple sit-to-stand test is recommended for screening for exercise-induced desaturation in COVID-19

Figure 1. QR codes of rehabilitation programs available for COVID and non-COVID patients. A: muscle stretching, B: swallowing training, C: pediatric chest physiotherapy, D: COVID-19 rehabilitation 1 and E: COVID-19 rehabilitation[2]

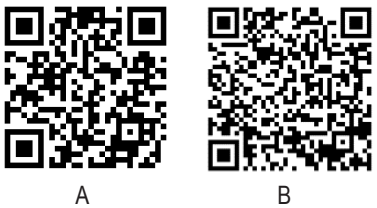

Figure 2. Long COVID. A: media for rehabilitation and B: guidelines for post COVID-19 syndrome

patients who do not have resting hypoxemia. Positive deoxygenation or 3% or more decrease of oxygen saturation (SpO_2) suggests that a patient may develop COVID-19 pneumonia and should be transferred from home or from a community isolation facility, a hospitel (a hostel serving as a hospital) to a hospital for increased safety.[19-21] During recovery from a COVID-19 infection, it is recommended that the individual gradually begin exercising, starting with light intensity aerobic exercise first, then gradually increasing the intensity. Non-infected persons should stay active with aerobic activity such as brisk walking and dancing or with outdoor activities such as walking, bicycling and gardening. Exercise at moderate intensity for 150 minutes per week is recommended. Physical distancing, at least 2 meters from others, is suggested. Individuals at high risk for SARS-CoV-2 exposure should refrain from exhaustive exercise and overtraining.[22]

Rehabilitation medicine education

The Rehabilitation Medicine Residency Training Program has been disturbed by the COVID-19 pandemic. Teaching and learning activities have had to be changed under the prevention scheme for infection control. Certain academic activities and events have been either cancelled or postponed. Nevertheless, during the crisis there has been great opportunity for online versions of those activities, e.g., classroom sessions, academic meetings and scientific conferences. However, hands-on and skill training has been negatively impacted due to a reduction in the number of patients available. Resource material has been reduced by travel restrictions and limitations on the number of inpatient beds for non-COVID-19 patients. This situation has unquestionably decreased the training capacity of medical academic institutes. Elective activities and rotations to other training institutes have been affected from time to time during the country lock down periods following a very high daily infection rate. The Medical Council, the University Hospital Network, MOPH, the Royal College of Physicians of Thailand and the Infection Disease Association of Thailand have established guidelines on safe conditions (environment, vaccination and active surveillance). All training institutes have to follow those guidelines to help ensure the safety of the residents in training.[23] In addition to changes in the learning experience, the Royal College of Physiatrists of Thailand conducted an online oral examination, in-house examination instead of an examination at a central examination facility and has placed emphasis on workplace-based assessment (WPBA) instead of the usual face-to-face exit examinations. The WPBA of the Rehabilitation Medicine Residency Training Curriculum established before the pandemic was revised in 2021 to ensure the appropriateness and completeness of evaluations during training.[24] Advantages of the online oral examination and the evaluation based on WPBA include time saving, cost saving, no travel expense, and minimized risk of both examinees and examiners contracting disease. Disadvantages of the online examination include dependence on the quality of the internet signal and system and limited opportunity to observe the body language and manner of the examinees.

Research in rehabilitation medicine

Research projects conducted by physiatrists and in-training residents have been similarly interrupted during the COVID-19 pandemic due to difficulty in recruiting subjects, more patients lost to follow-up, protocol deviations and drop outs. Methodology modifications and amendments to protocol, e.g., changing from an onsite follow-up to a phone or VDO call, were instituted to allow research work to continue to completion. New research projects conducted by residents in training during this pandemic period are mostly questionnaire-based and/or based on retrospection. However, there is opportunity for case reports,[25] telerehabilitation, and COVID-19-related research.

Conclusions

The COVID-19 pandemic has impacted on rehabilitation services, residency training programs and research. The Royal College of Physiatrists of Thailand, the Sirindhorn National Medical Rehabilitation Institute, and the Rehabilitation Medicine training institutes and their members have had to change their roles and adjust their services, training programs, and research projects so that service recipients, including rehabilitation patients and in-training residents, could receive optimal rehabilitation and educational services. Telerehabilitation and online teaching have partly replaced the traditional face-to-face services and learning experience. Moreover, the DMHTT strategy, the use of PPE, COVID-19 screening policies, and national vaccination policies have been essential means in helping ensure workplace safety and disease prevention. Online learning and evaluation, as well as workplace-based assessment, has been implemented to overcome the interruption of training programs. Research in rehabilitation has also been similarly affected by the pandemic. However, the pandemic situation does allow opportunity for case reports as well as for research on telerehabilitation and for COVID-19 related research.

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Review Article

A Systematic Review of Clinical Practice Guidelines for the Management of Shoulder Pain in Patients with Stroke

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ABSTRACT

Objectives: To assess the quality, scope, and consistency of relevant clinical practice guidelines (CPGs) recommendations for hemiplegic shoulder pain (HSP) management among stroke patients.

Study design: A systematic review of CPGs.

Setting: Publishing regions were North America, Europe, Asia, and Oceania.

Subjects: Adult (≥ 18 years) stroke patients who had HSP.

Methods: Seven databases were used to search for CPGs. A total of 267 articles were screened; 8 guidelines met the inclusion criteria. The Appraisal of Guideline for Research and Evaluation (AGREE-II) was used for evaluating the quality of the selected CPGs.

Results: The recommendations of 5 high-quality guidelines for post-stroke HSP management were synthesized and 5 scopes of consistent recommendations were found comprising assessment, prevention, medical treatment, physical therapy treatment, and management of shoulder subluxation.

Conclusions: The key recommendations proposed that the assessment should evaluate muscle tone and pain level; advice and education be provided to family members and caregivers on how to handle and position the shoulder correctly, and avoid exercises involving overhead pulleys to prevent HSP; medical treatment should consider the administration of analgesics, high doses of botulinum toxin injections, subacromial corticosteroid injections, and suprascapular nerve blocks; and that physical therapy approaches should employ active exercises, taping or strapping, and the management of shoulder subluxation via slings and electrical stimulation. Future up-to-date guidelines should consider all domains of AGREE-II in order to improve their quality.

Keywords: assessment, guideline, hemiplegic shoulder pain, rehabilitation, stroke

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Introduction

Although the current incidence of stroke is declining in most regions worldwide,[1] stroke still remains a serious global health problem, which is a major cause of mortality, morbidity, and disability.[1,2] Stroke is a leading cause of long-term disability;[3,4] between 15.0% and 30.0%[3,5] of stroke survivors have severe and often permanent disabilities, while 40.0% have a moderate disability.[3] As a consequence, many stroke survivors experience difficulties when performing activities of daily living (ADLs) and have a reduced quality of life,[6,7] which may result in secondary complications.[8] Hemiplegic shoulder pain (HSP) is a complex and intense complication following a stroke.[9,10] The incidence of HSP is high;[11] however, it varies between 5.0% and 84.0% depending on the definition of shoulder pain, type, severity, and timing of evaluation.[6,9,11-18] HSP affects the stroke survivors' physical and mental well-being.[13] Persons with HSP experience intense pain[15] resulting in a limited range of motion (ROM),[13] impaired upper limb movement,[14,19] and restricted ability to perform ADLs,[13,17,20,21] which lead to a worsening of their functional status.[20] Moreover, these problems contribute to sleep disorders and depression.[15,17,19,21] This results in poor functional recovery,[12, 3,15,19,21] decreased participation in social activities,[13,17] and a lower quality of life.[12-17,19,21,22]

The precise causes of HSP are still unclear,[10,15,23] but it is hypothesized that multiple factors play a role in its development.[6,11,15,17,18,24] The diverse mechanisms and contributing factors that cause HSP can be present irrespective of recovery stage.[15] Such factors include (1) motor control impairment (e.g., muscle weakness, flaccidity, or limited ROM),[10,15,17,18] (2) soft-tissue lesions (e.g.,shoulder subluxation,adhesive capsulitis,or rotator cuff tear),[10,11,14,15,17,20,25] (3) muscle tone changes (e.g.,spasticity)[10,11,14,17,25] (4) other peripheral and central nervous system dysfunctions (e.g., complex regional pain syndrome (CRPS), brachial plexus injury, peripheral

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nerve entrapment, somatosensory abnormalities, and central post-stroke pain),[10,11,14,15,17,18,20] and (5) psychological factors (e.g., anxiety and depression).[15] These presentations may occur either alone or in combination.[15] Given the fact that HSP has multifactorial causes,and our understanding of its pathogenesis is still unclear,the treatment of stroke patients with HSP is challenging. Even though,various treatment approaches have been advocated,no specific treatment has been shown to be superior.[9,11,14,17,20]

However, the provision of care should be based on clinical practice guidelines (CPGs). Such guidelines are systematically developed based on the current best scientific evidence to assist members of multidisciplinary care teams in various settings. Therefore, educating and encouraging care providers to follow the recommendations of CPG can increase the knowledge of care team members, enhance patient care, reduce practice variance, increase care efficiency, and ultimately improve treatment outcomes for stroke patients.[26,27] Different countries employ different CPGs depending on the context of the country and the guideline developers, thus they vary in content, scope, and detail. Consequently, some differences exist between guidelines in terms of the level of evidence, strength of recommendations, and details of each recommendation.[26] Hence, the purpose of this study was to assess the quality, scope, and consistency of different guideline recommendations using a systematic review of CPGs for HSP management among stroke patients.

Methods

This systematic review was approved by the Human Research Ethics Committee of the Faculty of Medicine, Prince of Songkla University (REC. 64-058-30-2). This study followed the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).

Identification and selection of guidelines and their recommendations

Guideline eligibility was based on the Population and Clinical Areas, Interventions, Comparators, Attributes of CPGs, and Recommendation characteristics (PICAR) framework[28] (Appendix 1) as well as on some adapted criteria from PEDro.[29] The inclusion criteria consisted of CPGs: (1) developed by a government or private health profession association from North America, Europe, Oceania (Australia and New Zealand), and Asia (China, Japan, Korea, and Thailand); (2) developed based on systematic literature review and containing recommendations, methods, or information to guide decisions related to the appropriate management of shoulder pain in stroke patients; (3) intended for adult stroke patients 18 years of age or older, excluding transient ischemic attack; (4) reporting at least one recommendation regarding the management of shoulder pain in stroke patients; (5) published or reported in English or Thai from 1 January, 2016 to 23 February, 2021; and (6) with the latest version selected in case of successive editions.

Search for guidelines

Literature search strategies used medical subject headings and text words related to guidelines for shoulder pain in persons with stroke. The databases consisted of Medline, Cochrane Library, Physiotherapy Evidence Database, American Physical Therapy Association, The National Institute for Health and Care Excellence, Guidelines International Network, and Google Scholar. In addition, reference lists of selected CPGs were screened for additional eligible guidelines. The keywords used in the search for guidelines comprised “cerebrovascular disease,” “stroke,” “post-stroke,” “shoulder pain,” and “guidelines.” Keywords were combined using the Boolean operators “AND” and “OR.” Two investigators (WY and LK) independently screened potential CPGs based on titles and abstracts. Disagreement on inclusion was resolved through discussion with a third investigator (TS). All decisions were made by consensus, and the reasons for excluding guidelines were recorded. The potential full-text guidelines were evaluated in the same manner.

Appraisal of guidelines

The Appraisal of Guideline for Research and Evaluation (AGREE-II) was used to assess the methodological quality of selected CPGs. It consists of 6 domains: (1) scope and purpose, (2) stakeholder involvement, (3) rigor of development, (4) clarity and presentation, (5) applicability, and (6) editorial independence. The 23-item AGREE-II tool uses a scoring system involving 7 levels from 1 (strongly disagree) to 7 (strongly agree). The higher the scores, the greater the methodological quality of the guideline. In this regard, the guidelines that achieved a score equal to or more than 60% (scores for each domain minus the lowest possible score divided by the highest possible score minus the lowest possible score) in domains 1, 3, and 6 were considered to be of a high quality,[28] and their recommendations for the management of shoulder pain in stroke patients were synthesized. Two investigators (WY and LK) assessed the full text of the selected CPGs independently according to the AGREE-II criteria. Total score discrepancies of more than 10% were discussed and re-assessed independently by a third investigator (TS).[29]

Synthesis of guideline recommendations

Using textual descriptive synthesis, the scope, context, and consistency of the selected CPG recommendations were evaluated. Initially, one author (WY) read each selected CPG in order to familiarize himself with the overall information of its content. Then he coded the CPG with the aim of identifying the scopes covered by the guideline. The initial codes were identified and refined via the constant comparison of recommendations in each CPG as the data collection progressed. Finally, the guideline recommendations were compared across CPGs in order to identify any similarities and/or discrepancies related to each scope.[29]

The level of evidence and the degree of recommendations for each CPG were converted into the same format followed the American Heart Association.[6] This scale allows for comparison between the different recommendations of each CPG. It employs 3 levels of evidence–A (strong), B (moderate), and C (low) (Appendix 2). Four degrees of recommendation were adapted from the Oxford Center for Evidence-based Medicine Levels of Evidence. They consisted of: very recommendable, moderately recommendable, not recommended, and controversial (Appendix 3).[30] The authors (WY and LK) compared the selected guidelines in terms of the different scopes they covered, scope consistency, and congruence related to both their content and recommendations. Finally, the recommendations from the high-quality guidelines based on the 23-item AGREE-II tool were synthesized in order to provide an overview of all the identified recommendations.[29]

Results

Search results

The database search found 324 guidelines in total; after removing irrelevant or duplicate guidelines, 267 relevant guidelines remained. After screening the titles and abstracts when available, 244 guidelines were excluded. Twenty-three full-text guidelines were retrieved and reviewed based on the inclusion criteria. Finally, eight guidelines were included in the study analysis (Figure 1).

Selected guideline characteristics

The 8 selected guidelines were published or reported between 2016 and 2020. Seven of them were applicable to all types of stroke, and 1 guideline was developed for ischemic stroke. Two guidelines (2 organizations) were from the United States,[6,31] another 2 (2 organizations) came from Canada,[19,32] 2 more (1 organization) from Thailand,[33,34] and 1 guideline each was developed in the United Kingdom[23] and Australia[35] (Appendix 4).

Methodology quality

The AGREE-II domain scores for each CPG (n=8) are presented in Table 1. The percentages of the total mean domain scores obtained ranged between 35.99% and 83.51%. The mean scores (range) of each domain were: (1) scope and purpose 79.17% (47.22%–100%); (2) stakeholder involvement 64.19% (8.33%–94.44%); (3) rigor of development 65.99% (17.71%–94.79%); (4) clarity of presentation 90.97% (75%–100%); (5) applicability 27.53% (12.5%–60.42%), and (6) editorial independence 59.15% (0%–100%). Five were high-quality guidelines with a score equal to or more than 60% in domains 1, 3, and 6.

Synthesis of recommendations

Only 5 high-quality guidelines were used in recommendation synthesis and comparison. The guideline recommendations were found to be consistent in 5 scopes: assessment, prevention, medical treatment, physical therapy treatment, and management of shoulder subluxation. In brief,

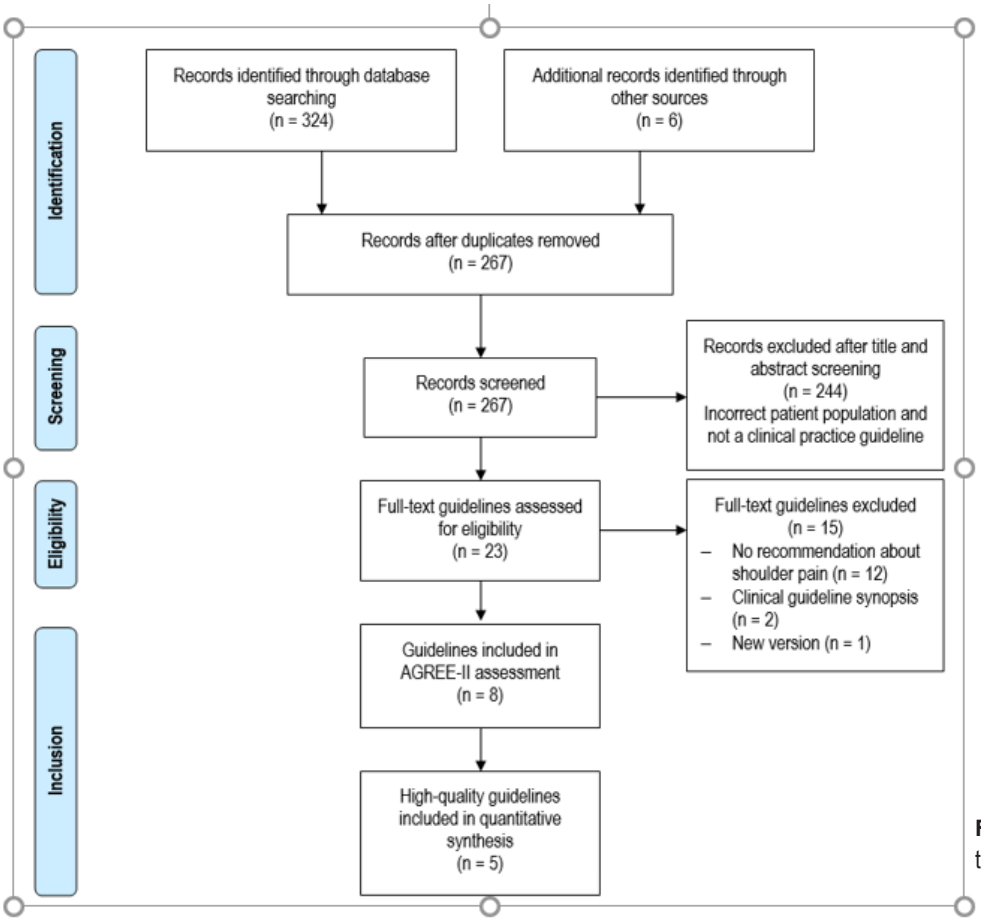

Figure 1. Flow chart of papers through the review

Table 1. Guideline assessment using the AGREE-II instrument (n = 8)

Guideline authors/organization/society	Domain scores (%)						Total mean domain score (%)
	Scope and purpose	Stakeholder involvement	Rigor of development	Clarity and presentation	Applicability	Editorial independence	
USA							
1. U.S. Department of Veterans Affairs and U.S. Department of Defense (VA/DoD)[31]	97.22	94.44	86.46	97.22	16.67	87.5	79.92
2. Winstein CJ, et al.[6] American Heart Association/American Stroke Association	100	52.4	82.1	100	28.6	85.7	74.8
Canada							
3. Teasell R, et al.[19] Heart and Stroke Foundation of Canada	83.33		80.56	78.13	37.5	100	78.07
4. Iruthayarajah J, et al.[32] Heart and Stroke Foundation of Canada and Canadian Partnership for Stroke Recovery	55.56		8.33	64.58	12.5	0	35.99
UK							
5. Rudd AG, et al.[23] Intercollegiate Stroke Working Party	100	86.11	94.79	80.56	39.58	100	83.51
Australia							
6. Stroke Foundation[35]	100	69.44	75	100	60.42	75	79.98
Thailand							
7. Tantiritthisak T, et al. Prasat Neurological Institute, Department of Medical Services, Ministry of Public Health[33]	47.22	55.56	17.71	94.44	12.5	12.5	39.99
8. Masakulpan P, et al. Prasat Neurological Institute, Department of Medical Services, Ministry of Public Health[34]	50	66.67	29.17	91.67	12.5	12.5	43.75

%: Domain scores are calculated by adding all the points of the individual domain items and standardizing the total, as a percentage of the maximum possible score for that domain using the following formula: (Score obtained - Minimum possible score) / (Maximum possible score - Minimum possible score) x 100.

Table 2. Synthesized of high-quality guidelines recommendations for shoulder pain management (n = 5) and their comparison with guidelines from Thailand (n = 2)

Guideline recommendation scopes	1VA/DoD[31]	2Winstein[6]	3Teasell[19]	5Rudd[23]	6Stroke Foundation[35]	7Tantiritthisak[33]	8Masakulpan[34]
1. Assessment							
- Muscle tone		C**	C**				
- Pain level			C**	*		C*	C*
2. Prevention							
- Family or caregivers education; proper protection, positioning, and handling of affected arm			A*	*		C*	C*
- Avoidance of overhead pulley exercises		C*	A*	*		A*	A*
3. Medical treatment							
- Analgesics			C**	*			
- Botulinum toxin		A**	B**		**		
- Subacromial corticosteroid injection		B**	B**	*	**		
- Suprascapular nerve block		B**			**		
4. Physical therapy treatment							
- Active exercise			B*		*	A*	B**
- Taping or strapping			A**		**	A?	
- Patient and family education		C*			*		
5. Shoulder subluxation							
- Positioning		C**			*	C*	C*
- Supportive devices and slings		C**			*	B**	B**
- Electrical stimulation; FES and NMES	**	A**			**	A**	A**

A strong, B modertae, C low, *very recommendable, **moderately recommendable, Xnot recommendable, ?controversial (neither recommended nor disapproved)

FES, functional electrical stimulation; NMES, neuromuscular electrical stimulation.

the synthesized recommendations for the management of shoulder pain in stroke patients are shown in Table 2. A clinical assessment should evaluate muscle tone and level of pain.[6,19,23] The prevention of shoulder pain should focus on the family and caregiver education related to the proper protection,positioning,and handling of the affected arm,for instance,careful positioning and helping to support the affected arm during moves such as transferring the patient and avoiding pulling on the hemiplegic arm. Moreover,patients should avoid overhead pulley exercises.[6,19,23] In terms of medical treatment, patients can be offered analgesics,[19,23] botulinum toxin for those with shoulder pain caused by the spasticity of the muscles surrounding the shoulder joint,[6,19,35] subacromial corticosteroid injections in cases of injury or inflammation in the subacromial region (e.g., rotator cuff or bursa injury),[6,19,23,35] and suprascapular nerve block.[6,35] Physical therapy treatment is recommended via active exercise,[19,35] taping or strapping,[19,35] and patient and family education regarding ROM exercise and positioning is also advised.[6,35] Shoulder subluxation should be treated using advice for proper positioning,[6,35] supportive devices and slings,[6,35] and electrical stimulation (ES) via either functional electrical stimulation (FES) or neuromuscular electrical stimulation (NMES).[6,31,35]

Discussion

The evaluation of the methodology quality of the 8 selected CPGs found that 5 of them were of a high quality and the other 3 had scores less than 60% in AGREE-II domain 1, 3, and 6. Among the selected CPGs, the highest total mean domain score was 83.51% corresponding to the United Kingdom study,[23] meanwhile the study from Canada had the lowest total mean domain score of 35.99%.[32] Clarity and presentation had the highest mean domain score (90.97%), and applicability yielded the lowest one (27.53%). For both Thai CPGs, the total mean domain score was about 40%. There was only 1 domain higher than 60% (clarity and presentation). Therefore, the future Thai CPGs should pay closer attention to the other 5 domains, especially rigor of development, applicability, and editorial independence in order to improve their quality. After synthesizing the contents of the 5 high-quality CPGs, 14 recommendations for the management of shoulder pain in persons with stroke were found consistently between them. Therefore, the adherence to these recommendations by treatment or multidisciplinary teams would constitute a primary quality assurance for the care standard of shoulder pain in stroke patients. In addition, the upcoming Thai guidelines for the management of HSP after stroke should include a recommendation to persistently inquire about shoulder pain in stroke patients with upper limb weakness as well as to perform pain measurement and monitor the severity of the pain using precise instruments. Other treatment approaches that Thai guidelines should consider for the treatment of patients with HSP include analgesics, pain neuromodulation, botulinum toxin, subacromial corticosteroid injections, suprascapular nerve block or surgical tenotomy, and NMES to maximize the potential of achieving the best outcome in these patients.

Assessment

Three of the 5 high-quality guidelines shared the same recommendations for the assessment of shoulder pain; they included muscle tone[6,19] and pain level assessment.[6,23] Moreover, other guidelines recommended that the severity of shoulder pain should be monitored regularly using a validated pain assessment tool, and the impact of pain on physical and psychological health should also be assessed.[19,23] Besides,changes in the length of soft tissues and the alignment of shoulder girdle joints,[19,33,34] active movement,trunk posture,[19] and sensation should be assessed,[6,33,34] and any possible shoulder subluxation should be identified.[6,33,34] In addition,ultrasound may be considered as a diagnostic tool for soft tissue injury in HSP.[6,33,34]

Prevention

Three high-quality guidelines reported the same recommendations regarding the prevention of HSP, i.e., providing relevant education to family members and caregivers and avoiding overhead pulley exercises.[6,19,23] Hence,healthcare staff,patients,family members,and caregivers should be educated adequately on how to properly protect, position,and handle the affected arm—for instance, while transferring the patient from wheelchair to bed and vice versa and the need to avoid pulling on the hemiplegic arm.[19,23,33]

Medical treatment

Four of the 5 high-quality guidelines recommended the use of medical treatment for HSP consisting of analgesics,[19,23] botulinum toxin,[6,19,35] subacromial corticosteroids injections,[6,19,23,35] and suprascapular nerve block.[6,23] Analgesics, such as ibuprofen or narcotics, can be used regularly simply to reduce HSP-related pain without any contraindications.[19,23,26] Botulinum toxin injections are beneficial for pain relief in persons with HSP related to upper extremity spasticity involving muscles such as the pectoralis and subscapularis.[6,19,26,32,35,36] It has been reported that high doses (500U) of botulinum toxin are required to improve pain and ROM.[12] Furthermore, subacromial corticosteroid injections may be used in cases of injury or inflammation of the subacromial area such as the rotator cuff or bursa.[19,23,26,32,35] However, suprascapular nerve block injections, e.g., using methylprednisolone and bupivacaine, may be used as an adjunctive intervention to reduce shoulder pain.[6,12,32,35]

Physical therapy treatment

The recommendations of 3 from the 5 high-quality guidelines consisted of physical therapy treatment involving active exercise,[19,35] taping or strapping,[19,35] and providing advice and education to patients and their family members.[6,35] Active ROM exercises should be implemented gradually, along

with alignment restoration and exercises to strengthen weak muscles around the shoulder girdle in order to improve limb function.[19,26,33-35] Aggressive ROM exercises, such as those involving overhead pulleys, increase HSP compared to those that do not employ pulley exercises.[12,33,34] Therefore, the use of overhead pulley exercises should not to be used in stroke patients.[6,19,23,26,32-34] Moreover, taping or strapping the hemiplegic shoulder can be used to relieve pain[12,19,32,35] and prevent the incidence of shoulder pain.[34] Patient and family education regarding ROM exercises, shoulder positioning, and proper patient transfer,[6,34,35] especially before discharge or transitions in care, is recommended for HSP treatment following a stroke.[6]

Shoulder subluxation

Three of the 5 high-quality guidelines gave consistent recommendations about shoulder subluxation management consisting of positioning,[6,35] supportive devices and slings,[6,35] and ES.[6,31,35] Both positioning and correct manual handling of the hemiplegic shoulder have been identified as strong recommendations to prevent and minimize shoulder subluxation. For example, when the patient is in the upright position such as sitting or standing, hemiplegic arm should be supported with pillows or slings, movements that can cause injury to the affected arm, e.g., excessive ROM, should be avoided, as should shoulder movements of more than 90 degrees during shoulder flexion or abduction, unless the scapula is upwardly rotated and the humeral head is in external rotation, and pulling on the affected arm when transferring the patient.[6,33-35] In addition, a suitable sling can be used to reduce shoulder subluxation[33,34] both at rest[6,12,36] or when standing or walking.[35] Moreover, firm support devices such as a lap-tray may be used for the management of shoulder subluxation.[6,35,36] ES, such as FES or NMES, may be also used to prevent or diminish shoulder subluxation; stimulation at the supraspinatus, posterior deltoid, and long head of biceps muscles is recommendation,[6,31,33-35] particularly in the first six months following a stroke.[35]

There are some limitations to this systematic review. Firstly, the CPGs involved came only from certain countries; thus, the study sample may not cover all the regions around the world. Secondly, AGREE-II is an assessment tool that focuses on the CPG development process, but it does not assess the content of the CPG recommendations.[29]

Conclusions

Five of the 8 selected CPGs were determined to be high-quality guidelines. Five scopes of consistent recommendations for HSP management in stroke patients were identified–assessment, prevention, medical treatment, physical therapy treatment, and management of shoulder subluxation. However, for the development of up-to-date CPGs in the future, all domains of the AGREE-II should be considered in order to improve the quality of guidelines.

Disclosure

The authors declare that they have no conflict of interest regarding the publication of this review article.

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Appendix

Appendix 1. PICAR framework for guideline-specific criteria.

	Guideline-specific criteria
Population and clinical condition	- Adult (≥ 18 years) stroke patients who had shoulder pain, excluding transient ischemic attack
Interventions	- Any interventions
Comparators	- Any comparators
Attributes of eligible CPGs	- Language: Available in English or Thai - Year: Published from 1 January, 2016 to 23 February, 2021 - Publishing region: North America, Europe, Oceania (Australia and New Zealand), and Asia (China, Japan, Korea, and Thailand) - Version: Latest version only - Development: A government or private health profession association - System of rating evidence: Systematic literature review and containing recommendations, methods, or information to guide decisions related to the appropriate management of shoulder pain in stroke patients - Scope: National or international guidelines in the management of shoulder pain in patients with stroke - Recommendations: At least one recommendation regarding the management of shoulder pain in stroke patients - Minimum quality score: A score of ≥60% in AGREE-II domains 1, 3, and 6
Recommendation characteristics	- Any recommendations for the management of shoulder pain in patients with stroke

PICAR, Population and Clinical Areas, Interventions, Comparators, Attributes of CPGs, and Recommendation characteristics

Appendix 2. Level of evidence of guideline recommendations.

Level of Evidence	Type of Study	Level of Confidence
A	Systematic review Meta-analysis	Strong
B	Randomized clinical trial Non-randomized clinical trial	Moderate
C	Case studies Opinion of expert committee	Low

Appendix 3. The degree of guideline recommendations according to the Oxford Center for Evidence-based Medicine Levels of Evidence.

Grade of Recommendation	Meaning
*	Very recommendable
**	Moderately recommendable
X	Not recommended
?	Controversial (neither recommended nor disapproved)

Appendix 4. Characteristics of included guidelines (n = 8)

	Guideline authors/organization/society	Guideline name(s)	Year of publication	Type of stroke
	USA			
1	U.S. Department of Veterans Affairs and U.S. Department of Defense (VA/DoD)[31]	VA/DoD clinical practice guideline for the management of stroke rehabilitation	2019	All
2	Winstein CJ, et al.[6] American Heart Association/American Stroke Association	Guidelines for adult stroke rehabilitation and recovery: a guideline for healthcare professionals from the American Heart Association/American Stroke Association	2016	All
	Canada			
3	Teasell R, et al.[19] Heart and Stroke Foundation of Canada	Canadian stroke best practice recommendations: rehabilitation, recovery, and community participation following stroke. Part one: rehabilitation and recovery following stroke; Updated 2019	2020	All
4	Iruthayarajah J, et al.[32] Heart and Stroke Foundation, Canadian Partnership for Stroke Recovery	Evidence-based review of stroke rehabilitation	2018	All
	UK			
5	Rudd AG, et al.[23] Intercollegiate Stroke Working Party	National clinical guideline for stroke: 5th edition	2016	All
	Australia			
6	Stroke Foundation[35]	Clinical guidelines for stroke management	2017	All
	Thailand			
7	Tantiritthisak T, et al.[33] Prasat Neurological Institute, Department of Medical Services, Ministry of Public Health	Clinical practice guidelines for ischemic stroke	2019	Ischemic stroke
8	Masakunpan P, et al.[34] Prasat Neurological Institute, Department of Medical Services, Ministry of Public Health	Clinical practice guidelines for stroke rehabilitation	2016	All

Original Article

Efficacy of a Newly Designed Custom-Fitted Shoulder Subluxation Orthosis for Stroke Patients: A Single-Blinded Crossover Randomized Controlled Trial

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ABSTRACT

Objectives: To compare the efficacy of a newly designed custom-fitted shoulder subluxation orthosis (SSO) with a commercial Bobath sling for shoulder subluxation in stroke patients.

Study design: A single-blinded crossover randomized controlled trial.

Setting: Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand.

Subjects: Sixteen post-stroke patients with hemiplegia/hemiparesis

Methods: A radiologist measured the acromiohumeral (AH) distance in anterior-posterior view radiographs of normal and affected shoulders of patients in a sitting position when not using any orthosis, when wearing a Bobath sling which supports the proximal humerus only, and when wearing an SSO. Comparison of the AH distance was conducted using the paired t-test.

Results: Without any orthosis, the mean (SD) of the affected and normal shoulders were 47.9 (7.5) and 36.2 (4.6) mm, respectively. The AH distance of the affected shoulder while wearing SSO was reduced to 36.8 (4.7) mm which is not statistically significant different from the normal shoulder distance ($p = 0.49$), whereas the mean AH distance wearing a Bobath sling was only reduced to 44.9 (7.7) mm., statistically significantly greater than the normal shoulders ($p < 0.01$).

Conclusions: The newly designed custom-fitted proximal-distal type shoulder subluxation orthosis for hemiplegia/hemiparesis patients, can reduce the AH distance significantly closer to that of a normal shoulder than a Bobath sling.

Keywords: shoulder subluxation, radiograph, orthosis, stroke, rehabilitation

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Introduction

Stroke is a major health problem in Thailand, with an incidence of up to 250,000 cases per year. It results in approximately 50,000 deaths per year and is the leading cause of death and disability in Thailand.[1]

Shoulder pain is a common stroke complication, found in up to 33.9% of stroke patients.[2,3] Multiple causative factors for shoulder pain have been proposed due to the complex anatomy and biomechanics of the shoulder. Shoulder subluxation is often a suspected cause. In some studies, a higher prevalence of post stroke shoulder pain was found in patients with shoulder subluxation.[4-6] Both the shoulder pain and subluxation interfere with rehabilitation and negatively affect quality of life,[7-11] making prevention of shoulder subluxation and the reduction of shoulder pain and its complications an important goal.

Currently, there are many methods to help prevent and reduce shoulder subluxation in stroke patients, e.g., shoulder orthosis, positioning of shoulder, and neuromuscular electrical stimulation. Shoulder orthosis support methods can be divided into 3 main types according to the point of support. The first type is proximal humeral support (P-S) which supports only proximal part of the upper extremity. The second type is whole arm with elbow flexion support (Wh-S) which supports the entire upper arm and keeps the elbow in the flexed position. The last is the proximal distal support (P-D-S) which supports both the proximal and distal parts of the upper extremity.[11]

A systematic review of published reports found that the shoulder orthoses that provide the greatest shoulder subluxation reduction is the Wh-S, followed by the P-D-S and, finally, the P-S type. Although the P-D-S type reduces subluxation slightly less than the Wh-S type, unlike the Wh-S orthosis, it does not limit elbow motion,[11,12] allowing the elbow to move more naturally. However, the P-D-S type shoulder orthoses are not available in Thailand and imported P-D-S orthoses are expensive.

At our institute, only the Bobath sling (P-S type) is widely available and generally prescribed for stroke patients in spite of its limitations, i.e., according to several studies, the P-S shoulder orthosis is unable to clinically significantly reduce shoulder subluxation.[13] An occupational therapist (BC) on

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our rehabilitation team recently designed a custom-fitted shoulder subluxation orthosis (SSO). The SSO, classified as a P-D-S type, can be made from locally available materials, making it both easily accessible and inexpensive. The objective of this study was to evaluate the efficacy of the SSO and to compare it with the Bobath sling in reducing shoulder subluxation in hemiplegic/hemiparetic stroke patients.

Methods

Study design

This single-blinded crossover randomized controlled trial was approved by the Institutional Review Board, Faculty of Medicine, Ramathibodi Hospital (approval number ID 12-60-02).

Participants

Post-stroke patients at our hospital with the following characteristics were recruited during March to December 2018: shoulder subluxation more than 5 mm as measured by physical examination; able to sit without support for at least 30 minutes and willing to participate in the study, including giving written informed consent. Patients were excluded if they had bilateral hemiplegia, were unable to communicate, had neurological, muscular or bone conditions other than stroke that affected movement of the shoulder, or declined participate in the study. The sample size was calculated with the power of 0.8, 5% type I error and 20% type II error, resulting in total of 16 subjects.

Materials

The newly designed custom-fitted SSO was made using ethylene vinyl acetate (EVA) foam sheet, canvas fabric, cloth straps, elastic bands, 3 oval loop rings, Velcro straps, a tape measure, scissors and a sewing machine. The device is divided into proximal and distal parts (Fig. 1). The proximal part rests on the weak or hemiplegic shoulder and the strap from the posterior crosses under the opposite axilla to the front. The distal part wraps around the forearm and is connected to the proximal part by anterior and posterior straps. The posterior strap also passes behind elbow. All straps are adjustable. The cost is about 400-500 baht and requires about 45-60 minutes to make. A petty patent has been applied for with the Department of Intelletual Property, Ministry of Commerce, Thailand (application number 2103000837 Date March 19th, 2021).

The commercial Bobath slings used in the study are available in 3 sizes, small, medium and large, with the appropriate size is determined based on the circumference of the mid arm.

Intervention

The objectives of the study and the research methods were explained to all participants. Patients were randomly assigned to first apply either the SSO or the Bobath sling to the affected shoulder, then later to apply the other type. Randomization was done using a sealed envelope method. Application of both orthoses was done by the same occupational therapist assistant who had been previously trained by a qualified occupational therapist. The rest time between each orthosis application was 5-10 minutes during which participants sat with their arm hanging at the side of their body.

Four anteroposterior radiographs of both shoulders in sitting position (Fig. 3) were taken, the first and the second without any shoulder orthosis, the third and the fourth with either the SSO or the Bobath sling according to the randomization. The acromiohumeral (AH) distances were measured by a radiologist who was blinded to the type of orthosis used.

Demographic data, including age, gender and medical history, were collected. Participants assessed their level of pain using a visual analog scale (VAS), and the researcher (PP), a physiatrist, assessed shoulder range of motion (ROM), muscle tone using modified Ashworth Scale (MAS) and the muscle strength of the deltoid muscle.

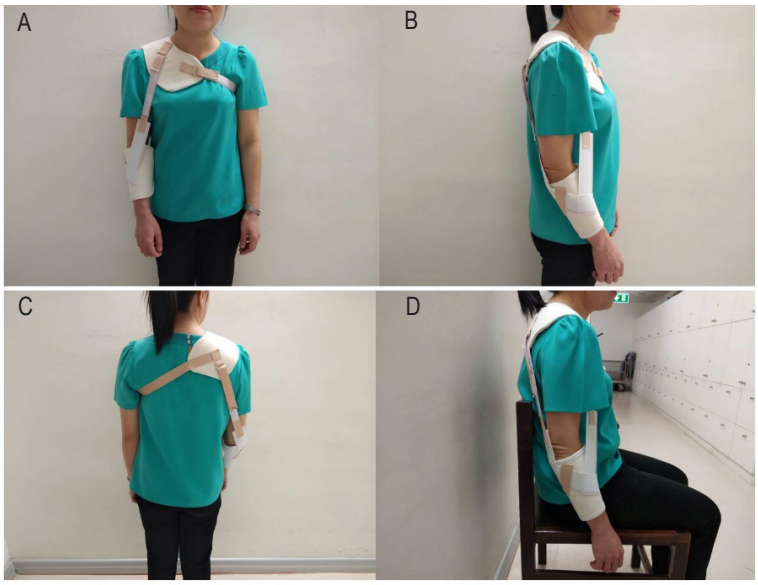

Figure 1. The newly designed shoulder subluxation orthosis in anterior (A), lateral (B) and posterior view (C), and sitting position for radiographs (D)

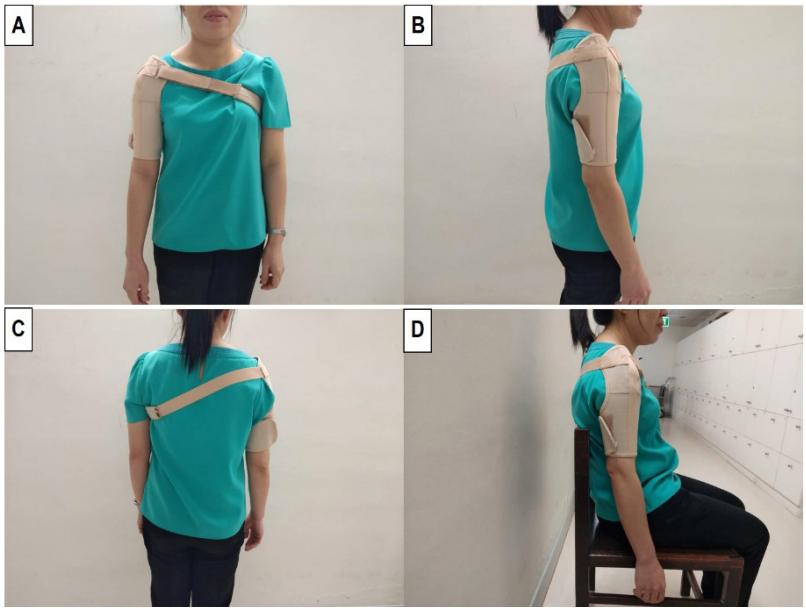

Figure 2. The Bobath sling in anterior (A), lateral (B) and posterior view (C), and sitting position for radiographs (D)

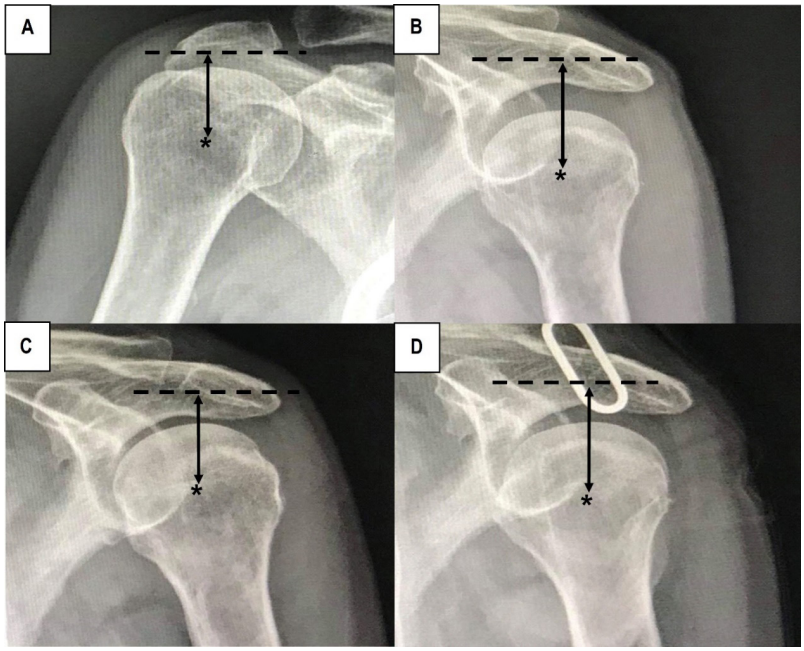

Figure 3. The acromiohumeral (AH) distance measurement in anteroposterior view of a shoulder radiograph: (A) normal shoulder, (B) affected shoulder without orthosis, (C) affected shoulder wearing a shoulder subluxation orthosis (SSO), (D) affected shoulder wearing a Bobath sling. In the figures, an asterisk * marks the center of the humeral head, a double arrow line represents the AH distance, and a horizontal dotted line shows the most inferolateral level of the acromioclavicular joint.

Outcome measurements

The primary outcome of this study was the AH distance, the vertical distance from the most inferolateral surface of acromioclavicular joint to the center of humeral head (Fig. 3).[16]

Statistical analysis

SPSS version 21 was used for data analysis. The demographic data were defined using descriptive statistics, i.e., frequency, mean and standard deviation (SD). The AH distance between the normal and affected shoulders, the AH distance of the affected shoulder without a shoulder orthosis and wearing each type of shoulder orthosis, and the difference in AH distance between the two orthoses was analyzed using the paired t-test. The statistical significance level was set at a $p < 0.05$.

Results

Table 1 shows the demographic characteristics and clinical findings of the 16 stroke participants.

The normal and the affected shoulders had a mean AH distance (SD) of 36.2 (4.6) and 47.9 (7.5) mm, respectively. Table 2 shows the AH distance while wearing the different orthoses. The AH distance of the affected shoulder was reduced significantly when wearing both orthoses; however, the AH distance with the SSO approached that of the normal shoulder ($p = 0.49$), but not with the Bobath sling ($p < 0.01$). The mean distance reduction was significantly greater with the SSO than with the Bobath sling (11.1 vs 3.0 mm, $p < 0.01$).

Discussion

In this study, the efficacy of the SSO, our newly designed custom-fitted P-D-S shoulder orthosis, was evaluated and

Table 1. Demographic data (n = 16)

Characteristics	
Age (years)[1]	61.5 (12.1) [37.0-77.0]
Sex (male : female)[2]	10 : 6
Affected side (right : left)[2]	4 : 12
Shoulder pain VAS score[3]	2.7 (2.2)
Etiology of stroke (ischemic : hemorrhagic)[2]	12 : 4
Affected shoulder ROM[3]	
Flexion : abduction	137.5 (31.7) : 140.6 (31.3)
Internal rotation : external rotation	65.0 (24.2) : 71.9 (28.2)
Affected shoulder spasticity[2]	
MAS 0-1	8
MAS 1+	8
Manual muscle test of deltoid muscle[2]	
Grade 0-1	5
Grade 2	11
Time since diagnosis (months)[3]	5.8 (3.8)

[1]Mean (SD) [range], [2]number, [3]mean (SD)

MAS, modified Ashworth scale; ROM, range of motion; SD, standard deviation; VAS, visual analog scale

Table 2. Acromiohumeral (AH) distance in millimeters (mm) of the normal and affected shoulders and AH distance reduction while wearing the shoulder subluxation orthosis (SSO) and the Bobath sling

AH distance (mm)				AH distance reduction (mm)	
Normal shoulder	Affected shoulder			Affected shoulder	
	Without orthosis	With SSO	With Bobath sling	With SSO	With Bobath sling
36.2 (4.6)	47.9 (7.5)	36.8 (4.7)[a,b] $p < 0.01$[a] $p = 0.49$[b]	44.9 (7.7)[a,b] $p < 0.01$[a] $p < 0.01$[b]	11.1 (5.2)[c] $p < 0.01$[c]	3.0 (2.4)

Mean (SD)

Paired t-test statistical significance level < 0.05, [a]comparison between with and without orthosis, [b]between the affected and normal shoulders, and [c]between using the SSO and the Bobath sling

compared to the Bobath sling which is a P-S type. We found that both types of shoulder orthoses could reduce shoulder subluxation in stroke patients. However, support from the SSO could reduce the AH distance much more than the Bobath sling, approaching the distance of the normal shoulder. The results of this study are in congruence with a previous systemic review study which reported that application of P-D-S and Wh-S shoulder orthoses for the hemiplegic shoulders can help in reducing shoulder subluxation better than P-S type orthoses.[11,12]

In our study, the Bobath sling was shown to reduce shoulder subluxation statistically significantly, but not clinically significantly, which is in line with a previous study.[13] The upward force to support the upper extremity relies only on the proximal support wrapped around the arm. The arm is cylindrical in shape and is composed predominantly of soft tissue. As a consequence, the upward force is not transferred to the bone effectively. This is probably the cause of the lower efficacy of the Bobath sling compared to the P-D-S type.

To the best of our knowledge, two designs of P-D-S are available, GivMohr® sling and OmoNeurexa, both of which have been studied for their efficacy. The GivMohr® sling can decrease shoulder subluxation better than the Rolyan humeral cuff, a P-S type, which cannot significantly reduce shoulder subluxation. The GivMohr® sling is also able to reduce the AH distance closer to that of the normal shoulder side.[17,18] The other P-D-S type shoulder support, OmoNeurexa, can also reduce shoulder subluxation by approximately 8 mm, statistically significantly more than the Bobath sling.[11,15,17]

The other type of shoulder orthosis, the Wh-S type, includes the Harris Hemi Sling and the ordinary triangular bandage. A systematic review showed that the Wh-S type can provide the greatest reduction in shoulder subluxation among the three types, but it restricts the elbow to the bent position which probably increases spasticity and may even cause elbow flexion contracture.[11,12,17] In contrast, the P-D-S and P-S types allow the elbow to move freely, thus permitting the upper extremity to swing naturally during ambulation. As a result, application of Wh-S is limited. Overall, the P-D-S shoulder orthosis seems to be the best for subluxation in hemiplegic shoulders. However, the GivMohr® sling and OmoNeurexa are not generally available in Thailand and the cost of importing these items is high. Our rehabilitation team designed a new P-D-S orthosis, the SSO, which provides good efficacy and can be custom made for each patient in less than an hour from available materials and at an affordable cost.

The probable mechanisms behind the superior efficacy of the SSO may include the following. The distal support grabs the forearm well because there is less soft tissue around the forearm bones so. That, together with the anterior and posterior straps connected to the proximal part providing upward force, transfers more of the orthosis support to the bone. The posterior strap, which passes behind elbow, pushes the elbow into extension, transferring the upward force to the shoulder more effectively. The upshot is that the shoulder joint is adequately supported and subluxation is reduced.

The SSO and the P-D-S type shoulder orthoses, GivMohr® sling and OmoNeurexa, both utilize a similar mechanism. The SSO is similar to the OmoNeurexa, but there are differences in the designs. The proximal and distal support of both types of orthoses have a large contact surface area, and hence provide good force distribution. However, the OmoNeurexa requires more adjustment to fit the device to the individual patient, thus making it potentially more problematic to put on. The GivMohr® sling, unlike the SSO, provides proximal support from the shoulder harness and distal support at hand. However, the proximal and distal support of GivMohr® sling both have less contact surface area and thus less distribution of force which may negatively affect wearer comfort. Each of these 3 P-D-S type shoulder orthoses are different in design, proximal and distal support, and points of adjustment. Only the SSO can be custom-made for each patient, making it fit more comfortably, even for patients with extremely small or large body size, and allowing easier adjustment during donning.

This research demonstrated only the immediate effects of the SSO. Previous studies of long-term effects of shoulder orthosis wear by stroke patients has revealed that wearing an appropriate shoulder orthosis continuously for more than 4 weeks can improve gait pattern by normalizing muscle activation and allowing more symmetrical walking.[11,15,19] Further research on the long-term efficacy of the SSO, including not only reduction of shoulder subluxation and pain, but also evaluation of patients' walking and balance, level of satisfaction, convenience in donning and doffing, and compliance with long term use recommendations as well as durability of the orthotic itself are suggested.

Conclusions

The newly designed custom-fitted shoulder subluxation orthosis, which is classified as a proximal-distal-support type, can significantly reduce shoulder subluxation both statistically and clinically more than the Bobath sling, a proximal-support type. The SSO can effectively support the affected upper extremity and can reduce the acromiohumeral distance close to that of the normal, unaffected shoulder.

Disclosure

The authors declare no conflict of interest of any kind.

Acknowledgements

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Original Article

Clinical Outcomes between Using Prefabricated Toe Sleeve versus Toe Separator in Patients with Painful Hallux Valgus: A Single-Blinded Randomized Control Trial

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ABSTRACT

Objectives: To compare clinical outcomes between using a prefabricated foot-toe orthosis, a toe sleeve and a toe separator in treating painful hallux valgus/bunion.

Study design: A single-blinded randomized controlled trial.

Setting: Ramathibodi Hospital, Bangkok, Thailand.

Subjects: Patients with painful hallux valgus/bunion aged between 25 and 70 years old

Methods: Patients were randomly divided into two groups: a toe separator and a toe sleeve group, both received the same treatment protocols. Primary outcomes were pain using a visual analog scale (VAS) and functions using visual analog scale-foot and ankle (VAS-FA) at one- and three-month follow-ups, and patient compliance with adherence to daily use of the orthosis as a secondary outcome.

Results: Compared with the baseline, the mean VAS at one- and three-month follow-ups statistically significantly decreased in both groups [the toe sleeve group: 55.72, 21.72 and 19.33 (p < 0.01); the toe separator group: 66.00, 42.67 and 42.17 (p < 0.01) respectively]. The mean VAS-FA at both follow-ups statistically significantly increased in both groups [the former toe sleeve group:75.89, 88.67 and 83.83 (p = 0.01), the toe separator group: 53.72, 65.33 and 71.17 (p < 0.01), respectively]. The toe sleeve group showed significantly lower VAS scores than the toe separator group at both follow-ups, whereas the VAS-FA did not differ.

Conclusions: The toe sleeve significantly reduced pain better than the toe separator did in patients with hallux valgus at 1 and 3 months after usage. The VAS-FA also significantly improved in both groups without a significant inter-group difference. Both, a toe sleeve and a toe separator, improved functions.

Keywords*:* bunion, foot orthoses, hallux valgus, pain

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Introduction

Hallux valgus represents the most common forefoot deformity. The prevalence of this disease is 23-35 percent in the population aged over 18 years old.[1] The overall deformities of hallux valgus are a valgus deviation of the big toe, a pronation of the big toe, and a prominent medial aspect of the first metatarsophalangeal joint formed by a pronation of the first metatarsal bone with imbalanced intrinsic-extrinsic foot muscles and a ligamentous structure of the first ray.[2] The etiology of this disease is still not fully understood, but the predisposing factors of the disease include types of footwear, occupations, history of trauma, pes planus, and ligamentous laxity.[2] Hallux valgus can be both symptomatic and asymptomatic. Up to 75% of symptomatic patients complain about bunion pain or pain on the medial prominent of the first metatarsophalangeal joint.

The first-line treatments of hallux valgus/bunion are conservative methods,[3-5] such as modification of footwear, a specific hallux night splint,[6] a toe separator,[6-8] kinesiotaping,[9-10] manipulative therapy,[11] and a toe sleeve. A toe separator helps reduce the abduction of the big toe with a less prominent bunion. A custom-molded toe separator and a combined toe separator with a custom-molded insole are reported to help reduce pain and improve patients' abilities.[6,8] A toe sleeve is a silicone tube expanded to cover the bunion area and acts as a bumper between the bunion and the footwear.[12] Combined with the footwear modification, the toe sleeve can reduce compression and attrition between the footwear and the bunion, alleviating bunion pain as a result.[12]

Nowadays, there are many prefabricated foot-toe orthoses for treatment of hallux valgus or painful bunion available. People can buy at drug stores without need of doctor's prescription. Based on our observation, the toe sleeve might reduce the pain at the bunion better than the toe separator

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due to direct reduction of attrition between bunion and shoe. However, there have been no studies comparing between the use of a prefabricated toe sleeve and a prefabricated toe separator. This study aimed to compare clinical outcomes between the above-mentioned foot-toe orthoses.

Methods

We conducted a single-blinded randomized controlled trial at Ramathibodi Hospital, Thailand, between 2015-2017. After approved by the Institute Review Board of Ramathibodi Hospital, and the trial was registered in the Thai Clinical Trials Registry with the ID TCTR20200506003.

Participants

We enrolled patients with hallux valgus. The diagnosis of hallux valgus was confirmed by the weightbearing foot radiograph demonstrating either an intermetatarsal angle over 9 degrees or hallux valgus angle over 15 degrees.[12] The inclusion criteria were age between 25 and 70 years old, and a complaint of bunion pain. We excluded patients with osteoarthritic changes of the first metatarsophalangeal joint, a history of significant foot injury that affected their normal abilities, neuromuscular disorders, inflammatory joint disease, post infection of the first metatarsophalangeal joint, and allergies to non-steroidal anti-inflammatory drug (NSAIDs) acetaminophen and silicone. Drop out criteria were the patient who did not use foot-toe orthoses or not come to follow-up as schedule.

The sample size was calculated by using the mean visual analog scale (VAS) score from a study of Tehraninasr et al.[6] with alpha = 0.05 and beta = 0.10. The calculated sample size was 18 participants per group.

Randomization

The randomization was done by using a block size of four, generated by STATA 11.0 and concealed by an opaque envelope.

Intervention

The recruited patients were divided into two groups: a toe sleeve and a toe separator group. All participants were instructed to use the prescribed orthosis for at least 7 hours a day, 5 days a week, especially while doing physical activities, such as walking, running, or standing for a long period of time, and record the duration of usage in the logbook. Both groups were advised to wear shoes of one size larger to prevent overstuffing of the foot-toe orthosis and instructed to take either 500 mg of acetaminophen orally every 6 hours or 250 mg of naproxen twice a day after every meal for severe pain and record in a logbook.

The participants' baseline characteristics were recorded. The participants were followed up at one- and three- month for assessment of VAS and visual analog scale-foot and ankle (VAS-FA) after using the prescribed orthosis.

Materials

In the toe separator group, the participants were instructed to wear a prefabricated toe separator, a standard size firm curve silicone rubber (e-life orthopedic, Taiwan) (Figure 1 A).

In the toe sleeve group, the participants were instructed to wear a soft, stretchable fabric fully coated with proprietary polymer gel and one-sided recess to cover the bunion area, size L/XL (SILIPOS, USA) (Figure 1 B). Both foot-toe orthoses were approved by the Thai-FDA.

Outcomes

VAS and the Thai version of VAS-FA were the primary outcomes of the study. VAS was rated by the participants to quantify bunion pain, ranged from 0 (no pain) to 100 (extreme pain). The Thai version of VAS-FA is a validated functional scale which consists of 20 questions about pain (4 questions), functions/abilities (11 questions) and other complaint (5 questions).[13] The total point for entire scaling system is 2,000 points which is then divided by 20, resulting in score ranging 0 (extreme pain and limited function) to 100 (no pain and normal functions).[13]

In addition, patient adherence to the instruction of using the prescribed orthosis, the daily usage (hours), was recorded by participants in a provided logbook.

Statistical methods

The means of both VAS and VAS-FA at baseline were compared by student's t-test. The mean adherence in terms of usage hour was compared by student's t-test. Comparison the mean of VAS and VAS-FA in each group at baseline, and 1 and 3 months after treatment was done using repeated ANOVA. Comparison the mean of VAS and VAS-FA between the toe sleeve and the toe separator groups was done using ANCOVA, taking into account the significant difference at baseline of VAS-FA and possible confounding effects by

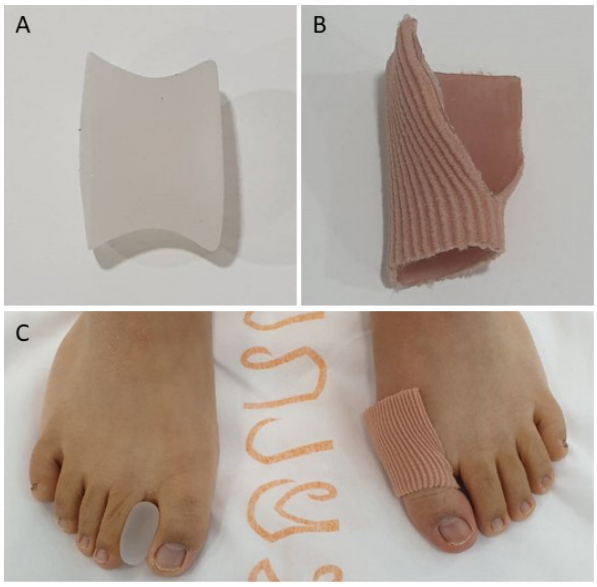

Figure 1. Two types of foot-toe orthoses used in this study: (A) a toe separator, (B) a toe sleeve and (C) showing how the orthoses are used

adherence to treatment. All statistical analyses were done by SPSS version 15 with statistical significance defined as $p < 0.05$. The participants were analyzed based on the intention-to-treat principle.

Results

Thirty-six participants were included in this study. All were female except one male participant in the toe separator group. There was no significant difference in the mean values of the baseline characteristics, hallux valgus angle, intermetatarsal angle, and VAS as shown in Table 1. The ranges of VAS were 13 to 84 in the toe sleeve group and 21 to 91 in the toe separator group. The baseline VAS-FA was, however, significantly different between the two groups, with the means of 53.72 and 75.89 ($p < 0.01$) in the group treated with a toe separator and the group treated with a toe sleeve, respectively (Table 1). There was no participant dropout during the study (Figure 2).

Within group analysis

The mean VAS-FA of both groups increased significantly at both follow-ups (Table 2). respectively. When using repeated-measure ANOVA, both groups were significantly different across the three time points. Post-hoc analysis shown a significant increase of VAS-FA at 1-month follow-up compared to baseline in the toe sleeve group whereas in the toe separator group VAS-FA was increased significantly at 3 months follow-up (Table 3).

Comparison between groups

By using ANCOVA, mean VAS was significant difference between the two groups at 1-month ($p = 0.01$) and 3-month follow-up ($p < 0.01$) (Table 4).

When comparing the mean VAS-FA between two groups at 1-month and 3-month follow-ups (Table 4), no significant difference was observed between the two groups at both time points ($p = 0.10$ and 0.59).

Table 1. Baseline characteristics, baseline disease profile and adherence: mean and standard deviation.

	Toe-sleeve (N = 18)	Toe-separator (N = 18)	*p*-value
Age (years)	51.50 (12.00)	48.00 (12.00)	0.38
Body mass index (Kg/m^2)	21.44 (2.06)	20.61 (2.09)	0.23
IMA (degree)	14.50 (2.40)	14.11 (1.50)	0.56
HVA (degree)	28.11 (5.00)	28.22 (4.00)	0.94
VAS (mm)	55.72 (20.86)	66.00 (14.68)	0.09
VAS-FA (mm)	75.89 (14.01)	53.72 (10.65)	< 0.01*

IMA, intermetatarsal angle; HVA, hallux valgus angle; VAS, Visual analoque scale; VAS-FA. visual analogue scale-Foot and ankle (Thai)
p-value comparing the mean between two groups.

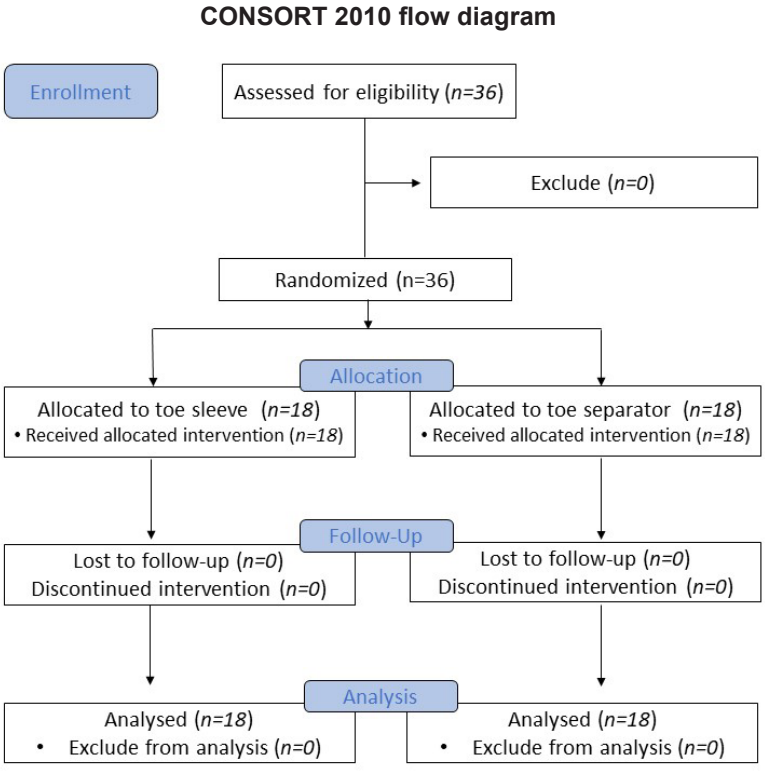

Figure 2. Flowchart of the trial

Table 2. Comparison of VAS and VAS-FA in each group: mean and standard deviation

	Toe sleeve group		Toe separator group	
	VAS	VAS-FA	VAS	VAS-FA
Baseline[1]	55.72 (20.86)	75.89 (14.01)	66.00 (14.68)	53.72 (10.65)
at 1-month FU	21.72 (11.64)	88.67 (12.03)	42.67 (25.72)	65.33 (18.11)
at 3-month FU	19.33 (9.61)	83.83 (11.78)	42.17 (24.58)	71.17 (12.65)
p-value*	< 0.01	0.01	< 0.01	< 0.01

VAS, visual analog scale; VAS-FA, visual analog scale-foot and ankle; FU, follow-up
p-value comparing the same device at different times

Table 3. Post-hoc analysis (pairwise comparisons)

	Toe sleeve group		Toe separator group	
	Mean difference (95% CI)	*p*-value	Mean difference (95% CI)	*p*-value
VAS				
Baseline - 1-month FU	34 (20.33-47.67)	< 0.01	23.33 (9.41-37.25)	< 0.01*
Baseline - 3-month FU	36 (22.94-49.83)	< 0.01	23.83 (10.67-37.00)	< 0.01*
1-month FU - 3-month FU	2.39 (-1.39-6.17)	0.33	0.50 (-37.00- -10.67)	1.00
VAS-FA				
1-month FU - baseline	12.78 (7.85-17.71)	< 0.01	11.61 (-0.23–23.46)	0.55
3-month FU - baseline	7.944 (-0.05–15.93)	0.05	17.44 (9.35–25.54)	< 0.01*
3-month FU - 1-month FU	-4.83 (-11.27–1.60)	0.19	5.83 (1.07-10.59)	0.01*

VAS, visual analog scale; VAS-FA, visual analog scale-foot and ankle; FU, follow-up
Negative mean difference of VAS-FA means worse

Table 4. Comparison of VAS and VAS-FA between the toe sleeve and the toe separator groups: mean and standard deviation

	Toe sleeve group	Toe separator group	*p*-value
VAS			
at 1-month FU	21.72 (11.64)	42.67 (25.72)	0.01*
at 3-month FU	19.33 (9.61)	42.17 (24.58)	< 0.01*
VAS-FA			
at 1-month FU	88.67 (12.03)	65.33 (18.11)	0.10
at 3-month FU	83.83 (11.78)	71.17 (12.65)	0.59

p-value compared between devices at the same period; FU, follow-up

Patient adherence and use of pain medication

In terms of patient adherence to the instruction of using a toe sleeve/toe separator and taking pain medication, there was no significant difference between the two groups with the mean foot-toe orthosis usage of 38.17 (19.65) hours per week in the toe separator group and 36.63 (22.56) hours per week in the toe sleeve group (p = 0.83). There was no reported use of pain medication nor any problems e.g. discomfort from the foot-toe orthoses during the study.

Discussion

In theory, toe sleeve could reduce the pressure on the bunion by padding that covers the bunion and toe separator could reduce the pressure by reduced the deformities of the hallux valgus.[6,12] Here, our study compared the usage of foot-toe orthoses between a toe sleeve and a toe separator using the pain VAS for self-rating painful bunion and the Thai version of VAS-FA for self-assessment of foot and ankle functions. We found that both orthoses could reduce pain and improve function after using them for a month. A comparison between the two orthoses revealed that the toe sleeve had superior outcomes in terms of VAS and VAS-FA over the toe separator, although the baseline VAS-FA of the toe sleeve treatment group was better than that of the toe separator treatment group.

Tehraninasr et al. concluded that a toe separator could reduce pain after three months of follow-up from baseline.[6] The foot-toe orthoses in their study was custom fabricated and used with semi-rigid insole but our study used prefabricated foot-toe orthoses but still can relieved pain and improved functions of patients.

The data show that there were no differences in the VAS and VAS-FA scores when comparing between at one-month and at three-month follow-ups in both groups. The patients still had pain but less, improved functions but still had some limitation. This might be because the foot-toe orthoses could help relieved the pain from the deformities but not totally corrected them so the pain and limitation of functions were not totally resolved.

In terms of the adherence and pain relievers, we found no significant difference in both outcomes between the two groups. Both could treat hallux valgus patients without any reported problems. The foot-toe orthoses in our study were prefabricated and easy to wear. The mean usage hours per week of both foot-toe orthoses were closed to the report by Chadchavalpanichaya et al. in the 3-month follow-up but after 3 months the adherence from their study was decrease.[8] Our study may need more follow-up time to evaluate the adherence in long term.

Our study is a randomized controlled trial with a specific attention to only painful bunion in hallux valgus patients who completed the protocol. The outcomes of our study were measured in reference to the patients' pain and functions. Our limitations were that the majority of the study participants had mild to moderate degrees of hallux valgus, and could not be extrapolated to the patients with severe hallux valgus. Type of footwear of each patient was not evaluated as a baseline characteristic. The follow-up period was only 3 months. A longer period of follow-up, evaluation the type of footwear and inclusion of more types of prefabricated foot-toe orthoses may need to be studied in the future.

In conclusion, daily use of a prefabricated toe separator or a toe sleeve significantly decreased pain and improved the functional mobility of patients with mild to moderate degree of hallux valgus patients and bunion pain. The toe sleeve better relieved pain than the toe separator did in patients with hallux valgus after one month of usage and the pain reduction was maintained at three months.

Disclosure

The authors declare no related activity with or benefits from companies producing the foot-toe orthoses used in the study.

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Original Article

Urological Management and Long-Term Complications in Patients with Spinal Cord Injury and Neurogenic Lower Urinary Tract Dysfunction in Thailand: A Retrospective Study

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ABSTRACT

Objectives: To describe urological assessment, management and long-term complications in patients with spinal cord injury (SCI) and neurogenic lower urinary tract dysfunction (NLUTD) in Thailand.

Study design: Retrospective study.

Setting: Two university hospitals and three A-level hospitals in Thailand.

Subjects: Patients with SCI and NLUTD.

Methods: Medical records of patients with traumatic and non-traumatic SCI and NLUTD from five tertiary/A-level hospitals were obtained and manually reviewed to evaluate urological assessment, management and related complications. Descriptive statistics were used for the evaluation.

Results: Among the 5,822 medical records retrieved, 1,066 cases had been diagnosed with SCI and NLUTD. In the initial NLUTD assessment, it was found that 51.9% of the patients had undergone urodynamic study (UDS). The last bladder emptying techniques included indwelling transurethral catheter (38%), reflex voiding (30.1%), and self-catheterization (clean intermittent catherization) (20.3%). Approximately 40% of patients had had no regular urological follow-up. Among the 760 patients who had undergone imaging, 36.9% had upper urinary tract complications. There were significant differences between the university hospitals and the Ministry of Public Health hospitals in terms of urological assessment, management and follow-up protocol.

Conclusions: There were differences in methods of initial assessment, management, and surveillance follow-up protocol for SCI and NLUTD patients in university hospitals and those in MOPH hospitals in Thailand. Among the patients who underwent surveillance and investigation, a substantial number were found to have upper urinary tract complications.

Keywords: neurogenic lower urinary tract dysfunction, neurogenic bladder, spinal cord injury, rehabilitation, complications

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Introduction

Neurogenic lower urinary tract dysfunction (NLUTD) or neurogenic bladder is a secondary condition found in various neurological diseases. The condition affects a significant number of people with traumatic and non-traumatic spinal cord injury (SCI), myelomeningocele, and multiple sclerosis.[1,2] Neurogenic detrusor overactivity and detrusor external sphincter dyssynergia can cause upper urinary tract complications, e.g., vesicoureteral reflux (VUR), hydronephrosis, and renal failure.[3,4] Surveillance follow-up to monitor upper urinary tract condition is therefore necessary.[2,5,6]

There are many guidelines offering proposals for the management of NLUTD for specific diseases.[2,5-8] The recommendations can be categorized into the initial evaluation, management (which varies based on the results of the evaluation), and long-term follow-up protocol. Most guidelines agree on the need for early assessment of both upper and lower urinary tract anatomy and function, including renal ultrasonography, intravenous pyelography (IVP), renal scans, creatinine clearance, urodynamic studies, voiding cystourethrography (VCUG), and cystoscopy. One guideline also suggests urine analysis and culture to identify infections.[6] Long-term annual surveillance of detrusor and renal function including potential complications of NLUTD, such as bladder cancer, hydronephrosis, and stones, is also recommended. In summary, there are areas of general agreement regarding the assessment of urinary tract structures and functions, both in the initial phase and the surveillance follow-up protocol; there are, however, minor differences such as the rationale for and recommended frequency of urine analysis and culture.[5,6]

Some studies investigated the NLUTD management practices of physicians in high-income countries.[9-12] In 2004, a study by Bycroft et al. found that the practices in spinal units in the United Kingdom and Ireland, were quite varied; however, long-term annual follow-up was usually scheduled,

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including ultrasonography and urodynamic study.[10] A decade after that study, however, practices of these spinal units tended to be limited to annually upper tract imaging with ultrasonography without routine urodynamics.[12] Surveys among urologists in the Netherlands and the United States found a variety of practices in assessment and surveillance investigations; however, the frequency of follow-up was usually every 6 to 12 months.[9,11] In summary, there have been several proposals regarding the management of NLUTD; the actual practices of physicians, however, are even more varied.

In Thailand, there is no general consensus regarding NLUTD management and surveillance follow-up guidelines. Few studies have been conducted in the country to identify problems related to NLUTD. Studies from a rehabilitation department at a university hospital in the Northeastern region revealed a high prevalence of vesicoureteral reflux (VUR) in SCI and myelomeningocele patients of approximately 20% and 40%, respectively.[13,14] A study of a specialized SCI rehabilitation ward at a university hospital in the Northern region found abnormalities in KUB ultrasonography in 30% of males with SCI who were using a reusable silicone catheter for clean intermittent self-catheterization (CISC).[15] In another study, the prevalence of UTI in SCI patients performing CISC was 15.4%.[16] A study of chronic SCI in Thailand revealed 62% of patients still used CISC as their preferred bladder emptying method.[17]

It is difficult to get an accurate estimate of the magnitude of the urological problems in SCI patients including the number with NLUTD, the treatments received, and post-treatment complications. This study aimed to extensively explore the urological management and long-term complications in SCI patients with NLUTD in Thailand by retrospectively reviewing medical records of five tertiary hospitals in different regions of the country. This review study was designed to reflect the current NLUTD management situation and to offer a portrait of the long-term condition of NLUTD patients in Thailand which could pave the way for the development of a national guideline.

Methods

This research was a part of a three-part research project, 'Access to proper urological care in persons with NLUTD,' which is comprised of three distinct sections: 1) quantitative research on the utilization and urological management in hospitals (the focus of the present project), 2) mixed method research on the availability of urological care resources in hospitals, 3) qualitative research on the perspective of persons with SCI related to accessing urological-related care in a hospital. The same study sites were selected for all three projects. The selection process included the following. First, three to five provinces in each of the five regions; northern, northeastern, central and eastern, southern, and Bangkok and perimeter area; with the highest total number of persons with disabilities were selected and disabled people organizations (DPO) in each of those areas were contacted. One province in each of the five regions with a strong and cooperative disabled people organization was selected to serve as the base for contacting persons with SCI in the community for the third project. The five provinces are Lampang, Khon Kaen, Chonburi, Surat Thani, and Bangkok. Next, the tertiary hospitals, their network hospitals, and medical schools in these five provinces were then invited to participate in the second project. Each of the selected tertiary and medical school hospitals had all professionals necessary to care for persons with SCI, i.e., orthopedists, physiatrists, and urologists. Finally, three of the five locations were purposively selected for a medical record review based on the willingness to cooperate of the provincial coordinator. The three locations are Khon Kaen, Surat Thani, and Bangkok. The researchers in this study then recruited five tertiary/A-level hospitals in these three provinces, including two university hospitals (Srinagarind Hospital and Ramathibodi Hospital) and three Ministry of Public Health (MOPH) hospitals (Khon Kaen Hospital, Surat Thani Hospital, and Rajavithi Hospital), for a medical record review to explore details of the medical services received by patients with SCI and NLUTD.

Search strategy

After receiving approval from the research ethics committee of each hospital, the hospital coordinator was asked to retrieve medical records of patients with the following criteria: patients who had paid a visit to the hospital between October 1st 2015 and September 30th 2016 and whose medical records had one or more of the following ICD-10 codes for diagnoses: neuromuscular dysfunction of bladder (N31.0-9), potential causes of NLUTD, e.g., SCI (S14.0, S14.1, S24.0, S24.1, S34.0, S34.1, T09.3); sequelae of spinal cord injury (T91.3); other diseases of the spinal cord (G95.0-9); paraplegia or tetraplegia (G82.0-5); spina bifida (Q05.0-9); other congenital malformation of spinal cord (Q06.0-9); transverse myelitis (G37.3); neoplasm of the spinal cord (C72.0-1); cauda equina syndrome (G83.4); and multiple sclerosis (G35).

Inclusion-exclusion criteria

The researchers (DS, physiatrist; PW, registered nurse; PS; registered nurse) screened the medical records. Only records with one of the following types of evidence of NLUTD problems were included: 1) diagnosis of NLUTD/neurogenic bladder by a physician, 2) signs/symptoms of voiding dysfunction, e.g., incontinence or inability to void, or 3) use of long-term bladder emptying assistance techniques, e.g., clean intermittent self-catheterization (CISC), indwelling transurethral catheter, using external collecting devices or, 4) having investigations related to NLUTD such as urodynamic study or cystometry. Exclusion criteria were medical records of patients who were referred to other medical facilities at the first visit of diagnosing NLUTD, patients who were denied treatment, and patients who had died.

Data extraction

The researchers created a checklist for NLUTD assessment by combining key features of the two guidelines for urological management prepared by SCI experts in the United Kingdom and in Taiwan.[5,6] Initial NLUTD assessments were categorized into six groups: 1) bladder diary or post-void residual urine (PVR), 2) urine analysis, 3) urine culture, 4) serum creatinine, 5) ultrasonography or intravenous pyelography (IVP) or voiding cystourethrography (VCUG), and 6) cystometry or urodynamic studies (UDS).[5,6] The time from onset to each assessment investigation was recorded. In addition, long-term surveillance investigations, urological complications, the most recent bladder emptying technique used, and medication received for treatment of NLUTD were also recorded. This data, as well as the patients' demographic and clinical characteristics, were extracted and recorded by the researchers (DS, PW, and PS)

Surveillance/follow-up investigations for the five years following initial onset were recorded, including whether there were appointments with physicians as well as any check-ups on upper and lower urinary tract function using serum creatinine, ultrasonography or IVP or VCUG, and cystometry or UDS. The frequency of each type of surveillance investigation was also recorded.

Statistical analysis

The retrieved data were analyzed to identify 1) the type of initial urological assessment and the date of that assessment, 2) what proportion of SCI patients had cystometry or UDS done to diagnose NLUTD and how soon after reporting symptoms the diagnosis was done, 3) the latest bladder emptying techniques used, 4) the types of medications for NLUTD prescribed and how frequently they were used, 5) the prevalence of upper urinary tract complications, 6) the types and frequently of investigations done for urological follow-up surveillance during the first 5 years, and 7) whether there were differences in urological management and outcomes of NLUTD between university hospitals and MOPH hospitals. Descriptive statistics are reported as numbers and percentages; inferential statistics were used to compare MOPH hospitals and university hospitals using chi-square for categorical data and the Mann-Whitney U test for non-parametric nominal data.

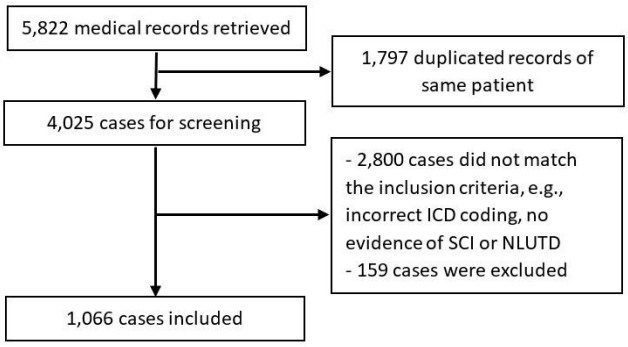

Figure 1. Flow of evaluation of the medical records of recruited cases

Results

Among the 5,822 cases retrieved, 1,066 cases were included in the study (Figure 1). Table 1 shows demographic and clinical characteristics of the included patients. The majority were male (62.6%) and the average age of all patients was 44.9 years.

Table 2 shows the six categories of initial NLUTD assessment. The most frequent was checking serum creatinine (85.9%), followed by urine analysis (75%), USG or IVP or VCUG (71.3%), UDS (51.9%) and bladder diary or PVR (49.1%). There was a statistically significant difference ($p < 0.001$) in the percentage of all categories of the initial NLUTD assessments between the university hospitals and MOPH hospitals. Overall, only 23.8% of patients received all six categories of assessment as part of the initial evaluation. Table

Table 1. Demographic and clinical characteristics of the recruited cases

	Overall (n = 1066)	University hospitals (n = 643)	MOPH hospitals (n = 423)
Demographics			
Gender, male[1]	667 (62.6)	378 (58.8)	289 (68.3)
Age (years)[2]	44.9 (21.5)	42.3 (22.6)	49.3 (18.5)
SCI characteristics			
Cause of SCI[1]			
Traumatic	380 (35.6)	231 (35.9)	149 (35.2)
Non-traumatic			
Congenital diseases	150 (14.1)	124 (19.3)	26 (6.1)
Acquired abnormalities	112 (10.5)	47 (7.3)	65 (15.4)
Neoplastic	123 (11.5)	83 (12.9)	40 (9.5)
Infection	84 (7.9)	58 (9)	26 (6.1)
Unspecified	217 (20.4)	100 (15.6)	117 (27.7)
Severity, paraplegia[1]	646 (60)	461 (71.7)	185 (43.7)
Duration of NLUTD (months)[2]	98.1 (101.3)	111.6 (102.7)	76.8 (95.3)
Duration of NLUTD (months)[3]	62 (27-132)	82 (39-156)	35 (21-88.5)

[1]Number (%), [2]mean (SD), [3]median (IQR)

MOPH, Ministry of Public Health; SCI, spinal cord injury; NLUTD, neurogenic lower urinary tract dysfunction

Table 2. Comparison of initial NLUTD assessments performed at university and MOPH hospitals

Assessment	Overall (n = 1066)	University hospitals (n = 643)	MOPH hospitals (n = 423)	*p*-value*
Bladder diary or PVR	529 (49.6)	440 (68.4)	89 (21.0)	< 0.001
Urine analysis	800 (75.0)	521 (81.0)	279 (65.9)	< 0.001
Urine culture	487 (45.7)	322 (50.0)	165 (39.0)	< 0.001
Serum creatinine	916 (85.9)	587 (91.3)	329 (77.8)	< 0.001
USG or IVP or VCUG	760 (71.3)	577 (89.7)	183 (43.3)	< 0.001
Cystometry or UDS	554 (51.9)	513 (79.8)	41 (9.7)	< 0.001

Number (%); *statistically significant ($p < 0.05$)

IVP, intravenous pyelography; MOPH, Ministry of Public Health; NLUTD, neurogenic lower urinary tract dysfunction; PVR, post-void residual urine; UDS, urodynamic study; USG, ultrasonography; VCUG, voiding cystourethrography

Table 3. Comparison of time since the diagnosis to first urological assessment at university hospitals and at MOPH hospitals (months)

	Months from onset of symptoms to first assessment [mean (range)]			
	Overall	University hospitals	MOPH hospitals	*p*-value*
Bladder diary or PVR assessment	10 (2-40)	10 (2-39.25)	8 (3.5-48)	0.294
Urine analysis	12 (2-50)	15 (3-56)	6 (1-36)	< 0.001
Urine culture	15.5 (3-59)	18 (5-53)	9 (1-71.25)	0.053
Serum creatinine	13 (2-58.5)	17 (4.25-68.75)	5 (1-42)	< 0.001
USG or IVP or VCUG	14 (4.25-60)	13 (4-49)	17 (6-80)	0.019
Cystometry or UDS	16 (4.75-63.25)	16 (4-61.75)	18.5 (7-190.25)	0.032

Median (IQR), *Mann-Whitney U test statistical significance $p < 0.05$

IQR, interquartile range; MOPH, Ministry of Public Health; NLUTD, neurogenic lower urinary tract dysfunction; PVR, post-void residual urine; IVP, intravenous pyelography; VCUG, voiding cystourethrography; UDS, urodynamic studies, USG, ultrasonography

Table 4. Comparison of urological follow-up management during the first five years after onset

	Overall (n = 1,066)	University hospitals (n = 643)	MOPH hospitals (n = 423)	*p*-value*
Complied with annual follow-up	632 (59.3)	461 (71.7)	171 (40.4)	
No appointment given for follow-up	196 (18.4)	59 (9.2)	137 (32.4)	< 0.001
Referred to other hospitals	29 (2.7)	11 (1.7)	18 (4.3)	
Lost to follow-up	209 (19.6)	112 (17.4)	97 (22.9)	

Number (%); *Chi-square statistically significant ($p < 0.05$)

MOPH, Ministry of Public Health

3 shows the time from onset to the initial NLUTD assessment. The median time to UDS/cystometry was 16 months (IQR: 4.75-63.25).

The combined frequency of the most recent bladder emptying techniques used in both types of hospitals were indwelling transurethral catheter (38%), reflex voiding (30.1%), CISC (20.3%), clean intermittent catheterization (CIC) (6.3%), suprapubic cystostomy (2.1%), and others (2.7%). The overall percentage of those who were trained to perform CIC/CISC was 47%. A total of 262 patients (24.6%) experienced urinary incontinence which required the use of external collecting devices. Of these patients, 48% managed their bladder with reflex voiding, 38.9% used CIC, and 8% used an indwelling transurethral catheter.

Of the 1,066 patients, 56.7% had never received an anti-muscarinic agent for detrusor overactivity. Of the 42.5% who had received an agent, only 32.8% still used the medication at their latest visit. Among the 350 patients who still received medication, 90% were followed up at university hospitals. The median duration from onset to the first prescription of an anti-muscarinic agent was 24 months (IQR 8-69.25).

Table 4 compares urological follow-up management during the first five years after the onset of disease. Approximately 60% of patients complied with a regular appointment for urological follow-up, 19.6% were lost to follow-up, and 18.4% did not receive a follow-up appointment. There was a statistically significant difference in the follow-up appointment scheduling and patient compliance between the university and the MOPH's hospitals.

In the analysis of patients with the time from the initial diagnosis of at least 5 years, 574 patients were excluded, leaving 492. Table 5 shows the frequency with which patients received long-term urological follow-up for investigation of upper urinary tract functions and structures. The frequency of annual follow-ups was 49.8% for serum creatinine, 46.7% for USG/IVP/VCUG, and 34.1% for UDS/cystometry. Only 98 patients (19.9%) received all categories of NLUTD assessment annually, all of whom were followed up at a university

Table 5. The frequency of urological investigations during the first 5 years of follow-up

	Frequency of investigations	Overall (n = 492)	University hospitals (n = 360)	MOPH hospitals (n = 132)	*p*-value*
Serum creatinine	Annually	245 (49.8)	190 (52.8)	55 (41.7)	< 0.001
	2 times in 5 years	123 (25.0)	95 (26.4)	28 (21.2)	
	1 time in 5 years	38 (7.7)	27 (7.5)	11 (8.3)	
	Never received	86 (17.5)	48 (13.3)	38 (28.8)	
USG or IVP or VCUG	Annually	230 (46.7)	201 (55.8)	29 (22.0)	< 0.001
	2 times in 5 years	111 (22.6)	93 (25.8)	18 (13.6)	
	1 time in 5 years	23 (4.7)	19 (5.3)	4 (3.0)	
	Never received	128 (26.0)	47 (13.0)	81 (61.4)	
UDS or cystometry	Annually	168 (34.1)	167 (46.4)	1 (0.8)	< 0.001
	2 times in 5 years	82 (16.7)	80 (22.2)	2 (1.5)	
	1 time in 5 years	22 (4.5)	18 (5.0)	4 (3.0)	
	Never received	220 (44.7)	95 (26.4)	125 (94.7)	

Number (%); *$p < 0.05$

IVP, Intravenous pyelography; MOPH, Ministry of Public Health; VCUG, voiding cystourethrography; UDS, urodynamic study; USG, ultrasonography

Table 6. Incidence of upper urinary tract complications (n = 760)

Upper urinary tract complications	
Vesicoureteral reflux grade 1-3	47 (6.2)
Vesicoureteral reflux with hydronephrosis	192 (25.3)
Chronic kidney disease	28 (3.7)
Chronic kidney disease with renal replacement therapy	9 (1.2)
Other upper urinary tract complications	5 (0.7)
Total	281 (36.9)
No Upper urinary tract complications reported	479 (63.1)

Number (%)

hospital. The significant disparity in the long-term surveillance investigations between the university and the MOPH hospitals is shown in Table 5.

Of the 760 patients that received at least one USG or IVP or VCUG, 3.2% had urinary tract calculi and 36.9% had upper urinary tract complications of different degrees as shown in Table 6.

Discussion

The first urological assessment for NLUTD determined that about half the patients had either a UDS or cystometry which was performed late, about 1-2 years post-onset of injury/post-diagnosis of the primary disease and only one-fourth of the patients had a complete urological assessment. The incidence of complete assessment and UDS was higher in the university hospitals than in the MOPH hospitals, with less than 10% of UDS or cystometry tests performed in MOPH hospitals. This difference could be due to limited resource availability, e.g., only one of the three MOPH hospitals had a urodynamic machine.

The management of NLUTD in Thailand differs from that in high-income countries. For example, the United Kingdom offers an initial urological assessment to all SCI patients at 3-6 months post onset.[5] In addition, SCI units in the UK mandate the evaluation of kidney-ureter-bladder imaging together with urodynamics as part of the initial assessment, with more than 80% of all units using video-urodynamics in the assessment process.[12] In comparison, only half of the patients in our study received UDS/cystometry as a part of the first assessment, even though one-channel simple cystometry is an alternative and safe technique of assessing detrusor functions[18] and has been one of the procedural skills taught in the rehabilitation medicine residency training program in Thailand.[19] The low percentage of UDS/cystometry found in this study suggests that all rehabilitation medicine training institutes should increase emphasis on simple cystometry and provide more opportunity to practice during the training program so that every physiatrist could master this competency. Additionally, assessment of bladder diaries and PVR helps physiatrists/urologists to evaluate the effectiveness and appropriateness of bladder-emptying techniques. However, they were performed in less than one-third of patients during the first assessment.

Two-third of the patients in our study used urinary catheters to empty the bladder, more used indwelling catheters, and about one-third used reflex voiding. These findings are not congruent with the recommendations of the existing guidelines.[2,5,7] Reflex voiding should be used only when UDS shows that the bladder situation is safe and an adequate follow-up is guaranteed. Indwelling catheters are not recommended for long-term use because of the risk of urinary complications.[2,6,7,20] According to the available evidence, bladder emptying techniques used by a patient can be changed over time. El-Masri followed SCI patients for 8-12 years and discovered that 84% learned to used CIC, 67% were using CIC at the time of SCI rehabilitation unit discharge, but only 18% still used CIC at 8-12 years.[21] In Taiwan, long-term follow-up in NLUTD patients similarly showed a decreasing number of patients using CIC over time.[22] Our study findings were similar, with about half the patients who were trained still continuing to perform CIC/CISC at their latest visit. According to a previous study in Thailand, the main reason that chronic SCI

patients choose indwelling catheters is convenience; however, the quality of life of those performing CISC/CIC and those with indwelling catheters are not different.[17]

One-fourth of the patients in this study reported urinary incontinence which is far lower than another study which reported 52.3% urinary incontinence in SCI patients.[23] This difference could, at least in part, be due to the inadequate medical recording as well as to the retrospective nature of the present study. Improper management of incontinence may prompt patients using CIC/CISC to shift back to using indwelling catheters. According to an economic evaluation study in Thailand, the cost of using external collecting devices is a significant burden for people with physical impairment.[24] That added burden could influence patients' choice of bladder management. However, some of the patients using indwelling catheters in our study also had urinary incontinence which might be due to lack of or inadequate anti-muscarinic medications and/or improper care of long-term indwelling catheter usage which can cause bladder neck and urethral erosion.[20]

All NLUTD guidelines recommend controlling detrusor pressure for patients with detrusor activity in order to prevent upper tract damage as well as recommending an annual urological follow-up.[2,5-7,25] To effectively control detrusor pressure, anti-muscarinic mediations are needed,[20] but more than half the patients in our study had never received such medications. For those who did receive it, the medication was received late, about 2 years after the onset of the injury/diagnosis, and only one-third were still taking the medications at the time of their latest visit. Lack or delay in providing anti-muscarinic medication prescriptions and inadequate regular urological follow-up might be two main reasons why one-third of patients in our study had developed upper urinary tract complications.

The upper urinary tract complications rate in our study was 36.9%, higher than rates reported in other countries.[21,26] The proportion of patients with VUR and hydronephrosis in the current study was 31.5%, higher than the 20% in Thongchim's study in Thailand.[13] This difference is probably due to the latter study having been conducted in a single university hospital which has SCI specialists who conducted regular urological follow-ups, whereas some of the patients' records in our study were obtained from MOPH hospitals where NLUTD services are limited. Another recent study conducted in a MOPH tertiary hospital in Thailand found a comparable percentage of hydronephrosis in patients with NLUTD, and reported a high percentage of patients using indwelling catheterization (66.5%) and reflex voiding (16.5%). That study also reported that the bladder emptying method is a strong predictor of hydronephrosis and/or VUR.[27] It is crucial to note that the number of complications in our study could be higher than reported in the medical record as one-third of the patients never had USG, IVP, or VCUG. Five percent of patients in this study had experienced chronic kidney disease (CKD) which could also be an underestimate as the number of CKD patients in the general Thai population is as high as 17.5% and given that NLUTD patients are a high-risk group for CKD.[28] There is also a prediction based on estimated glomerular filtration rate (eGFR) that up to one-third of SCI patients experience some level of CKD but with no diagnosis in their medical record.[29]

Most guidelines suggest at least an annual surveillance check-up for NLUTD patients.[2,5-7] This study explored the period during the first five years of follow-up. About one-third of those who had at least 5 years of follow-up had received UDS/cystometry. In contrast, at the 8-year follow-up in the United Kingdom, up to 64% of patients still received a regular annual check-up.[21] One vital difference between the medical system in Thailand and that in the UK is that rehabilitation service in the UK is under the management of SCI units where there are 12 units in the country offering holistically long-term SCI care.[12] In contrast, rehabilitation services in Thailand are integrated in an acute hospital setting with very limited resources, resulting in limitations in access to care.[30-32] Our study demonstrates that there are significant differences in the provision of urological assessment and follow-up investigations and in bladder emptying techniques and anti-muscarinic prescriptions between university hospitals and MOPH hospitals. These differences reflect the uneven and insufficient NLUTD management for patients with SCI in Thailand, e.g., presently, specialized SCI rehabilitation facilities, which by far provide better functional outcomes, are located only in university hospitals.[33] The policy makers of the MOPH as well as the National Health Security Office (NHSO) should consider developing at least one SCI-specialized rehabilitation facility in each NHSO region to ensure adequate SCI management in the acute, post-acute and long-term phases of treatment.

There are certain limitations in this study due to the nature of the retrospective method used. First, the data were retrieved from only 5 hospitals, which might not be representative of the situation of all Thai patients with SCI. Second, it was a retrospective review of only available medical records, and some data were missing or hard to interpret. Additionally, many investigations, for example, urine analysis, urine culture, and serum creatinine, could have been performed as part of an assessment of other co-morbidities. Even though the investigations included in the study were counted as part of NLUTD evaluation, it was difficult to interpret the intention of the physician at that time, i.e., whether an investigation was performed specifically for NLUTD care or not. In addition, there was a limitation in determining the actual number of patients receiving a complete initial NLUTD assessment. Due to the lack of a standardized NLUTD protocol in all hospitals, each of the six categories of initial assessment was performed over a wide time interval. If this study had included only cases where a strict protocol had been followed and all assessments were done within the prescribed time frame,

the percentage of patients who received a proper initial assessment would be far lower than the 23.8% reported in this study. Finally, the upper urinary tract complication rates might have been higher if all patients had undergone the appropriate investigations, e.g., USG/IVP/VCUG. To overcome these limitations, a prospective study should be conducted in a larger number of hospitals which would better represent the actual situation.

Conclusions

There is a wide variety in the initial assessment and long-term care provided for patients with SCI and NLUTD in Thailand. The majority of patients receive the first urological assessment more than a year post-onset which could result in inappropriate and/or insufficient management as well as an increase in the number of upper urinary tract complications. The retrospective data in this study was insufficient to develop a strong recommendation; however, the available evidence suggests that there might be problems due to the insufficient availability of services and the limitations in the knowledge of healthcare providers related to NLUTD management, especially in the MOPH hospitals. Development of standardized guidelines for NLUTD management which take into account the context of Thai healthcare system would be highly beneficial for both healthcare providers and for NLUTD patients.

Disclosure

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The authors declare that there is no conflict of interest.

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Original Article

Demographics, Clinical Characteristics and Functional Outcome of Non-Traumatic Spinal Cord Injury Undergoing Inpatient Rehabilitation in University Malaya Medical Centre

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ABSTRACT

Objectives: To describe the demographics and functioning of patients with non-traumatic spinal cord injury (NTSCI) undergoing inpatient rehabilitation.

Study design: Retrospective study.

Setting: A tertiary hospital in Malaysia.

Subjects: Patients (N = 141) with NTSCI who had undergone initial inpatient rehabilitation between 1st January 2015 to 31st December 2019.

Methods: This was a retrospective study design where information was obtained from patients' electronic medical records. The etiology of NTSCI, demographic information, length of stay in rehabilitation, American Spinal Injury Association Impairment Scale (AIS) grade at initial rehabilitation and discharge, and Spinal Cord Injury Independence Measure Version III (SCIM III) score at initial rehabilitation and discharge, were recorded and analyzed.

Results: A total of 141 patients with NTSCI were referred for inpatient rehabilitation. The mean age was 58.1 years (range 20-88), and 59.6% were men. The mean duration of inpatient rehabilitation was 32.3 days (range 7-198). The top three etiology were spine degeneration (34.0%), spine neoplasms (30.5%), and infection (23.4%). The commonest neurological impairment was incomplete paraplegia (52.5%). Most patients were classified as AIS D (n=84, 60.4%); only 14 (10.1%) patients were found to be AIS A. The mean difference of SCIM III score between initial and completion of rehabilitation all NTSCI etiologies achieve clinical significance, with mean score ranges from 12.7 to 21.9 points.

Conclusions: Spine degeneration and spine neoplasm were the most common etiology of NTSCI in this study. Regardless of the etiology of NTSCI, all patients benefited from inpatient rehabilitation program, and had similar functional gain.

Keywords: etiology, demography, functional outcome, spinal cord injury, rehabilitation

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Introduction

Spinal cord injury (SCI) is a chronic condition which affects patients' physical, psychological health and social well-being, as well as causes heavy burden on families, communities, and health care systems.[1] The prevalence of SCI was from 440 to 526 per million people.[1] A recent survey in Malaysia where 298 people with SCI participated, 14.6% were non-traumatic spinal cord injury (NTSCI).[2] The incidence of NTSCI is reported to be higher than traumatic SCI in Australia and Canada.[3,4] The number of people with NTSCI is increasing due to aging populations. Therefore, it is anticipated that the incidence of NTSCI will increase with the aging global population.[3] Patients with NTSCI are older than those with traumatic SCI (TSCI), with the typical median age of 60 to 65 years old[2-5] and could possibly have worse functional outcome.

The common etiology of NTSCI are degenerative spinal conditions, benign or malignant neoplasm, vascular disorders, inflammatory disorders, and infection.[2,5,6] NTSCI in developed countries are commonly caused by degenerative conditions and neoplasms, while in developing countries caused by infections and neoplasms.[7]

Clinical characteristics and functional outcome of NTSCI is less often reported compared to traumatic SCI. When compared to NTSCI, TSCI group had a higher proportional of patients who were male (68-76%), tetraplegic (32.1-60.6%), and complete lesion (23-74%).[8-10] Tetraplegia occurred more commonly in patients with degenerative disorder of the spine, as compared to other etiologies.[5,11] Patients with vertebral infection were more likely to have incomplete paraplegia[6] whilst patients with malignant spinal cord compression had similar age and gender distribution compared to other causes of non-traumatic spinal cord injury.[13] Functioning of patients with NTSCI improved following inpatient rehabilitation, but patients with malignant neoplasm have lesser improvement.[5,11,12] Nevertheless, most patients with malignant neoplasms met their inpatient rehabilitation goals.[13]

There is scarce study on the functional outcome among different etiologies in patients with NTSCI in Malaysia. It is important to understand the characteristics of the different etiologies of NTSCI and their functioning changes following rehabilitation, as it might help to facilitate optimal rehabilitation and anticipated outcome of the patients. Thus, the purpose of this study is to describe the demographics, clinical characteristics and functioning profile of patients with NTSCI according to the etiology.

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Methods

This is a retrospective study of patients with NTSCI who were referred to the SCI rehabilitation team for initial inpatient rehabilitation in University Malaya Medical Centre (UMMC), between 1st January 2015 to 31st December 2019. The study was approved by the UMMC Medical Research Ethics Committee (MREC ID Number: 2020628-8831).

The inclusion criteria were patients with NTSCI, 18 years old and above, and referred for initial rehabilitation after the onset of NTSCI, and had Spinal Cord Independence Measure III (SCIM III) scores before and after rehabilitation were included. Those who were diagnosed as Guillain-Barre´ syndrome, multiple sclerosis, spina bifida, Friedreich ataxia, or a conversion syndrome were excluded. The information was gathered from UMMC electronic medical records. Age, gender, date of onset of SCI, duration of inpatient rehabilitation, etiology of NTSCI, level of spinal cord injury (tetraplegia vs paraplegia), and completeness of injury (complete vs incomplete). American Spinal Cord Injury Association Impairment Scale (AIS) grade and SCIM III score at the start of rehabilitation and discharge were collected.

The etiology of NTSCI was classified according to the classification used in the International Nontraumatic Spinal Cord Injury Data Set.[14] According to this classification system, the etiologies in this study were categorized as degenerative, neoplasms, infection and others. The duration of SCI was the date of onset of SCI to the date of initiation of rehabilitation, and were recorded as acute (≤ 1 day), subacute (> 1 day but ≤ 7 days), prolonged (> 7 days but ≤ 1 month), and lengthy (> 1 month).[14] The duration of rehabilitation stay was defined as the date of initiation of inpatient rehabilitation to the date of discharge.

The SCI Rehabilitation service in UMMC routinely uses SCIM III to document functional outcomes of patients with spinal cord injuries at the start and end of inpatient rehabilitation. The SCIM III covers three major domains: self-care (score 0-20), respiration and sphincter management (score 0-40) and mobility (score 0-40). The total score ranges from 0 to 100, where 0 indicates total dependence and 100 indicates complete independence.[15] SCIM III is a reproducible and valid functional outcome measure in patients with NTSCI.[16] The difference between initial rehabilitation and discharge was documented as the functional gain during the inpatient rehabilitation.

Statistical Package for the Social Sciences (SPSS) version 23 was used for data analysis. The chi square test was used to detect significant differences of demographic (gender and pattern of onset) and characteristics of SCI with etiology. One way ANOVA was used to compare age with etiology while Kruskal-Wallis rank sum test was used to compare duration of rehabilitation stay with etiology. Association between SCIM III score and subdomain SCIM III scores with etiology and characteristic of SCI were also analyzed. Kruskal-Wallis rank sum test and Mann-Whitney test was used because of the skewed distribution of the scores. *P* values of less than 0.05 were considered significant.

Results

A total of 141 patients were referred for rehabilitation during the study period (Table 1). The mean (SD) age was 58.1 (14.2) years old (range 20-88), and majority were men (n = 84, 59.6%). A total of 109 patients were admitted to the rehabilitation ward for rehabilitation, while the rest received rehabilitation in the primary ward. The mean duration of inpatient rehabilitation was 32.3 days (median 27, IQR 18-42, range 7-198). The commonest neurological impairment was incomplete paraplegic (52.5%). The top three etiologies were spine degeneration (n = 48, 34.0%), spine neoplasms (n = 43, 30.5%), and infection (n = 33, 23.4%).

At initial rehabilitation, most patients were classified as AIS D (n = 84, 60.4%), only 14 (10.1%) patients were found to be AIS A. At discharge, 36 (25.9%) patients showed improvement in the AIS classification, 102 (73.4%) remained the same, and one (0.7%) deteriorated.

Table 2 shows the comparison of demographic and characteristics of NTSCI between the etiologies. Patients with spine degeneration had a higher mean age (p = 0.07), were mainly men (p = 0.027), and had incomplete tetraplega (p = 0.00) compared to others. Patients with spine infection had the longest rehabilitation length of stay.

Out of the 141 patients with NTSCI who were referred for rehabilitation, only 65 patients had complete informa-

Table 1. Demographics and clinical characteristics of NTSCI patients (N = 141)

Age (years), mean (SD), range	58.1 (14.2), 20-88
Gender, number (%)	
Men	84 (59.6)
Women	57 (40.4)
Pattern onset, number (%)	
Subacute (> 1 day to ≤ 7 days)	11 (7.8)
Prolonged (> 7 days to ≤ 1 month)	45 (31.9)
Lengthy (> 1 month)	85 (60.3)
Characteristics of SCI, number (%)	
Paraplegia complete	11 (7.8)
Paraplegia incomplete	74 (52.5)
Tetraplegia complete	3 (2.1)
Tetraplegia incomplete	53 (37.6)
Ward, number (%)	
Rehabilitation ward	109 (77.3)
Primary ward	32 (22.7)
Etiology, number (%)	
Spine degeneration	48 (34.0)
Neoplasm - benign	7 (5.0)
Neoplasm - malignant	4 (2.8)
Neoplasm - metastasis	32 (22.7)
Infection - bacterial	19 (13.5)
Infection - tuberculosis	14 (9.9)
Others - inflammation	11 (7.8)
Others - vascular	4 (2.8)
Others - osteoporosis	2 (1.4)
Rehabilitation length of stay (days)	
Mean (SD)	32.3 (23.3)
Median (IQR), range	27 (18-42), 7-198

IQR, interquartile range; NTSCI, non-traumatic spinal cord injury; SCI, spinal cord injury; SD, standard deviation

Table 2. Comparison of demographics, characteristics of NTSCI and rehabilitation by etiology

Characteristics	Degenerative	Neoplasm	Infection	Others	*p*-value
Number (%)	48 (34.0)	43 (30.5)	33 (23.4)	17 (12.1)	
Age (years) mean (SD)	62 (14.2)	56.6 (13.5)	57.3 (13.3)	52.2 (16.2)	0.07[a]
Sex, number (%)					
Men	36 (75)	21 (48.8)	20 (60.6)	7 (41.2)	0.027[b]
Women	12 (25)	22 (51.2)	13 (39.4)	10 (58.8)	
Pattern onset, number (%)					
Subacute (> 1 day, ≤ 7 days)	4 (8.3)	1 (2.3)	3 (9.1)	3 (17.6)	0.016[b]
Prolonged (> 7 days, ≤ 1 month)	8 (16.7)	18 (41.9)	10 (30.3)	9 (52.9)	
Lengthy (> 1 month)	36 (75.0)	24 (55.8)	20 (60.6)	5 (29.4)	
Characteristics of SCI, number (%)					
Paraplegia complete	1 (2.1)	5 (11.6)	3 (9.1)	2 (11.8)	0.000[b]
Paraplegia incomplete	15 (31.2)	30 (69.8)	19 (57.6)	10 (58.8)	
Tetraplegia complete	0 (0.0)	0 (0.0)	2 (5.9)	1 (5.9)	
Tetraplegia incomplete	32 (66.7)	8 (18.6)	9 (27.3)	4 (23.5)	
Ward, number (%)					
Rehabilitation ward	46 (95.8)	33 (76.7)	17 (51.5)	13 (76.5)	0.000[b]
Primary ward	2 (4.2)	10 (23.3)	16 (48.5)	4 (23.5)	
Length of stay (days), median (IQR)	18 (13)	28 (21)	37 (23)	28 (27)	0.000[b]

[a]One way ANOVA, [b]Pearson chi-square test, cKruskal-Wallis rank sum test; level of significance $p < 0.05$
IQR, interquartile range; NTSCI, non-traumatic spinal cord injury

tion on initial rehabilitation and at discharge total SCIM III scores. Meanwhile 59 out of the 65 patients had complete information on the breakdown of scores of the three functioning domains of SCIM III. The demographics of patients who had complete SCIM III scores were similar with total NTSCI patients referred for rehabilitation. Due to small number and heterogenous nature of patients in the 'Others' category, it was excluded from the analysis involving SCIM III total and subdomain score. Thus, the analysis involving total SCIM III scores involved 57 patients whilst analysis involving SCIM III subdomain involved 52 patients.

All etiologies showed almost similar mean SCIM III scores at initial rehabilitation, ranging from 35.9 to 38.2 points (Table 3). SCIM III scores at discharge were higher than the initial score in all etiologies, ranging from 50.5 to 57.8 points. Patients with spinal infection had the highest SCIM III score gain (21.9 points), followed by those with neoplasm (15.7 points) and degenerative diseases (12.6 points). However, there was no significant statistical differences between etiologies and SCIM III score at initial rehabilitation and at discharge.

In the subdomain of SCIM III (self-care score, respiration and sphincter management score, and mobility), there is no difference in score at initial rehabilitation, at discharge, and gain between the different etiologies. Nevertheless, our data showed that patients with spine neoplasms and spine infection had higher self-care score at initial rehabilitation and at discharge. Meanwhile, patients with spine degenerative had higher scores in respiration and sphincter management at initial rehabilitation and discharge. In the mobility domain, patients with spine degeneration and spine neoplasms had lower scores at initial rehabilitation but had higher gain at discharge. Patients with spine infection showed highest gain in self-care and respiration and sphincter management but had the lowest gain in mobility.

As can be seen from Table 4, functional outcome was compared between incomplete paraplegia and incomplete tetraplegia patients. There was no between group differences observed for total SCIM III score at initial rehabilitation, at discharge and gain. As expected, incomplete paraplegic patients compared to incomplete tetraplegia had significantly higher self-care scores at initial rehabilitation and at discharge. There was no significant difference in the initial and discharge SCIM score in the respiration and sphincter management score, and mobility score.

Discussion

This is the first study that provided insight to the demographic and functioning of people with NTSCI in Malaysia. The two common etiologies in this study were spine degeneration and spine neoplasms, which is in line with other studies in the developed countries.[7,11,12,17-20] The current study showed patients with NTSCI had improvement in functioning following inpatient rehabilitation regardless of the etiologies. This includes patients with spinal metastases who formed the majority of patients in the spine neoplasms group. The current study showed that all patients had improvement in their SCIM III score. A study by Sciveletto reported that an improvement of at least 4 points of the total SCIM is needed to obtain a small significant improvement and of 10 points to obtain a substantial improvement.[21] Thus in this study patients with NTSCI, regardless of the etiology, achieved clinically significant change in their functioning following rehabilitation.

Although various outcome measures were used in previous studies, all showed NTSCI patients had improvement in functional outcome with inpatient rehabilitation. Most studies used Functional Independence Measure (FIM)[22-25], in which New et al. reported mean admission FIM motor score of 39.6 and discharge FIM motor score of 58.7.[22] Jolien et al. used

Table 3. Comparing total and subdomains SCIM III score with etiologies of NTSCI

Etiology	N	Mean (SD)	Median	IQR	[a]*p*-value
SCIM III score					
At initial rehabilitation (0-100)					
Degenerative	24	37.9 (17.8)	36	24.5-47.0	0.947
Neoplasm	22	38.2 (13.7)	31	29.5-53.0	
Infection	11	35.9 (13.2)	34	30.8-49.3	
Total	57	37.9 (15.4)	33	26.5-51.5	
At discharge (0-100)					
Degenerative	24	50.5 (20.7)	45	36.0-75.0	0.470
Neoplasm	22	53.9 (14.8)	48	43.0-63.5	
Infection	11	57.8 (12.9)	57.5	44.5-66.3	
Total	57	53.9 (17.3)	52	43.0-71.5	
Self-care score					
At initial rehabilitation (0-20)					
Degenerative	21	9.1 (5.3)	8	4.5-12.5	0.068
Neoplasm	21	11.8 (3.4)	11	10.0-14.5	
Infection	10	11.1 (2.8)	11	8.8-13.3	
Total	52	10.6 (4.2)	10	8.0-14.0	
At discharge (0-20)					
Degenerative	21	12.1 (6.2)	13	6.0-17.0	0.065
Neoplasm	21	15.3 (2.9)	17	13.5-18.0	
Infection	10	16.9 (2.6)	17.5	14.0-19.3	
Total	52	14.3 (4.8)	16	11.0-18.0	
Respiration and sphincter management score					
At initial rehabilitation (0-40)					
Degenerative	21	21.7 (10.1)	19	13.5-32.0	0.421
Neoplasm	21	19.7 (10.0)	15	10.0-30.0	
Infection	10	17.1 (7.0)	15	10.8-22.0	
Total	52	20.0 (9.5)	17	11.0-29.0	
At discharge (0-40)					
Degenerative	21	27.0 (9.7)	29	17.0-36.0	0.295
Neoplasm	21	23.9 (9.9)	22	16.0-33.5	
Infection	10	28.4 (8.5)	27.5	20.8-36.0	
Total	52	26.1 (9.4)	25	17.0-35.0	
Mobility score					
At initial rehabilitation (0-40)					
Degenerative	21	7.2 (6.5)	6	2.0-11.0	0.294
Neoplasm	21	7.1 (4.2)	6	4.0-10.0	
Infection	10	9.6 (4.4)	9	5.8-14.0	
Total	52	7.4 (5.2)	7	3.0-11.0	
At discharge (0-40)					
Degenerative	21	13.1 (6.6)	13	7.0-20.0	0.465
Neoplasm	21	13.1 (4.7)	14	12.0-15.5	
Infection	10	11.6 (3.5)	11.5	9.5-13.8	
Total	52	13.1 (5.6)	13	10.0-16.0	

[a]Kruskal-Wallis rank sum test.

IQR, interquartile range; NTSCI, non-traumatic spinal cord injury; SCIM Spinal Cord Independence Measures; SD, standard deviation

functional status scale consisting of 5 items (mobility, self-care, bladder management, bowel management, and transfers), reported the median score of 47.5 at admission and 90 at discharge.[11] A study in India reported improved functional status using Barthel Index, with mean scores of 31.3 at admission and 55.6 at discharge.[26]

In contrary to the current study, previous studies reported that malignant neoplasms had lesser neurological recovery and poorer functional outcome as compared to other etiologies.[11-13,17] Although the current study did not differentiate between benign and malignant cases, majority (36/43) of cases in the neoplasm group are malignant. There are two possible reasons for this difference; patients in previous studies were older (mean age ranged from 59 to 69), while the mean age in the current study was 54.5 years. Besides that, UMMC is a tertiary center whereby patients can receive advanced high-efficacy anticancer therapeutic agents and radiotherapy, and therefore could have led to a better outcome.

McKinley et al. reported that the most significant improvements achieved during the rehabilitation stay were noted in wheelchair transfers, upper and lower extremity dressing, and toilet and tub transfers.[27] In this study, patients with spine neoplasm compared to other etiologies had higher self-care score and mobility score at discharge. However, our patients

Table 4. Total and subdomains SCIM III scores with NTSCI at initial rehabilitation and at discharge

Characteristic of NTSCI	N	Mean (SD)	Median	IQR	*p*-value
Total SCIM III score					
At initial rehabilitation (0-100)					
Paraplegia incomplete	35	39.9 (14.6)	34.0	30.0-53.0	0.200
Tetraplegia incomplete	24	36.2 (17.5)	31.0	22.5-50.0	
Total	59	38.4 (15.8)	34.0	26.0-53.0	
At discharge (0-100)					
Paraplegia incomplete	35	57.7 (15.1)	57.0	44.0-73.0	0.092
Tetraplegia incomplete	24	49.1 (20.0)	44.5	30.3-71.5	
Total	59	54.2 (17.7)	52.0	43.0-73.0	
Self-care score					
At initial rehabilitation (0-20)					
Paraplegia incomplete	32	11.6 (3.4)	10.0	9.25-14.75	0.029*
Tetraplegia incomplete	21	8.9 (5.2)	8.0	4.5-11.5	
Total	53	10.5 (4.3)	10.0	8.0-14.0	
At discharge (0-20)					
Paraplegia incomplete	32	15.7 (3.4)	16.5	14.0-18.0	0.012*
Tetraplegia incomplete	21	11.7 (5.7)	13.0	6.0-16.0	
Total	53	14.1 (4.9)	15.0	11.0-18.0	
Respiration and sphincter management score					
At initial rehabilitation (0-40)					
Paraplegia incomplete	35	19.3 (9.4)	15.5	10.0-28.75	0.202
Tetraplegia incomplete	24	22.3 (9.8)	20.0	15.0-32.0	
Total	53	20.5(9.6)	17.0	11.0-30.0	
At discharge (0-40)					
Paraplegia incomplete	32	26.4 (9.3)	25.0	17.0-35.0	0.956
Tetraplegia incomplete	21	26.4 (9.8)	24.0	17.0-37.0	
Total	53	26.4 (9.4)	25.0	17.0-35.0	
Mobility score					
At initial rehabilitation (0-40)					
Paraplegia incomplete	35	8.1 (5.0)	9.0	4.0-10.75	0.278
Tetraplegia incomplete	24	6.7 (6.1)	6.0	1.5-11.0	
Total	53	7.6 (5.5)	8.0	2.5-11.0	
At discharge (0-40)					
Paraplegia incomplete	32	13.7 (4.7)	14.0	12.0-16.75	0.553
Tetraplegia incomplete	21	12.7 (7.1)	12.0	7.0-20.0	
Total	53	13.3 (5.7)	14.0	10.0-17.5	

Mann–Whitney test, *$p < 0.05$

IQR, interquartile range; NTSCI, non-traumatic spinal cord injury; SCIM Spinal Cord Independence Measures; SD, standard deviation

had lower sphincter management scores at discharge. Most of the patients who had spinal metastasis were kept with indwelling catheter for convenience of care, as many are still undergoing active radiotherapy or chemotherapy. This could have contributed to the lower score in this subdomain.

Kennedy et al. and Kay et al. had reported that patients with spine infection had more rehabilitation needs and lower rehabilitation outcome.[6,12] The current study showed the opposite; patients with spine infection had improvement in all domains and had equal functional outcomes with other etiologies. This could be attributed to the fact that there were a higher proportion of patients with complete injury[6], and thoracic level involvement[12] as compared to our patients. Apart from that, another possible reason was our patients had longer stay to complete the antibiotic treatment, which allowed more time for rehabilitation.

There is paucity of studies comparing the functional outcome between the levels of injury in NTSCI patients. Our data had demonstrated that both incomplete paraplegia and incomplete tetraplegia group had similar SCIM III median score at initial rehabilitation, at discharge and gain. There was significant difference in self-care score, and this is self-explanatory as persons with paraplegia has no impairments in their upper limbs. As majority of patients in this study were incomplete motor (AIS D), this explains the similar gain in all other domains. This particular finding indicates that despite the different baseline score between individuals with incomplete paraplegia and tetraplegia, the net gain in SCIM III score remains the same.

There are several limitations in our study. As this is a retrospective study, missing values, and incorrect documentation may exist causing inaccuracies. Besides that, SCIM III score was not done or documented for all NTSCI patients, therefore only a small sample size was available for the analysis of the functional outcome. The second limitation is that there is selection bias as not all NTSCI patients are referred to the rehabilitation team, for example, the patients with minimal impairments, those who are not ready to participate in rehabili-

tation, those who are medically unstable, those who are in an advanced stage, or probably no available beds in the rehabilitation ward. The number of patients included in this study is not adequate to achieve statistical power. Sample size calculation indicated that this study needs 190 patients to achieve 95% confidence interval with 5% margin of error. There are a small number of patients in each etiology, and some etiologies need to be combined into a group to obtain enough for analysis. This might be the reason why some of our data showed a difference in the SCIM III score between groups, but it was not statistically significant. Furthermore, our data might not represent the national population as this is a single center study.

Conclusions

Spine degeneration and spine neoplasms were the most common etiology of NTSCI in this study. All etiologies had functional gain during the inpatient rehabilitation. However, there were no significant differences between etiologies and level of functioning. Therefore, all NTSCI patients should be given equal opportunity to rehabilitation in order to improve functional status. A prospective study involving larger groups of patients are needed to provide better quality evidence on the functional outcome of people with NTSCI.

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Short Communication

An Upper Extremity Self-Exercise Programme Increases Duration of Exercise in an Acute Rehabilitation Unit and Adherence After Discharge

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ABSTRACT

Objectives: To assess the effects of an upper extremity self-exercise programme within an acute inpatient rehabilitation unit on the duration of inpatient exercise and post-discharge treatment adherence.

Study design: Observational study.

Setting: Acute inpatient rehabilitation unit within Changi General Hospital, Singapore.

Subjects: Stroke patients with SAFE (Shoulder Abduction Finger Extension) score not less than 5, admitted to the Inpatient Rehabilitation Unit between July 2019 and March 2020.

Methods: This study was initiated as a quality improvement project. The self-exercise programme was adopted from TRIO (Targeted Rehabilitation Improved Outcomes) Home Programme. It was applied as an adjunct to conventional neurorehabilitation. The duration of daily self-exercise was documented. Patient's feedbacks were obtained before discharge. Post discharge 4-6 weeks, adherence to the programme was followed up via a telephone call.

Results: Two hundred and fifteen stroke patients were screened. Thirty patients participated in the project. While admitted, the median number of days spent in the upper extremity self-exercise programme was 6 days with an average of 25.88 (SD 11.80 minutes) per session. Eighty-three percent of patients gave feedback that the programme was helpful for their recovery. On follow up, 56.7% reported continued adherence after discharge and 36.7% were not contactable.

Conclusions: After the early implementation of an upper extremity self-exercise adopted from the TRIO Home Programme within an acute inpatient rehabilitation unit, the average time spent during admission (25.88 minutes) is approaching the minimum recommendation duration of 30 minute per session and promotes treatment adherence after discharge.

Keywords: stroke, upper extremity, exercise, treatment adherence, rehabilitation

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Introduction

Various stroke guidelines advocate intensive inpatient rehabilitation with a recommended duration of 3 hours per day.[1] According to the National Institute for Health and Care Excellence (NICE) guidelines, it is recommended to initially offer the relevant therapy for at least 45 minutes, 5 days per week.[2] There are various reasons for not providing the amount of therapy according to various stroke guidelines that include time spent on the exchange of information, documentation, and the way work is organized.[3]

Research has also shown that post-stroke rehabilitation can aid patients with stroke in the recovery of function and mobility.[4] Beyond inpatient rehabilitation programmes, rehabilitation extended into the home setting post-discharge has shown to facilitate effective treatment.[5] There has been much research done to analyse factors affecting adherence to home-based exercise programmes. These range from the evaluation of various methods of engagement - usage of smart technology versus paper-based modalities[6] or pictorial versus written instructions and studies to identify barriers to home-based exercise programmes.[7] These include the degree of stroke, patients' motivation, caregiver involvement, and external motivation from family.[8] However, there has been limited research on incorporating home-based exercise programmes in an inpatient setting to promote adherence and thereby maximise the benefits reaped.

At our hospital, admissions correspond to various diagnoses, but approximately 40% of the patients admitted per year were diagnosed with stroke. Generally, most patients are transferred to the acute inpatient rehabilitation unit as early as third day after stroke (median interval of 0 days from stroke unit referral to transfer to inpatient rehabilitation). According to the survey of our inpatients, the average duration of occupational therapy per stroke patient per weekday was 21 minutes. To improve the upper extremity functions, the team utilised the Targeted Rehabilitation Improved Outcomes (TRIO) home

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exercise booklet, developed by Auckland University,[9] as it is readily available, with permission to be used and downloaded from the website.[7] Curating a new programme was thus not necessary.

The TRIO home exercise programme targeted patients with shoulder abduction and finger extension (SAFE)[10] scores of 5 and above and was designed to utilise commonly available items to promote both strength and finger dexterity. The SAFE score[10] was calculated by scoring shoulder abduction and finger extension separately, using the Medical Research Council Muscle Scale.[11] The patient's muscle strength in each of these movements was scored between 0 and 5, whereby 0 reflected a lack of muscle activity and 5 reflected normal strength and range of movement. The TRIO programme was modified for simplicity and higher acceptability by patients. With a smaller range of selected tasks, patients can be more focused in the exercises, resulting in increased number of repetitions and intensity of each exercise. The objective of this project was to assess the effects of an upper extremity self-exercise programme adopted from the TRIO home exercise programme within an acute inpatient rehabilitation unit on the duration of exercise during admission and post-discharge adherence.

Methods

This project was initiated as a quality improvement (QI) project in an acute inpatient rehabilitation unit of Changi General Hospital, Singapore. The institutional review board (IRB) has reviewed and determined that the project does not require further ethical deliberation. (IRB Reference number: 2020/2811).

Participants

Stroke patients admitted between July 2019 and March 2020 were screened by medical officer in charge on admission as per inclusion criteria of age > 18 years, SAFE score ≥ 5, the cognitive functional independence measure (FIM) ≥ 5[12] in each component and verbal consent was given. Exclusion criteria included laceration or abrasion or musculoskeletal issues like joint pain, tendon tear or fracture that prevented effective participation. Patients with cognitive impairment who were unable to follow the instructions were excluded.

Materials

The self-exercise toolbox which was supplied to each enrolled patient included the following (Figure 1): a ball (wooden or plastic), cloth pegs, a writing board with pen, a weight-adjustable dumbbell (a fully filled dumbbell weighs 1 kg), plastic cups and spoon, a deck of cards, and a TRIO exercise booklet downloaded from Auckland university website.[7]

Intervention

The self-exercise toolbox was placed at the patient's bedside for easy access throughout their inpatient stay. In the inpatient setting, the patient was shown how to utilize each of the 5 items in the TRIO box. The patient would demonstrate that they understand by performing the exercises to the team member instructing the patient and was encouraged to engage in the exercise of his/her own volition with a recommended minimal duration of 30 minutes a day. The time spent on self-exercise and adherence was documented by the nurse in charge.

The self-exercise programme was not initiated immediately on the day of transfer to the acute rehabilitation unit (which would be after 2 days following stroke admission) if a patient was transferred in after normal work hours. The programme was terminated one day prior to discharge.

On discharge, one of the team members whether a nurse or a medical officer administered a patient feedback survey and reinforced adherence to the exercise programme at home. The patient was provided with a TRIO booklet and advised to utilize common household items such as canned food, fork and spoon, paper and pen and paper cups as illus-

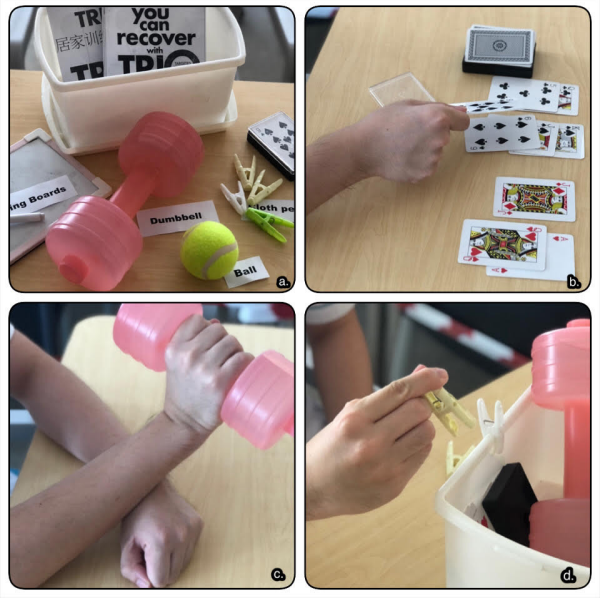

Figure 1. a. Self-Exercise Box: contains TRIO booklet, writing board with pen, water-filled dumbbell, cloth pegs, ball and cards, b. cards sorting, c. wrist extension using water-filled dumbbell, d. cloth pegs clipping onto the box

trated in the booklet for the home exercise programme. The TRIO box was not supplied to the patient on discharge. The patient was advised to perform the exercises for 30 minutes a day. These patients were followed up between four to six weeks post-discharge via a telephone call to enquire if they adhered to the self-exercise programme. In addition, relevant clinical data such as admission Fugl-Meyer score and National Institutes of Health Stroke Scale or NIH Stroke Scale (NIHSS) of the recruited patients were gathered. The SAFE and the NIHSS scores were re-assessed at discharge.

Outcome measurements

The primary outcome measures were the time spent in performing the exercises while being in the inpatient rehabilitation unit and adherence to the programme post discharge. Post discharge, the patient was deemed to be adherent if he/she performed the exercises daily for minimum of 15minutes. Secondary outcome measures were admission and discharge SAFE and NIHSS.

Statistical analysis

Descriptive statistics were used for age, gender and stroke classifications. Continuous data were summarized as mean (standard deviation) or median (interquartile range) for symmetrically distributed and skewed data respectively. Categorical data were summarized by frequency (%). Data analysis was performed using IBM SPSS version 25.0. Pre- and post-data were performed using single-tailed t-test and a p value of < 0.05 was considered statistically significant.

Results

Amongst the 215 patients with stroke screened by the QI team on admission to the inpatient rehabilitation unit between July 2019 and March 2020, 30 patients fulfilled the inclusion criteria for the programme. The baseline demographics and clinical data including the side of the stroke, admission Fugl-Meyer and NIHSS scores, and the rehabilitation length of stay are detailed in Table 1.

During admission, the median duration of the programme was 6 days and the average time spent per day was 25.88 (SD 11.80) minutes. The average SAFE score on admission was 7.9, at discharge score was 8.3, and the average improvement was 0.30 (p = 0.204) after completion of the programme. The average NIHSS score on admission was 5.2, at discharge score was 2.5, and improved by 2.63 (SD 3.94, p = 0.001) in this group of patients.

Twenty-seven (90%) patients gave the feedback regarding the self-exercise programme on the day of discharge, of whom 25 (83.33%) were positive about the programme. They perceived that it was helpful to their recovery, and 24 (80.0%) patients reported that the programme offered them confidence to perform the exercises at home correctly. (Figure 2)

Between four to six weeks post-discharge, 19 (63.33%) patients were contactable for follow-up whereas 11 (36.67%) were not. Seventeen patients (89.47% of the total contactable patients) reported that they continued the exercises according to the TRIO booklet daily. Therefore, 56.67% of all programme participants adhered to the home exercise programme. (Figure 3)

Table 1. Baseline demographics and clinical characteristics of the patients (n = 30)

Demographic information	
Age, mean (SD)	62.26 (12.3)
Gender, n (%)	
Male	23 (76.67)
Lesion characteristic	
Stroke types, n (%)	
Ischaemic	26 (86.67)
Haemorrhagic	4 (13.33)
Stroke sites, n (%)	
Right	17 (56.67)
Left	11 (36.67)
Bilateral	2 (6.67)
Baseline scores	
SAFE score, mean (SD)	7.9 (1.74)
Admission Fugl-Meyer UE motor, median (IQR)	61.5 (48, 64)
Admission Fugl-Meyer UE total, median (IQR)	122 (108.25, 124)
NIHSS, median (IQR)	5 (2, 6)
Length of inpatient rehab stay, median (IQR)	10.5 (7.7, 15)

SAFE, Shoulder Abduction Finger Extension; NIHSS, National Institutes of Health Stroke Scale; UE, upper extremity.

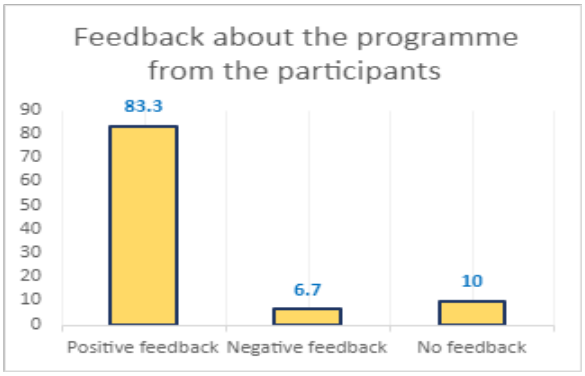

Figure 2. Feedback from the patients participated

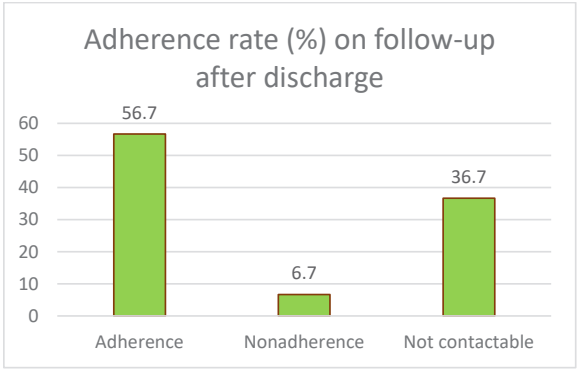

Figure 3. Adherence rate (%) on follow-up

Discussion

Rehabilitation after stroke is not an intervention provided at a single point in time. If we were able to encourage greater patient autonomy and participation at the point of discharge, there could be potential gains later in the journey.[13] Upper extremity impairments are a major contributor to post-stroke functional limitations, which have downstream effects on activities of daily living.[14] In this project of implementing the TRIO home exercise programme within an acute rehabilitation unit, the median duration of the self-exercise programme was 6 days whereas of the rehabilitation length of stay was 10.5 days, and the average time spent per day was 25.88 minutes. According to our previous observation before implementing the TRIO home exercise programme, the average duration of occupational therapy per stroke patient per weekday was 21 minutes. These demonstrate the benefit of early intervention of upper extremity self-exercise programme within an acute rehabilitation phase by promoting more therapy duration during admission.

In addition, majority of the patients gave positive feedback about the programme and the self-reported rates of post-discharge adherence to the programme were 89% in those who were contactable and 56.67% in all patients. These were higher than the adherence rates reported for other home exercise programmes (24.5%).[15] One reason might be that the patients were allowed as integral stakeholders in the rehabilitative process, with some degree of autonomy over therapy duration and time during the rehabilitation admission. They can practice even on weekends when conventional therapy is not available. This shift in their mind-set potentially increased ownership and facilitated greater adherence to the home-based exercise programme post-discharge. Lastly, through the introduction of home-based exercise programmes in an inpatient setting, both patients and their caregivers have a greater length of time being exposed to and familiarising themselves with the exercises. They had many opportunities to clarify any questions concerning the exercises. This may potentially promote greater adherence to post-discharge exercises.

Regarding neurological recovery, the improvement in the SAFE score and NIHSS were modest. The average NIHSS score was improved by 2.63 at discharge. In this study, the rehabilitation length of stay was relatively short and most of the strokes were mild as one of the inclusion criteria was SAFE score at least 5. It was therefore difficult to demonstrate a greater degree of improvement within a short period of time. However, Kerr et al. (2012) found that NIHSS was sensitive to change as early as after 7 days post stroke.[16]

As this study was initiated as a departmental-level QI pilot, the sample size was limited. Furthermore, no pre-intervention data besides baseline duration of occupational therapy (OT) were available. The length of stay was generally short and discharge functional scores such as Fugl-Meyer was not available. Self-reported compliance rates might have been subject to respondents' recall bias, which could potentially over represent adherence rates in this population. In addition, to establish the long-term benefit of early intervention of upper extremity self-exercise programme in patients with acute stroke, it is necessary to follow-up the patients over a period of time. Further collaboration with allied health professionals for assessment of neurological and functional outcomes will strengthen the study. The average time spent in OT was assessed in an earlier cohort of patients. It is assumed that the additional 25.8 minutes which spent in self-exercise would be able to make up to 45 minutes per day of OT per NICE guideline.

Conclusions

Based on the preliminary results, it is possible to initiate and incorporate the TRIO home-based exercise programme as an upper extremity self-exercise programme in an acute inpatient rehabilitation setting to promote post-discharge adherence for patients with mild stroke. This provides patients with greater autonomy in their recovery process and increases the duration of time patients spend exercising their upper extremities every day. This is an innovative way to address two issues with one intervention.

Disclosure

The authors declare no potential conflicts of interest.

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Case Report

A Combined Outpatient and Home-Based Rehabilitation Program for a Patient with an Open Atrial Septal Defect (ASD) and Severe Pulmonary Hypertension: A Case Report

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ABSTRACT

Objectives: This paper presents a rehabilitation intervention for improving functional capacity and physical activity level in a patient with an open atrial septal defect (ASD) with severe pulmonary hypertension contraindicated to ASD closure.

Study design: Case report.

Setting: Hasan Sadikin General Hospital, Bandung, West Java, Indonesia.

Subjects: A-37 year old female, an elementary school teacher, complained of shortness of breath when doing daily activities, walking, and speaking for three years. She was planned for ASD closure but could not be done because of severe pulmonary hypertension. The right heart catheterization showed pulmonary hypertension (mean Pap: 70 mmHg). In addition, the CT-Scan showed cardiomegaly with pulmonary hypertension and pulmonary fibrosis.

Methods: A combined outpatient and home-based comprehensive rehabilitation program including cardiopulmonary endurance exercise with a treadmill, breathing exercises (controlled breathing and deep breathing), and sustained maximum inspiration technique were prescribed to reduce fatigue and dyspnea on exertion.

Results: Eight weeks after following the program, there were improvements in cardiorespiratory fitness (from 2.92 to 5.27 METs), maximum inspiratory volume (from 1,500 to 2,500 ml), the Modified Medical Research Council (MMRC) scale (from 2 to 1), and the Fatigue Severity Scale (FSS) (from 71 % to 45 %).

Conclusions: In a limited inpatient rehabilitation service country like Indonesia, a combined outpatient and home-based rehabilitation program of exercises benefits the functional capacity of a patient with an open ASD with severe pulmonary hypertension and mild pulmonary fibrosis.

Keywords: atrial septal defect, dyspnea, exercise, fatigue, pulmonary hypertension

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Introduction

The second most common congenital heart disease (CHD) is atrial septal defects (ASDs).[1] It accounts for roughly 13% of CHD cases, with a female to male ratio of 2:1.[1,2] Al though most ASDs are benign, left to right shunting can occasionally overwhelm the right heart, resulting in RHF and arrhythmias.[1] In the context of severe shunting and symptoms of RHF, shunt closure is recommended.[1] Closure of ASD is not recommended if irreversible pulmonary arterial hypertension (PAH) develops due to the risk of right ventricular decompensation and death following the operation.[1,3]

Pulmonary hypertension (PH) is a chronic illness that worsens over time. Dyspnea frequently appears gradually in the early stages of PH, delaying diagnosis.[4] Physical activity was thought to negatively affect PH patients since it increased the risk of disease progression, right ventricular decompensation, and sudden cardiac death. As a result, people with PH were advised to limit their physical activity, which worsened their mobility and exercise tolerance.[4] Despite improved medical treatment, most individuals with PH, continue to experience symptoms, decreased exercise capacity, poor quality of life (QoL), and disease progression.[5] In most cases, medication will not be able to completely stop or reverse right ventricular dysfunction, nor will it be able to normalize pulmonary vascular resistance.[5] Exercise training is helpful in various illnesses, including cardiac and pulmonary diseases, and is one of the most essential, safe, and cost-effective therapy alternatives.[5]

Long-term endurance exercise, according to research, increases right ventricle size and improves early diastolic right ventricular function and left ventricular stiffness.[5] As a result, moderate physical activity has been recommended to avoid various cardiovascular problems.[5] Exercise training for patients with left heart failure was given a 1A recommen-

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dation in the most recent guidelines. It has been shown to improve QoL and exercise capacity, as well as lower the risk of heart failure-related hospitalization and morbidity events.[6] However, excessive physical activity, particularly in untrained individuals, can increase the risk of myocardial infarction.[5]

There have been no exercise guidelines for patients with PH. However, in addition to pharmacological therapy, recent guidelines advocate a supervised and thoroughly monitored exercise and respiratory training program in specialized clinics for stable PH patients (class II, level of evidence B).[5] Exercise training for patients with PH, on the other hand, is only frequently reimbursed by insurance programs or government financing in a few high-income countries[5], including phase 2 cardiac rehabilitation in Indonesia.

According to the guidelines, for patients with severe PH who are stable on medical therapy, an inpatient and outpatient program should be used.[5] The majority of rehabilitation programs and services are provided at outpatient clinics in our setting; there are no rehabilitation beds or wards for inpatient treatment. As a result, the goal of presenting this case is to show that employing current guidelines at a limited health/rehabilitation care institution can successfully rehabilitate a patient with an open ASD and severe PH, which causes limitations in daily activities and restrictions in working as a school teacher.

Case presentation

A-37 year old female, an elementary school teacher, came to the rehabilitation clinic with a chief complaint of shortness of breath while doing daily activities such as sweeping and mopping, which started three years ago after giving birth. The symptoms disappeared with resting. However, the symptoms restricted her work as a teacher. She could not teach because of shortness of breath when speaking for more than 10 minutes.

The oxygen saturation was sometimes below 90% if she developed shortness of breath. Later, she also felt easily tired when doing daily activities, walking more than 150 meters, and speaking for more than 10 minutes, and became sedentary because of shortness of breath and fatigue. An atrial septal defect (ASD) closure was planned but could not be done because of severe pulmonary hypertension. For about 10 minutes, the oxygen saturation was reduced during the talk. The maximal inspiratory volume was 1,500 ml with chest expansion at axillary, nipple, and xiphisternum levels of 2 cm, respectively. The trunk alignment was straight (normal posture). Her body weight was 43 kg, her body height was 146 cm, and body impedance analysis revealed 21% visceral fat, 13.7 kg of skeletal muscle mass, and 56.6% of total body water.

The spirometry test was requested and showed mild restrictive. The echocardiography revealed dilated right atrium and ventricle, diastolic dysfunction, and reduced right ventricular contractility with a high probability of pulmonary hypertension. The right heart catheterization showed secundum ASD with balance shunt; pulmonary hypertension (mean pulmonary arterial pressure of 70 mmHg); low flow, high resistance, and nonreactive oxygen test. The CT scan of the thorax with contrast showed: cardiomegaly with pulmonary hypertension; minimal fibrosis spread over the lateral segment of the middle lobe, the anterobasal segment of the inferior lobe of the right lung, and almost the entire segment of the left lung; minimal left pleural thickening; minimal ground-glass opacity in the superior and anterobasal segments of the left inferior lobe of the left lung, compatible with idiopathic pulmonary fibrosis (IPF).

Using the Modified Medical Research Council (MMRS) Scale, the dyspnea scale was 2 (moderate dyspnea). The cardiorespiratory fitness using the treadmill exercise stress test with the “Bruce protocol” showed low cardiorespiratory fitness (METs = 2.92) with desaturation during exercise and the Fatigue Severity Scale (FSS) was 45 (71.43%).

The patient was referred to a rehabilitation physician by a cardiologist at the outpatient clinic. Under the supervision of a rehabilitation physician, the patient got oxygen supplementation 2-3 liters/minutes via nasal cannula while performing cardiopulmonary endurance exercise, which consisted of a 20-minutes session of low-intensity conditioning treadmill exercise with warming-up and cooling-down activities for 5 minutes, 3 days per week. Exercise duration was increased by 5 minutes every 2 weeks as tolerated. The oxygen saturation was maintained at above 88%.

In addition, the patient was trained to perform a home program of sustained maximum inspiration (SMI) using an incentive spirometer for two sessions per day. Each session consisted of 3 sets of 10 repetitions, rest 2-3 minutes between

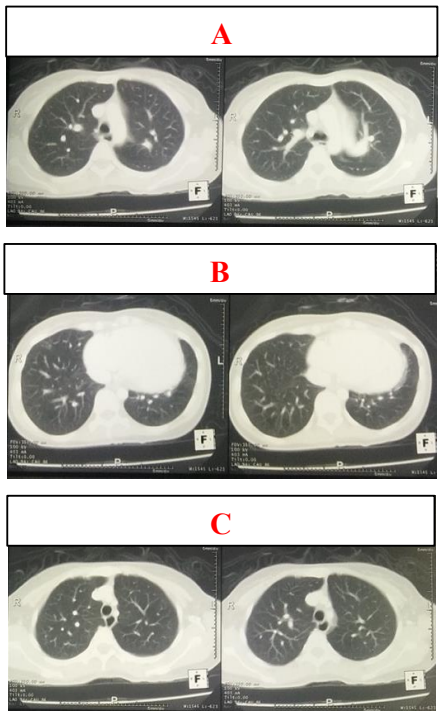

Figure 1. CT scan of thorax with the contrast of this patient showing (A) pulmonary hypertension; (B) cardiomegaly; (C) bilateral pulmonary fibrosis.

Table 1. The results before and after eight weeks of following the comprehensive rehabilitation program

	Before	After
MMRC score	2 (moderate dyspnea)	1 (mild dyspnea)
FSS score (%)	45 (71.4)	30 (47.6)
Maximum inspiratory volume (ml)	1.500	2.500
Chest expansion (cm)	2/2/2	3/3/3
Cardiorespiratory fitness (METs)	2.92	5.27
Oxygen saturation at rest (%)	92-93	95-96

MMRC, Modified Medical Research Council; METs, metabolic equivalents; FSS, fatigue severity scale
Max FSS score is 63; the higher the score, the greater the fatigue severity.[7]
Oxygen saturation during treadmill exercise was 87-91%

sets. The progression was to increase inspiratory volume every week as tolerated, and the target was 2,500 ml. Moreover, the patient was educated about controlled breathing during activity, relaxation techniques, and energy conservation.

The patient could complete the exercise program as planned. However, oxygen saturation was initially low, sometimes falling below 88% during exercise training. Therefore, the patient planned to provide the program for 8 weeks from the beginning.

Eight weeks after the comprehensive rehabilitation program, dyspnea and fatigue decreased while the maximum inspiratory volume, chest expansion, and cardiorespiratory fitness increased, as shown in Table 1. The patient could do daily activities with minimal shortness of breath and fatigue and resumed working as a part-time teacher.

Discussion

We describe a middle-aged female patient whose closure of ASD was contraindicated because of severe PH and the risk of right ventricular decompensation and death after the operation. The patient was referred to a rehabilitation physician (physiatrist) to rehabilitate a case that was not common in our setting. Before planning a comprehensive rehabilitation program for this patient, we were aware of her physical condition. Her respiratory disturbance might be caused by PH and restrictive lung disease due to IPF. This comprehensive exercise program aimed to lessen her symptoms of shortness of breath and dyspnea on exertion. The program consisted of controlled breathing techniques, which are generally used to improve pulmonary function tests, reduce dyspnea, reduce work of breathing, improve ventilator muscle function, facilitate relaxation, and are indicated in patients with obstructive and restrictive pulmonary problems.[8,9]

A home program of SMI with an incentive spirometer seemed like a cost-effective breathing exercise technique. After 8 weeks of SMI, her maximum inspiratory volume reached the target of 2,500 ml. This supports the evidence that SMI can increase chest expansion and lung volume to improve cardiorespiratory fitness for daily activities.[10,11] The target inspiratory volume of 2,500 ml was based on age.[12]

As spirometry showed mild restrictive lung disease in this case, we believe that the most likely cause of oxygen desaturation during exertion was of cardiac origin, rather than pulmonary. Therefore, besides breathing exercises, a cardiore¬spiratory exercise training program was planned at the outpatient rehabilitation clinic to improve her cardiorespiratory endurance. We started with light intensity aerobic exercise for patient safety, appropriate for patients with severe chronic disease or very deconditioned individuals.[13] The exercise duration was increased as tolerated based on recommended dyspnea ratings of between 3 and 6 on the Borg 10 scale.[14] And the exercise program was conducted at outpatient rehabilitation clinics under the supervision of a physiatrist. According to guideline recommendations, frequency is at least 3-5 days per week, and duration is 20-60 minutes per day at low-to-moderate intensities as tolerated.[5] In this case, we chose a session of 20 minutes of treadmill walking exercise as her cardiorespiratory fitness was low, and treadmill walking is generally the preferred method because walking is a functional activity.[15] We are also concerned about oxygen desaturation during exercise and prescribed oxygen supplementation, which is indicated for patients with a PaO_2 ≤ 55 mm Hg or a SaO_2 ≤ 88% while breathing room air,[16] so that SaO_2 is maintained at > 88% as recommended. After 8 weeks of this program, the patient's respiratory functions and cardiorespiratory fitness improved. The patient was advised to continue using the SMI technique at home. The patient was satisfied with the outcome of this rehabilitation program. She could perform her daily activities as usual, and go back to work as a teacher.

Conclusions

An 8-week combined outpatient and home program of cardiopulmonary and breathing exercises provided a beneficial result in improving the functional capacity and resuming work of a patient with an open ASD with severe pulmonary hypertension who is not fit for operation but is expected to reduce the risk of the worsening of pulmonary hypertension.

Disclosure

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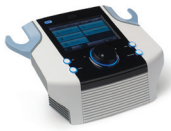

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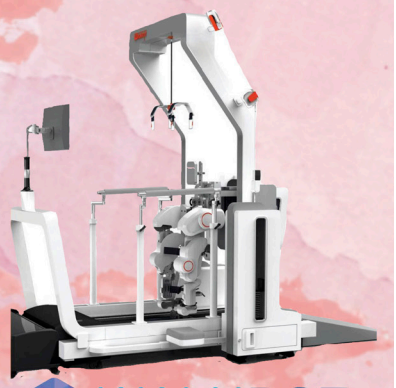

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