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Content

Application of ICF Framework for Preparedness of Rehabilitation Services during COVID-19 Outbreak

The outbreak of COVID-19 in China which started in December 2019, has globally affected everyone. The daily update on COVID-19 epidemiology shows the numbers of both new and accumulated cases have been increasing in the ASEAN countries. It has been predicted that it might last for a year or two. Therefore, rehabilitation physicians (physiatrists) and professionals in ASEAN countries have to be well-prepared so that we could continue our rehabilitation services safely, efficiently and effectively to our patients.

The ICF framework could be used to guide how rehabilitation services could still be continued during the COVID-19 outbreak. The most important strategy is to prevent our limited numbers of rehabilitation staff from contracting the virus so that their body functions (and mind) are still functional and not spread the virus to our patients. Next, is to think how to adapt the environmental factors to ensure a safe working environment.

The first factor is products and technology. Personal protective equipment (PPE)- masks, gloves and gowns should be available and used wisely, safely and effectively. Many countries do not have surplus supply of PPE to start with and during the COVID-19 outbreak, the PPE are much needed by the frontliners. Technology for communication and education such as use of mobile phone and internet for intra-team and cross-functional team communication should be implemented to lessen face-to-face communication, thus minimizing risk of spreading infection. And equipment used during rehabilitation services should be regularly cleaned according to the recommended guidelines.

The second factor is natural and human-made changes to environment and this concerns indoor air quality. Some treatment areas are in air-conditioned area. If outdoor air quality is not polluted, having treatment in an open-air space is better.

The third factor is support and relationships. As health professionals we have to provide rehabilitation services to patients with impairments and disabilities and at the same time we as well as our immediate family and friends are at risk of contracting or spreading the virus. This may affect support and relationships.

The fourth factor is attitude. Fear of contracting the virus should not prevent us from providing the services. Cognitive behavioral therapy (CBT: minimization of risk, beware of magnification of bias, better safe than sorry, distraction from fake news and social media, fear but not hate, time protection, etc.) might be helpful. We should believe that working with universal precaution and mindfulness could save us. Calm our patients and their family; provide appropriate facts and advise to nurture positive attitude towards isolation, good hand hygiene and social distancing.

The last factor is service, system and policy. National, hospital and department policy should be aligned. Policies should be implemented to minimize new cases, provide adequate medical equipment for prevention and treatment, and continue health services for those in need. There must be clear criteria on how to screen and select of cases that needs rehabilitation treatment and intervention. There is a need to ensure persons who need rehabilitation are not deprived but at the same time making sure that they are not exposed to unnecessary risk of contracting COVID-19. In time of crisis there is always a need to prioritize utilization of resources.

In this first issue of ASEAN J Rehabil Med 2020, there is a special article of recommendations for medical rehabilitation services and management during COVID-19 outbreak. I hope this article will be beneficial to all colleagues in ASEAN countries.

Apichana Kovindha, MD, FRCPhysiatrT
Editor

Recommendations for Preparedness of Medical Rehabilitation Services in Thailand during COVID-19 Outbreak

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The current pandemic of Coronavirus Disease 2019 (COVID-19), which occurs worldwide including in Thailand and other ASEAN countries, greatly affects medical rehabilitation services of physiatrists and the other rehabilitation team members. To establish resilience in this critical situation, our group of Thai physiatrists came together to rapidly prepare recommendations for medical rehabilitation services uring COVID-19 outbreak based on evidence-based documents from the previously affected countries such as China,[1-3] Singapore,[4] Italy[5] and the consensus of the opinions of experts from Thailand, which are described as followed.

1. The objectives of recommendations are

1.1 To ensure that each patient receivesthe proper rehabilitation management according to his/her medical conditions.

1.2 To protect rehabilitation professionals from the infection of SARS-CoV2 (Severe Acute Respiratory Syndrome Coronavirus 2).

1.3 To effectively use human and equipment resources in this limited situation.

2. Medical ethics

Medical ethics including beneficence (benefits of the patient from those rehabilitation programs), non-maleficence (avoiding the risk of SARS-CoV2 infection in both patients and providers) and justice (effects of providing those rehabilitation programs on society such as wide-spreading the infection from patient's transportation or overusing personal protective equipment (PPE) in non-urgent rehabilitation program) are taken into consideration in making decisions in medical rehabilitation management.

3. General recommendations for medical rehabilitation for non-COVID-19 patients

It always needs to be considered that face-to-face rehabilitation programs bring a significant risk of SARS-CoV2 infection for both providers and receivers. Also, patients who come to attend medical rehabilitation programs are probably categorized in a high-risk group for developing severe COVID-19 since they usually have multiple comorbidities such as stroke, spinal cord injury, hypertension or diabetes. Therefore, a face-to-face rehabilitation program should be carefully prescribed according to

- The benefit of the program, and
- The risk of infection of the program (Figure 1).

Besides, all programs should be provided in compliance with universal precautions and social distancing policies.

3.1 Both benefits and risk of infection of face-to-face rehabilitation programs should be comparatively considered. If the risk outweighs the benefits, a home-based rehabilitation program using media or written instructions with proper follow-up evaluation should be preferred. In addition, alternative methods of service provision including tele-rehabilitation services may be considered especially for those who need home isolation.

3.2 If the benefit of a face-to-face rehabilitation program outweighs the risk, before performing that rehabilitation program, history and clinical features of COVID-19 should be evaluated. If the patient has symptoms, signs or are at risk of COVID-19, referral to an acute respiratory infection clinic (ARI clinic) should be done according to the National or institutional guidelines.

3.3 After that, the rehabilitating procedures should be planned. They should be categorized according to their risk of COVID-19 transmission. Physical distance of 1-2 meters should be maintained from the patients when performing the

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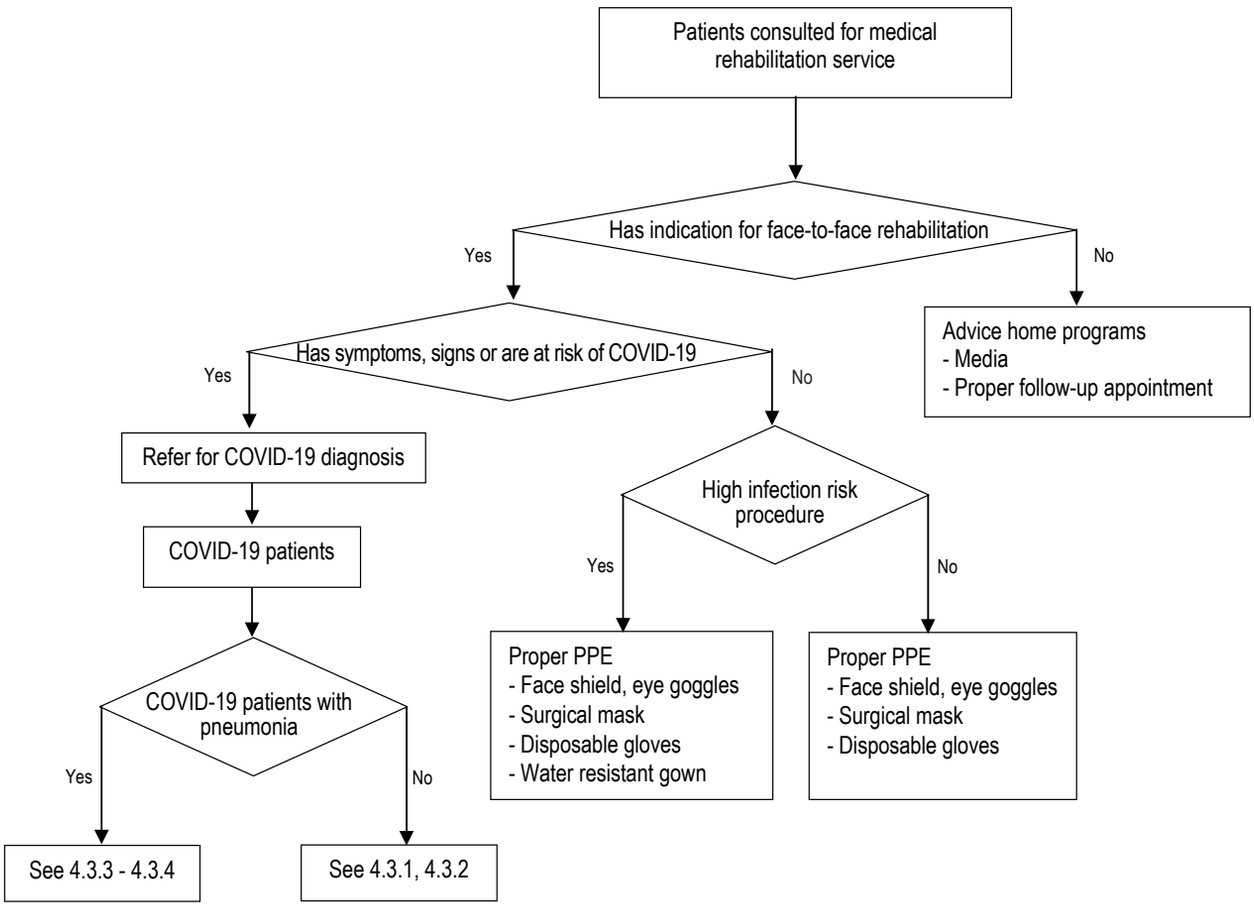

Figure 1. General recommendations flowchart for medical rehabilitation of non-COVID-19 patients

following high infection risk procedures:

- Procedures that require more than 5 minutes of close contact within 1 meter distance to the patient, including speech training and electrodiagnosis.

- Procedures which directly induce cough or sneezing, including swallowing evaluation and training, and chest physical therapy.[4]

3.4 In some possible activities, patients should be instructed to perform the procedures themselves such as swallowing, breathing, articulation exercises. Also, universal precautions and PPE should be properly applied.

3.5 When performing high-risk procedures, a surgical mask, disposable gloves, a face shield or medical eye goggles, and water-resistant gown should be worn. Whenever possible, healthcare providers should be at the back or side of the patient. Patients should always wear surgical masks and therapists should always stay upwind.[2,3]

3.6 An electrodiagnostic study, chemoneurolysis or musculoskeletal ultrasonography should not be performed unless its benefit outweighs the risk, since these procedures require close proximity and continuous contact with the patients. The provider should use PPE, at least a surgical mask, disposable gloves, and a face shield or medical eye goggles, whereas the patient should wear a surgical mask during the examination.[6]

3.7 When performing low-risk procedures such as ambulation or balance training when approaching the patient from the side or behind, a surgical mask, disposable gloves, and a face shield or medical eye goggles should be worn.[7]

3.8 Disinfect therapists' hands and contacted parts, as well as touched surface of the equipment for at least 20 seconds with proper washing techniques before and after each therapy session with a patient.

4. Medical rehabilitation recommendations for COVID-19 patients[4,5]

4.1 The objectives of medical rehabilitation are

- To relieve symptoms (decrease dyspnea/difficulty breathing, improve respiration efficiency and secretion clearance).
- To prevent deconditioning.
- To decrease stress, anxiety and increase the quality of life.

4.2 Regarding the severity of COVID-19, patients are clinically classified into[6]

1) Asymptomatic infection
2) Mild symptoms without major risk factors
3) Mild symptoms with major risk factors
4) Patients with pneumonia

- Mild pneumonia
- Severe pneumonia (including those who have extrapulmonary organ dysfunction, a high-flow nasal cannula (HFNC), non-invasive ventilation (NIV) or invasive ventilation (IV))

4.3 Medical rehabilitation programs for COVID-19 patients

1) Asymptomatic patients and patients with mild symptoms without major risk factor, who have good mobility but need isolation.[1,2]

- Type of services
  - o Non-face-to-face service by presenting with
    - Short video clips
    - Written instructions
    - Tele-rehabilitation
- Contents
  - o Information about the disease and its management to decrease stress and anxiety
  - o Self-administrated pulmonary rehabilitation program (see No. 5)
  - o Light to moderate aerobic exercise (Borg dyspnea score ≤ 3 out of 10) such as walking 15 minutes, 2 times/day, if
    - No dyspnea or absence of dyspnea for more than 3 days
    - Not in the first 7 days of diagnosis
    - Body temperature less than 38ºC
    - Blood oxygen saturation (SpO_2) more than 95%
    - Blood pressure between 90/60 and 140/90 mmHg
  - o Swallowing evaluation and training, speech training or electrodiagnosis should be postponed unless the patients have an exceptional indication, depending on the consideration of attending physiatrists and rehabilitation teams.

2) Medical rehabilitation services for COVID-19 patients with mild symptoms with major risk factors (such as age more than 60 years, have COPD or other lung diseases, chronic kidney disease, coronary artery disease, congenital heart disease, stroke, hypertension, diabetes, obesity (BMI ≥ 35 kg/m^2), liver cirrhosis, immunocompromised host)[6] are similar to those withmild symptoms without major risk factor but the underlying disease should be considered according to the recommendations of the American College of Sports Medicine (ACSM).[7]

3) Medical rehabilitation services for COVID-19 patients with mild pneumonia who are admitted in a cohort ward or ICU.[1-3]

- Type of services
  - o Non-face-to-face service by presenting with
    - Short video clips
    - Written instructions
    - Tele-rehabilitation
  - o Bedside physical therapy should be provided especially in case of patients who cannot exercise by themselves such as those with an underlying disease of chronic lung diseases or neuromuscular disorders[8] with an allowance of the consulting physiatrists and attending physicians. Chest physical therapy should be conducted by experienced physical therapists[8] with the appliance of proper PPE (N95 mask, disposable gloves, face shield or eye goggles, water-resistant gown and boots or closed work shoes are). The therapists always stay upwind.
- Contents
  - o Information about the disease and its management to decrease stress and anxiety
  - o Self-administrated pulmonary rehabilitation program (see No.5)
  - o Light to moderate aerobic exercise (Borg dyspnea score ≤ 3 out of 10) with Zheng's recumbent exercise[3] including 1) stepping (in the air) exercise, 2) bridging pose exercise and 3) stretcher sit-ups. These exercises should be prescribed for not exceeding 15 repetitions/exercise, 2 times/day if:
    - No dyspnea or absence of dyspnea for more than 3 days
    - Not in the first 7 days of diagnosis
    - Body temperature less than 38°C
    - Continuous improvement in 2 consecutive chest x-rays or CT
    - Blood oxygen saturation (SpO_2) more than 95%
    - Blood pressure between 90/60 and 160/100 mmHg
  - o Exercise should be stopped when the patient has:
    - More than a moderate degree of dyspnea (Borg dyspnea score > 3 out of 10).
    - Abnormal symptoms during exercise such as chest pain, dizziness, headache, blurred vision, palpitation, sweating, pallor, cyanosis or other abnormalities detected by the assessor.
  - o Swallowing evaluation and training, speech training or electrodiagnosis should be postponed unless the patients have an exceptional indication, depending on the consideration of attending physiatrists and rehabilitation teams.

4) Medical rehabilitation services for COVID-19 patients with severe pneumonia who are admitted to an intensive care unit (ICU)[1-3]

- Type of services: same as 4.3.3
- Contents
  - o Information about the disease and its management to decrease stress and anxiety
  - o Pulmonary rehabilitation (see No.5) if:
    - Respiratory system
      - □ Oxygen concentration (FiO_2) less than or equal to 0.6

□ Blood oxygen saturation (SpO_2) more than 95%

□ Respiratory rate less than or equal to 40/minute[2]

□ Use positive end-expiratory pressure (PEEP) less than or equal to 10 mmH_2O

□ Breathing with ventilator simultaneously

- Cardiovascular system

□ Systolic blood pressure (SBP) between 90-180 mmHg

□ Mean arterial pressure (MAP) between 65-110 mmHg

□ Pulse rate between 60-120/minute

□ No new arrhythmia or myocardial ischemia

□ No shock or blood lactic acid less than 4 millimole/liter

□ No venous thromboembolism or pulmonary embolism

□ No aortic stenosis

- Neurological system

□ Nearly normal consciousness (the Richmond Agitation Sedation Scale: RASS -2 to 2)

□ Intracranial pressure < 20 cmH_2O

- Other systems

□ No fracture

□ No severe or uncontrolled renal or liver dysfunction

□ No active bleeding

□ Body temperature less than 38.5 °C

o Aerobic exercise, swallowing evaluation and training, speech training and electrodiagnosis should be postponed until recovery from a critical period.

o Pulmonary rehabilitation should be stopped when

- Respiratory system

□ Blood oxygen saturation (SpO_2) less than 90% or decreased from baseline more than 4%

□ Respiratory rate more than 40/minute

- Cardiovascular system

□ Systolic blood pressure (SBP) < 90 or > 180 mmHg

□ Mean arterial pressure (MAP) < 65 or > 110 mmHg

□ Pulse rate < 60 or > 120/minute

□ New arrhythmia or myocardial ischemia

- Neurological system

□ Abnormal consciousness (Richmond Agitation Sedation Scale: RASS <- 2 or > 2)

- Other systems

□ Have abnormal symptoms during therapy such as chest pain, dizziness, headache, blurred vision, palpitation, sweating, pale, cyanosis other abnormalities detected by the assessor.

5. Pulmonary rehabilitation for COVID-19 patients[1,2,9]

The objectives of pulmonary rehabilitation are to decrease dyspnea, improve respiration efficiency, and prevent complications from prolonged bed rest including secretion obstruction, atelectasis, muscle weakness and deconditioning.

In patients with dyspnea or secretion obstruction but normal consciousness and no invasive mechanical ventilator needed, vital signs should be evaluated. If patients have hemodynamic instability including SBP < 90 or > 180 mmHg, MAP < 65 or > 110 mmHg, pulse rate < 60 or > 120/minute, respiratory rate more than 40/minute, only positioning to improve respiration and secretion drainage should be performed. In patients with stable vital signs, deep-slow breathing and active cycle of breathing technique should be added. In patients with an invasive mechanical ventilator, positioning and closed suction are recommended. (Figure 2)

The summary of pulmonary rehabilitation services in COVID-19 patients are as in Table 1.

The details of pulmonary rehabilitation are as followed.

5.1 Positioning

Position the patients at 30-60° upright for improved respiration and secretion drainage by adjustable bed.[1] However, it depends on patients' status and attending physicians' recommendations. For example, the application of prone positioning will be considered for severe acute respiratory distress syndrome (ARDS) since it could alter the mechanics and physiology of gas exchange to result consistently in improved oxygenation.[9-11] However, the prone position needs to be close monitored as it might induce side-effects, such as pressure sores and endotracheal dislocation.[9,10,12]

5.2 Deep-slow breathing

Deep-slow breathing improves chest expansion. The patients should raise their arms during slow inhalation and let it down during exhalation. The slow movement of upper extremities and slow breathing is done simultaneously 12-15 times/minute, 10 repetitions/session with 30-60 seconds rest interval. This could be done as frequently as the patient preferred.

5.3 Active cycle of breathing technique[1,2,13]

This technique aims to drain secretion and improve respiration efficiency. It includes 3 steps, which are:

1) Breathing control: The patient sits, inhales and exhales as usual.

2) Thoracic expansion breathing: The patient places their hands on the chest wall to sense chest wall movement during inhalation and exhalation. Relax all muscles during breathing.

3) Huffing: Position the patients in sitting or secretion drainage position, then tell the patients to do forced inhalation, hold for 1-3 seconds, open mouth and pharynx and forcefully exhale 1-3 times without inhalation. Abdominal muscles will

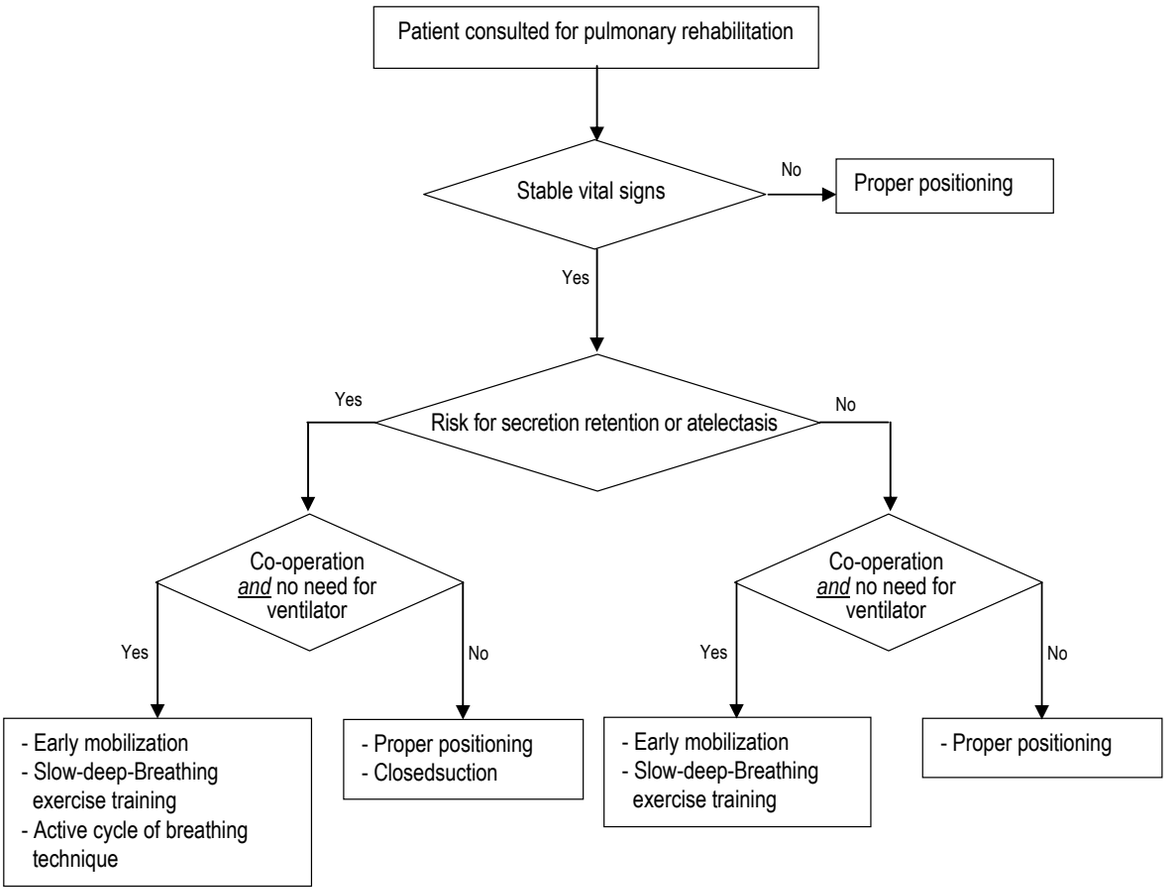

Figure 2. Flowchart for pulmonary rehabilitation in patients with COVID-19

Table 1. Pulmonary rehabilitation services for COVID-19 patients[8]

Patient classifications	Rehabilitation goals	Type of pulmonary rehabilitation
Asymptomatic or mild symptoms (with or without major risk factors)	Improved respiration	Self exercise programs by - Short video clips - Written instructions
Mild pneumonia without secretion obstruction	Improved respiration	
Mild pneumonia with secretion obstruction or with underlying diseases such as neuromuscular or respiratory disorders	Improved respiration Adequate secretion drainage	Self exercise programs by - Short video clip - Written instruction If unable to clear secretion, consider bedside chest physical therapy.
Severe pneumonia	Improved respiration Adequate secretion drainage	If unable to clear secretion, consider bedside chest physical therapy.

be contracted to clear secretions.

To start the active cycle of breathing technique, normal breathing should be advised for 5-10 times. Then, thoracic expansion breathing for 3-4 times and normal breathing before forced exhalation or do huffing 1-2 times. Huffing helps secretions move upward for easier coughing. If secretions remain, repeat this cycle.

5.4 Early mobilization

Early mobilizations improve respiration, secretion drainage and prevent deconditioning. If the patients have stable vital signs, progressive bed mobility and ambulation should be performed. However, the longer patients remain in the intensive care unit, the more likely they are to suffer long-term physical, cognitive and emotional effects of being sedated. To cope with the post-acute care of COVID-19 patients, rehabilitation might take as long as months, and very often, to help patients back to normal life.

6. Administrative recommendations for rehabilitation team management[4,5]

6.1 Rehabilitation teams should work strictly to their institute's guidelines about COVID-19.

6.2 Online meetings or conferences (teleconference) should be encouraged. If a face-to-face meeting could not be

avoided, sitting distance should be more than 1-2 meters.

6.3 If possible, working online or from home should be encouraged. Appropriate work assignments and assessments should be considered.

6.4 To take care of COVID-19 patients, rehabilitation teams should be split into at least 2 teams with restricted movement across teams. Alternate teams for taking care of COVID-19 patients to reduce the risk of widespread infection and prevent a situation of an inadequate workforce.

6.5 Rehabilitation teams who have risk factors for severe COVID-19 such as age more than 60 years, have COPD or other lung diseases, chronic kidney disease, coronary artery disease, congenital heart disease, stroke, hypertension, diabetes, obesity (BMI ≥ 35 kg/m^2), liver cirrhosis, immunocompromised host[6] should not be assigned to take care of COVID-19 patients.

6.6 Regular two-way communications within rehabilitation teams should be done in compliance with reliability, transparency and a trustworthy attitude.

There are some limitations. Given the recent pandemic of COVID-19, clinical recommendations may be altered if more studies about the natural course of this disease are present. These recommendations are inferred based on best evidences for current management of these patients. In addition, these recommendations should be adapted in each hospital/center according to the differences inpatients, contexts, laws and future researches.

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Original Article

The Effectiveness of Indoor Socks with Medial Arch Support in Decreasing Pain in Patients with Posterior Tibial Tendon Dysfunction: a Prospective, Double-blinded, Randomized Controlled Trial

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ABSTRACT

Objectives: To study the effectiveness of application of indoor socks with medial arch support in decreasing pain in patients with posterior tibial tendon dysfunction (PTTD).

Study design: Prospective, double-blinded, randomized controlled trial

Setting: Foot Clinic, Department of Rehabilitation Medicine, Siriraj Hospital

Subjects: Patients with PTTD and foot pain at the out-patient clinic, during August 2017 – August 2018

Methods: Forty–two patients were randomized into two groups, the study group (using socks with medial arch support, Rehband®) and the control group (using socks with flat foam). All were advised to wear them while walking and standing indoors for 2 weeks. Complication and duration of using the socks were recorded in a logbook. Foot pain was assessed with numeric rating scale (NRS) before and after 2 weeks of using them. Pre-post differences in pain and success rates of pain reduction (at least two points) were compared between the two groups.

Results: After using the socks for 2 weeks, there were statistically significant decreases in foot pain in both groups (the study group, $p < 0.001$ and the control group, $p = 0.004$). However, the pre-post intervention differences in foot pain between two groups was not statistically significant ($p = 0.07$). The success rates of pain reduction were statistically significant difference between the two groups (the study group 80.9% and the control group 42.9%, $p = 0.025$). No serious complication was reported.

Conclusion: In patients with posterior tibial tendon dysfunction, using indoor socks with medial arch support showed no statistically significant difference in decreasing foot pain when comparing with the control group using socks with flat foam. However, the former had higher success rate in pain reduction than the latter.

Keywords: posterior tibial tendon dysfunction, flat foot, medial arch support, foot pain

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Introduction

Posterior tibial tendon dysfunction (PTTD) is a common cause of adult-acquired flatfoot. This condition typically occurs in women aged 45 to 65 years old.[1-2] It is caused by increasing age, chronic overuse due to long periods of standing or walking, and obesity. Another cause that leads the tendon to be prone to degeneration is the anatomy of this tendon. The area 4 cm proximal to its insertion is the hypovascular region and the direction that the tendon passes through the medial malleolus is sharply flexed. Degeneration of this tendon results in the collapse of the medial longitudinal arch. When the medial structures of the foot are subjected to abnormal alignment, it leads to the development of inflammation and deformity in the structures such as foot flattening, forefoot abduction and hindfoot valgus.[3] Clinical presentation includes frequent pain at the medial aspect of the foot or ankle. In chronic cases, there is foot deformity. Further, pain may shift to the lateral side of the foot.[2]

PTTD can be divided into four stages.[2] In stage I, there may be pain and swelling along the posterior tibial tendon. No deformity is presented. Patients are able to perform the double heel-rise test and also the single heel-rise test. In stage II, there are more degenerative changes in the tendon. The foot deformity includes forefoot abduction and hindfoot valgus. However, all deformities remain flexible. The medial arch begins to collapse. They are unable to perform the single heel-rise test but may be able to perform the double heel-rise test. There is usually pain along the posterior tibial tendon and/or pain at the lateral side of the foot or lateral malleolus. The forefoot becomes splayed out, leading to more than 2 toes being seen from the back view. This is called the “too many toes” sign. In stage III, the deformities become rigid. The valgus of the hindfoot cannot be corrected while performing a double heel-rise. In stage IV, the ankle joint is involved. The deltoid ligament tear results in ankle eversion and degeneration of the tibiotalar joint.[3]

At present, the treatment of PTTD is based on each patient’s symptoms and the stage of the disease. There are

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non-pharmacological, pharmacological and operative treatments.[4] The primary goals of treatment include pain relief and foot deformity prevention. There are many kinds of non-pharmacological treatments, such as weight control, lifestyle modification, orthotic management, shoe modification, exercise, and physical therapy. Medial arch support is an orthosis generally used in the shoes to reduce foot pain and inflammation from PTTD. It showed reduction of hindfoot valgus deformity.[5] With shoe modification, it is recommended for patients with PTTD to rest the tendon leading to pain relief[6] and improve walking performance.[7]

There are many patients with PTTD who visit the foot clinic at the Department of Rehabilitation Medicine, Siriraj Hospital. After being diagnosed with PTTD, they receive treatments such as shoe modification and medial arch support. These can be effective for relieving pain after being used all the time while walking and standing. However, many patients in Thailand refuse to wear shoes in the house due to cultural traditions. They only wear shoes that are modified for outdoors. Although the pain is reduced while walking outdoors, they still feel pain while walking indoor barefoot. Even though they are suggested to wear shoes in the house, many patients do not comply with the advice. For this reason, the treatments do not relieve the pain effectively. Some of them ask to wear socks instead, but this may not be effective due to lack of support at the medial arch.

In this study, we created innovation: indoor socks with medial arch support. We chose to use an over-the-counter medial arch support, Rehband® which has been often prescribed at a foot clinic but inserted in the shoe. It is made from a material called Technogel®, which has high elasticity, provides good support, does not irritate the skin and is self-adhesive. There are 3 different sizes to fit foot size measured while sitting with non-weight bearing. We attached the medial arch supports to the non-slip socks with Velcro®, so these socks could be taken off for washing. We determined a proper position on the socks before attaching the Velcro®. We expected that this innovation could replace wearing modified shoes indoor. (Figures 1-2)

Since there had been no prior study that reported the effectiveness of indoor socks with medial arch support in decreasing pain, we carried out this study under the hypotheses that these socks with medial arch support could decrease foot pain while standing and walking indoors. The primary objective was to study the effectiveness of indoor socks with medial arch support in decreasing pain in patients with PTTD. The secondary objectives were to study the effectiveness in decreasing limitation of activities of daily living (ADLs), household activities, indoor walking, and foot instability, as well as complications, and patients' satisfaction and adherence to using these socks.

Methods

This study was approved by the Siriraj Institutional Review Board (SIRB), reference number 356/2560 (EC1) certification number Si 494/2017. This study was supported by the Siriraj Research Development Fund.

Participants

Patients who were diagnosed with posterior tibial tendon dysfunction by physiatrists at the foot clinic, Department of Rehabilitation Medicine, Siriraj Hospital from August 2017 – August 2018 were invited to participate in the study, and 42 patients gave informed consent were recruited in total.

Inclusion criteria

- Age not less than 40 years old
- Stage I or II PTTD with intermittent foot pain at least 6 weeks
- Barefoot pain at the medial aspect or along the posterior tibial tendon, with a numeric rating scale (NRS) of pain at least 5. If there was foot pain on more than one side, the most severe side was chosen, as considered with NRS and further physical examination.
- Wearing modified shoes outdoors regularly

Exclusion criteria

- Not being able to answer the questionnaire due to cognitive impairment or communication limitation
- Stage III or IV PTTD
- Taking NSAIDs or not taking NSAIDs less than 2 weeks prior to the screening
- Previous foot surgery
- Having an indoor shoe modification
- Foot numbness or foot ulcer
- Balance problem
- Having a traveling plan that might affect regular walking time during the study period

Sample size calculation

After reviewing previous studies, there was a study that might be relevant. Thammawijaya et al. reported that after using a custom-molded medial arch support in patients with plantar fasciitis, foot pain was significantly decreased from

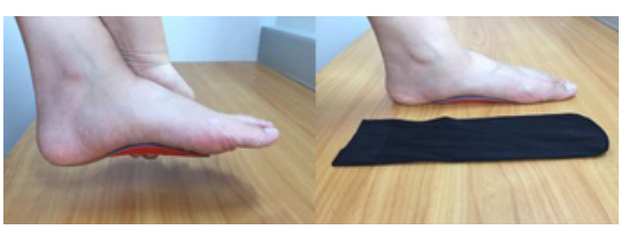

Figure 1. Measurement of proper size and position of the medial arch support

Figure 2. Attachment of the medial arch support to non-slip socks with Velcro®; left, top view; right, lateral view

4.87 (SD = 1.66) to 2.70 (SD = 1.93).[8] In this study, we expected that indoor socks with medial arch support could reduce the pain score by at least 2 points. Based on a power of 0.90 to detect a significant difference (5% type I error and 10% type II error, p = 0.05, two-sided), 21 patients were required for both the study group and the control group. The recruited sample size was 48 subjects in total (24 subjects per group with an estimated 10% drop-out).

Materials

- Three different sizes of Rehband®, an over-the-counter medial arch support (Figure 3)
- Flat foam with 2 mm thickness (Figure 3)
- Free adult size of non-slip socks
- Velcro®
- Glue

Study protocol

Patients who met the criteria were recruited for this study. An information sheet with verbal explanation was provided to the patients, and a signed informed consent form was obtained. Subsequently, they went to see the first investigator which was blinded in the study, to get a complete foot examination; and completed a questionnaire consisting of demographic data, foot problem, baseline foot pain while walking barefoot indoor in the past week, limitations in ADLs, household activities and indoor walking, and foot stability. Pain and limitations were assessed with NRS ranged from 0, no pain/limitation to 10, worst pain/complete limitation. Foot instability was also assessed with NRS ranged from 0, completely unstable to 10, completely stable.

The patients were then randomly allocated to either a study or a control group by a research coordinator who used a computer program to set sequential numbers and put each number in a sealed envelope. This made all patients had an equal probability of assignment to each of the groups. There were 21 patients in each group. Each patient got one envelope and went to see the second investigator who opened it and chose socks and medial arch support/flat form according to allocation numbers.

All received the same measurement, two pairs of socks and an instruction on how to use the socks by the second investigator. In the study group, the patients got indoor socks with medial arch support (Rehband®). In the control group, the patients got indoor socks with a sham made of flat foam with 2 mm thickness (Figure 3). It was permanently attached to the socks with glue and had the same size as the medial arch support in the study group.

In the first week, the patients in both groups had to increase duration of wearing the socks 5 minutes per day, for foot accommodation.

In the second and the third weeks, they were informed to wear socks as long as possible while walking and standing indoors as well as to continue using outdoor modified shoes; and to record patient's adherence to wearing the socks, complications and other treatments (if had) in a logbook for two weeks, from the second week to the third week.

At the end of the study, they came back to see the first investigator, who did not know which group they were in, to complete the questionnaire. In addition, patient's satisfaction in using the socks was assessed with NRS, from 0 (dissatisfaction) to 10 (most satisfaction). Any complication from using the socks was also recorded in the logbook.

Each patient returned the logbook to the first assessor on the follow-up day when the study ended.

Success rate of pain reduction was defined as decreasing in pain score at least 2 points.

Statistical analysis

For demographic data, an unpaired t-test and Mann–Whitney test was used to analyze the differences of quantitative data with normal distribution and non-normal distribution, respectively. Additionally, Fisher's exact test and chi-squared test were performed to analyze the differences in categorical data. Multiple logistic regression was used to analyze the association between duration of disease and the success rate.

To explore the primary outcome of foot pain and secondary outcomes, the Mann-Whitney U was used to analyze the comparison between the two groups at baseline (pre-) and post-intervention. Pre-post intervention differences in foot pain, activity limitations and foot instability between the two groups were also analyzed by the Mann-Whitney U test. Wilcoxon signed-rank test was used to analyze the pre-post intervention differences within the group.

Chi-squared test was performed to compare the success rates between the two groups.

Unpaired t-test was used to compare the duration of using indoor socks with medial arch support, duration of walking indoors, and percent of usage from the duration of standing and walking between two groups.

To explore satisfaction, the Mann-Whitney U test was used to compare between the two groups.

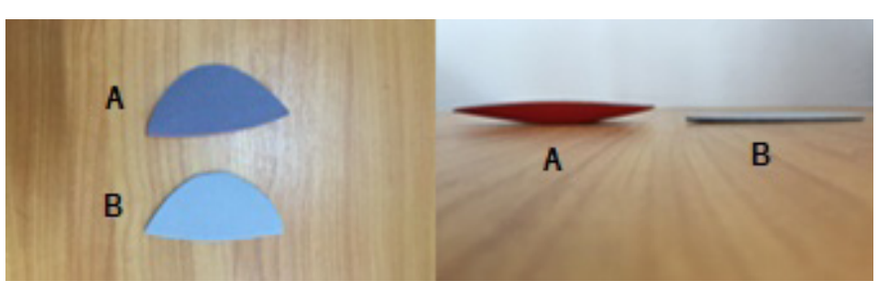

Figure 3. A: Rehband®, a commercial medial arch support; B: Sham, flat foam; left, top view; right, lateral view

All statistical analyses were performed using PASW Statistics (SPSS) 18.0 (SPSS Inc, Chicago, IL, USA). A *p*-value of less than 0.05 was considered a statistically significant difference.

Results

A total of 42 patients with PTTD participated in this study and all completed the protocol (Figure 4). Most of them were females aged from 42 to 80 years old, with a mean age of 60.55 years old. The analysis of the baseline measurements of the two groups revealed similarities in gender, body mass index (BMI), hours needed to stand and walk indoors and outdoors, duration of disease, side and stage of the of PTTD, and site of pain, as shown in Table 1.

Primary outcome

There was no statistically significant difference in pain between the two groups at baseline (p = 0.411) or after the end of the protocol (p = 0.486).There were statistically significant decreases in foot pain in both the study group (p < 0.001) and the control group (p = 0.004) compared with the baselines. However, when comparing the pre-post intervention differences of foot pain between the two groups, there was no statistically significant difference (p = 0.07), as shown in Table 2.

The success rates of the study group and the control group were 80.9% and 42.9%, respectively, and the difference between the two groups was statistically significant (p = 0.025). The multiple logistic regression showed that the duration of disease was not statistically significant associated with the success rate (p = 0.948).

Secondary outcomes

Table 3 shows no statistically significant differences between the two groups in limitations of ADL, household activity, indoor walking, and ankle instability at baseline (p = 0.779, 0.879, 0.572 and 0.278, respectively) and after using the socks (p = 0.939, 0.647, 0.430 and 0.878, respectively). When comparing the pre-post intervention differences in limitations of the above-mentioned activities between the two groups, there were no statistically significant differences (p = 0.652, 0.472, 0.191 and 0.076 respectively. In both groups, however, there were statistically significant decreases in limitations of ADLs, household activity, and indoor walking when comparing between the pre- and the post-intervention within the group.

Regarding foot instability, there was no significant change in the study group but there was a statistically significant decrease in foot instability in the control group when comparing between the pre- and the post- intervention (the study group: 7, 8; p = 0.321; the control group: 5, 8; p = 0.004), as shown in Table 3.

Table 4 shows patients' adherence to compliance with using the socks. There was no statistically significant difference in the duration of standing and walking indoor, duration of using indoor socks with medial arch support, and percent of usage from the duration of standing and walking between two groups (p = 0.179, 0.404 and 0.483, respectively).

Table 5 shows patients' satisfaction with the socks reported as median (min, max). The satisfaction scores were high in every aspect in both groups.

Complications from using the socks were seen in both groups. No patient had serious complications. Four patients

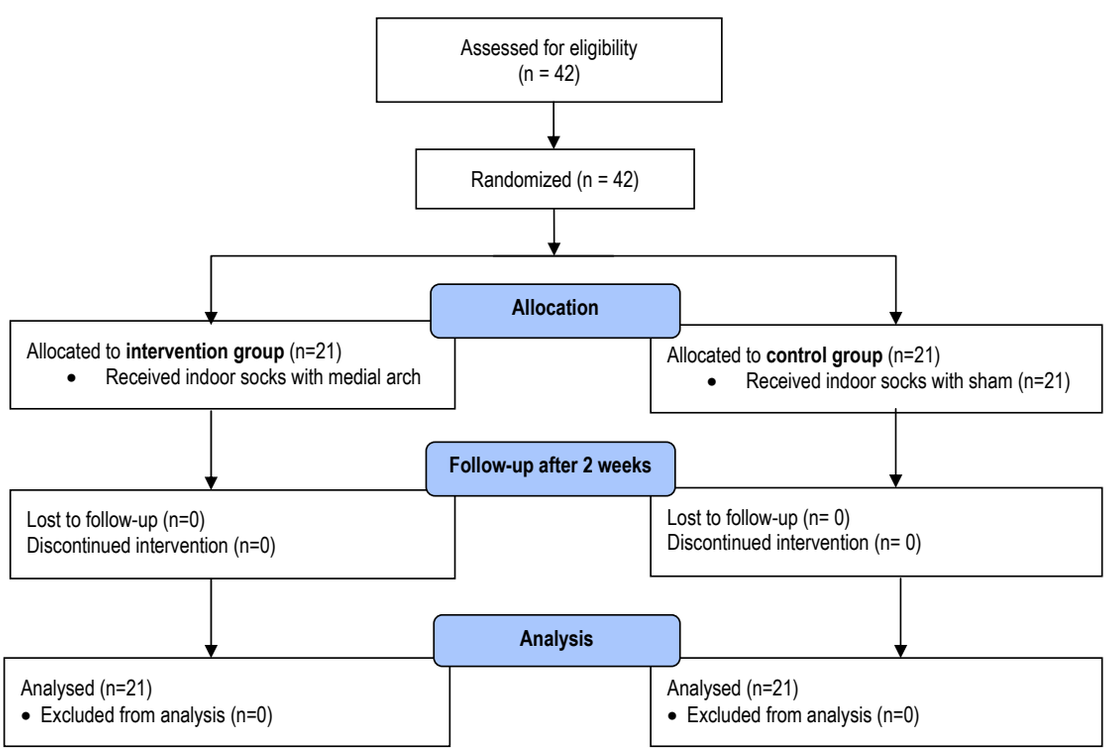

Figure 4. Flow diagram of the study

Table 1. Demographic data of participants

Characteristics	Study group (n=21)	Control group (n=21)	*p*-value
Gender[1]			
- Male	3 (14.3)	1 (4.8)	0.606[a]
- Female	18 (85.7)	20 (95.2)	0.381[b]
BMI [kg/m^2][2]	27.1 (5.4)	28.5 (4.9)	0.464[b]
Duration of stand or walk outdoors [hours per day][2]	4.0 (2.5)	3.5 (1.8)	0.551[b]
Duration of to stand or walk indoors [hours per day][2]	2.6 (1.8)	2.9 (1.3)	0.328[c]
Duration of posterior tibial tendon dysfunction [month][3]	120 (5, 240)	48 (6, 420)	
Side[1]			
- Right	2 (9.5)	4 (19.0)	0.222[d]
- Left	8 (38.1)	3 (14.3)	
- Bilateral	11 (52.4)	14 (66.7)	
Stage[1]			
- I	1 (4.8)	0 (0.0)	1[a]
- II	20 (95.2)	21 (100.0)	
Site of pain[1]			1[a]
- Navicular bone	5 (23.8)	4 (19.0)	1[d]
- Medial side of foot	10 (47.6)	10 (47.6)	1[d]
- Posterior to medial malleolus	9 (42.9)	10 (47.6)	0.606[a]
- Lateral side of foot	3 (14.3)	1 (4.8)	1[a]
- Others	0 (0)	1 (4.8)	

[1]Number (%), [2]mean (SD), [3]median (min, max)
[a]Fisher's exact test; [b]T-test; [c]Mann-Whitney U test; [d]Chi-squared test

Table 2. Baseline status of pain before study (pre-intervention) and pain after the study (post-intervention)

Pain NRS	Study group (n=21)	Control group (n=21)	*p*-value between the groups
Pre-intervention pain	8 (5, 10)	6 (5, 10)	0.411[a]
Post-intervention pain	4 (1, 8)	4 (0, 10)	0.486[a]
p-value within the group	0.001b	0.004[b]	
Pre-post intervention difference*	3 (0, 8)	1 (-1, 7)	0.070[a]

Median (min, max); NRS, numeric rating scale
*Minus value means pre-intervention score is less than post-intervention score
[a]Mann-Whitney U test, [b]Wilcoxon signed rank test

(19%) from the study group and two patients (9.5%) reported increase in minimal pain during the first few days of using the socks. Two patients (9.5%) from the study group reported the foot sliding from medial arch support into an improper position.

Patients' suggestions for improvement of the socks with medial arch support in the study group were as follows: attaching the medial arch support to the sock more tightly (28.6%), reducing the medial arch support height (14.3%), increasing the medial arch support height (4.8%),using the medial arch support with their shoes (9.5%), a waterproof material (4.8%), a more beautiful design (4.8%), and a proper sock size (4.8%); and in the control group as following: increasing the foam height (38.1%), a removable foam before washing (4.8%), a waterproof material (4.8%), a full foot support (4.8%), a proper sock size (4.8%), and a more beautiful design (4.8%).

When asking about a continuation to use the socks in the study group, 52.4% confirmed, 5 patients 23.8% were not sure, and 23.8% preferred discontinuation whereas in the control group, 57.1%would continue using them, 33.3% were not sure, and 9.5% wanted to discontinue using them. However, there were no statistically significant differences in their opinions between the two groups (*p*=0.580).

Discussion

Our study showed that there was a statistically significant decrease in foot pain after using indoor socks with Rehband®, a commercial medial arch support and also showed a high success rate in pain reduction (80.9%) in patients with PTTD stage I and II. In PTTD stage I and II, apart from pharmacological treatment and physical therapy,[9] shoe modifications (such as insert heel counter, medial wedge)and foot orthoses (such as total contact orthoses or medial arch support) are commonly prescribed.[10-12] These could help maintain heel alignment and support the medial longitudinal arch to reduce forces acting on the posterior tibial tendon,[5] resulting in decreased pain.[6] For examples, therapeutic insoles for mild flatfoot deformity using subject-based three-dimensional (3D) computed tomography (CT) models significantly suppressed

Table 3. Limitations of activities and foot instability before (pre-intervention) and after (post-intervention) the study

Pain NRS		Study group (n=21)	Control group (n=21)	*p*-value between the groups
Activities of daily living limitation				
Pre-intervention		7 (3, 10)	7 (4, 10)	0.779[a]
Post-intervention		5 (0, 10)	5 (0, 9)	0.939[a]
	p-value within the group	0.001[b]	0.003[b]	
Pre-post intervention difference		2 (-2,10)	1 (0, 9)	0.652[a]
Household activities limitation				
Pre-intervention		6 (1, 10)	6 (0, 10)	0.879[a]
Post-intervention		5 (0, 8)	4 (0, 9)	0.647[a]
	p-value within the group	0.005[b]	0.011[b]	
Pre-post intervention difference*		1 (-2, 10)	1 (-2, 9)	0.472[a]
Indoor walking limitation				
Pre-intervention		8 (2, 10)	7 (2, 10)	0.572[a]
Post-intervention		4 (0, 8)	5 (0, 9)	0.430[a]
	p-value within the group	0.002[b]	0.012[b]	
Pre-post intervention difference*		2 (-5, 8)	1 (-3, 9)	0.191[a]
Foot instability				
Pre-intervention		7 (2, 10)	5 (0, 10)	0.278[a]
Post-intervention		8 (3, 10)	8 (0, 10)	0.878[a]
	p-value within the group	0.321[b]	0.004[b]	
Pre-post intervention difference**		0 (-6, 2)	0 (-10, 0)	0.076[a]

Median (min, max)
Limitations and ankle instability were assessed with numeric rating scale
Pre-post intervention difference = pre-intervention score minus post-intervention score
*Plus value means limitation was decreased (0, no limitation and 10, complete limitation)
**Minus value means instability was improved (0, completely unstable and 10, completely stable)
[a]Mann-Whitney U test; [b]Wilcoxon signed rank test

Table 4. Patients' adherence to using indoor socks with medial arch support

	Study group (n=21)	Control group (n=21)	*p*-value
Duration of using indoor socks with medial arch support (hours per week)	18.2 (10.2)	22.3 (9.4)	0.179
Duration of standing and walking indoor (hours per week)	26.6 (13.2)	29.8 (11.4)	0.404
Percent of usage from duration of standing and walking	71.4 (26.8)	76.5 (18.8)	0.483

Mean (SD); T–test

Table 5. Satisfaction with the socks with medial arch support/flat foam in different aspects

	Study group (n=21)	Control group (n=21)	*p*-value
Pain control	7 (2, 10)	7 (0, 10)	0.601
Appearance	6 (2, 10)	7 (2, 10)	0.505
Easy to use	6 (2, 10)	8 (2, 10)	0.354
Easy to clean and care	8 (2, 10)	8 (2, 10)	0.959
Durable	7 (1, 10)	8 (2, 10)	0.488
Total treatment	6 (2, 10)	8 (2, 10)	0.077

Median (min, max)
Satisfaction was assessed with numeric rating scale
Mann-Whitney U test

the eversion of the talocalcaneal joint,[5] and non-operatively with orthoses and structured exercises could effectively treated stage I and II PTTD.[13]

However, there was also a statistically significant decrease in foot pain in the control group, despite using 2 mm thickness flat foam. This might be from the foam, which was attached at the medial longitudinal arch position, acting as a cushion. All patients in the control group had stage II PTTD with collapsed medial longitudinal arch. Despite the foam that could not rest the posterior tibial tendon or decrease the subtalar eversion, it could be a cushion to absorb the force that caused the pain, resulting in pain relief.

Besides foot pain reduction, our study found that using indoor socks with medial arch support or with 2 mm thickness flat foam under the medial arch support showed statistically significant decreases in limitations of ADL, household activity, and indoor walking. These could be from the effectiveness of decreasing pain in both groups, thus leading to reduced activity limitations.

In addition, using indoor socks with medial arch support increased the foot instability in the study group. This could be from the medial arch support sliding into an improper position, in spite of attaching it with Velcro®. Foot gliding on the

medial arch support might make patients feel more unstable. The smallest size of the medial arch support (Rehband®) was still too high for some patients with very flat arch, and caused their feet tilted and not in the right position. However, wearing shoes with counter could support the foot. To be noted, in the control group there was a statistically significant decrease in foot instability which might be due to flatness of the foam not tilting the foot. Further, a decrease in foot pain after using indoor socks with flat foam might lead to reduce instability.

There were no serious complications in our study. Four patients from the study group felt more pain at the beginning of the study, perhaps caused by sliding of medial arch support led to ineffective resting of the tendons and its improper position pressed on other parts of the foot. In our study, we informed the patients to increase duration of usage 5 minutes per day for first week before starting the study. However, some might need more than one week for foot accommodation. Two patients reporting more pain after using the devices had the medial arch support sliding into an improper position. Two patients complained of the medial arch support size not fitting their arches and thus not effectively resting the tibialis posterior tendon. Longer duration of walking and standing might be a cause of foot pain as one in the study group and two in the control group complained of more foot pain.

When asking the patients to rate their satisfaction, scores were high in every aspect, especially in pain control. More than half in both groups would like to continue using the socks with medial arch support/flat foam. We expect that adjustments according to the patients' suggestions, e.g., choosing an appropriate height of the medial arch support and preventing sliding of the medial arch support while walking and standing, the indoor socks with medial arch support would be a feasible alternative for reducing foot pain in patients who do not wear shoes indoors. Nevertheless, using medial arch support and shoe modifications is still the best solution for patients with PTTD who endure foot pain from long durations of standing and walking indoors.

There were some limitations in our study. Three sizes of over-the-counter/ready-to-use medial arch support did not fit all patients' medial longitudinal arches, and thus could not beeffective in decreasing pain. A custom-molded medial arch support should be investigated in a future study. Another limitation was using free-size socks which did not tightly fit some with small-sized feet and caused the medial arch support sliding into an improper position. Moreover, using Velcro® for attachment could not prevent the medial arch support sliding into an improper position and it might increase more height causing the feet tilted and uncomfortable feeling. Therefore, preparing different sizes of socks, choosing an appropriate size for the feet, and using another material for attachment of the medial arch support to the socks, should be considered to improve effectiveness.

In conclusion, there were no statistically significant differences in decreasing foot pain and activity limitations between using indoor socks with a commercial medial arch support and with flat foam in patients with stage I or II posterior tibial tendon dysfunction. However, those using indoor socks with medial arch support had higher success rate in pain reduction than those using indoor socks with flat foam. Improper size of medial arch support, sliding of medial arch support to improper position and more increased walking and standing could be factors that made patients experience more pain.

Disclosure

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Original Article

Psychometric Properties of the Thai Herth Hope Index in Stroke Patients

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ABSTRACT

Objectives: To investigate the psychometric properties, both validity and reliability, of the Thai version of the Herth Hope Index (Thai HHI) in stroke patients.

Study design: Descriptive study.

Setting: Department of Rehabilitation Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand.

Subjects: Stroke patients attending the Department of Rehabilitation Medicine during December 2017 to August 2018.

Methods: After translation to Thai language and after assessing the Thai translation for content validity, 70 stroke patients were assessed by using the Thai HHI to determine construct validity and internal consistency. Forty of those same 70 patients were then reassessed one week later to determine test-retest reliability. Convergent and discriminant validity were assessed by evaluating the correlation between the Thai HHI and the Rosenberg Self-Esteem Scale (RSES) and the Patient Health Questionnaire (PHQ-9), respectively, by defining the Spearman's correlation coefficient.

Results: The Thai HHI showed good content validity (CVI = 0.98), moderate convergent validity (r = 0.563), moderate discriminant validity (r = -0.545), acceptable internal consistency (Cronbach's alpha = 0.794), and good test-retest reliability (ICC = 0.776).

Conclusion: The Thai HHI was found to have good to moderate psychometric properties as evidenced by good content validity, moderate construct validity, acceptable internal consistency, and good test-retest reliability. These findings suggest that the Thai HHI can be used to evaluate hope among Thai stroke patients.

Keywords: psychometric properties, validity, reliability, hope, stroke, Thai Herth Hope Index

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Introduction

When a person experiences stress that is caused by negative emotions or illness, hope is a coping strategy that is often employed to help manage the problem or crisis.[1] Hope is a multidimensional force that is personally significant and used for achieving goals and overcoming obstacles.[2] Moreover, hope is a thought process that almost all people use throughout their life, especially when they are facing illness and/or losses.[3] In patients with chronic illness, hope is a prerequisite to effective coping and decision-making, and it has a protective function against stress.[4] In this setting, stress is reduced because hope encourages the strength needed to solve problems and to face losses and suffering, and this improves quality of life.[5]

In a chronic illness setting, stroke is a major disease of concern among physiatrists, because it was reported that approximately 30% of stroke patients developed depression – in both the subacute phase and the chronic phase.[6] Patients with severe disability tend to develop depression due to the high level of dependency caused by their condition.[7]

Although the mechanism is not yet clear, hope is believed to effectuate a positive effect on neurotransmission, which helps to promote neuro-recovery in stroke patients.[4] Moreover, hope was found to be one of the predictors of positive rehabilitation outcomes.[8] A previous study found that if patients had hope, they were more likely to overcome their stress and obstacles, which made them more likely to achieve better patient outcomes.[9] We hypothesized that more hope would positively influence better rehabilitation outcomes among stroke patients, so the authors aimed to identify a valid and reliable tool for evaluating hope so that association between hope and rehabilitation outcomes could be evaluated in our future study.

The Herth Hope Index (HHI) consisting of 12 items, was developed in 1992 from its predecessor (the Herth Hope Scale) with the objective of reducing the number and complexity of the questions, and to make it more precise and clinically usable. The HHI was found to have good psychometric properties,[5] and has been translated into many languages, including Chinese,[10] Portuguese,[11] German,[12] and Italian.[13]

A previous study translated the original version of the HHI into Thai language, but face validity and internal consistency

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were the only psychometric properties reported,[14] and this limited its clinical usefulness. Accordingly, the aim of this study was to translate the original version of the HHI to Thai language, and to evaluate its psychometric properties, including content validity, construct validity, internal consistency, and test-retest reliability, in Thai stroke patients with stroke onset of at least 3 months. This onset duration was chosen because it was reported that the disease reached its plateau for the recovery phase within 3 months,[15] at which point a more stable mood and level of hope were expected.

Methods

The protocol for this study was approved by the Siriraj Institutional Review Board (SIRB) of the Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand (COA no. 661/2560 [EC3]). This study complied with all of the principles set forth in the Declaration of Helsinki and all of its subsequent amendments, and all participating patients provided written informed consent to participate in this study.

Translation

Prior to starting the translation process, we contacted Mrs. Alexander Kaye Herth to request a formal permission to translate her original copyrighted version of the HHI from English to Thai. After permission was granted, the HHI was translated into Thai language by linguistic experts from the Mahidol University Research Institute for Languages and Cultures of Asia (Appendix). After that translation step, the Thai language questions were then back-translated into English by different linguistic experts from Mahidol University in order to prevent/minimize bias. That back-translated English version was then sent to yet another expert whose mother tongue is English to compare it with the original English language version of the HHI.

Participants

Inpatient and outpatient stroke patients, who were receiving treatment from the Department of Rehabilitation Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, met our inclusion criteria and were willing to participate, were eligible for recruitment. Patients aged > 18 years with onset of stroke ≥ 3 months and full consciousness were included. Those with cognitive impairment and/or an inability to communicate in Thai language were excluded. After written informed consent was obtained, demographic and clinical data were collected and recorded.

Validity

In this study, we evaluated both content and construct validity. For construct validity, we assessed both convergent and discriminant validity.

Content validity

The Thai HHI was given to 5 experts to determine its content validity. All of the experts are bilingual, and all have had experience in translation and instrument validation. They were asked to rate each of the 12 questions relative to their comparability or relevance to the original version, and whether or not each can evaluate the level of hope. Each question was then individually rated using a 4-point rating scale (from 1 = not relevant to 4 = highly relevant). Any item judged to be irrelevant by receiving a rating of 1 or 2 by more than 20% of experts would be amended. We then calculated the content validity index (CVI), the percentage of the total items rated as 3 or 4 for each question, and for all questions. A CVI score of 80% or higher is generally considered to indicate good content validity

Construct validity

Construct validity is composed of convergent and discriminat validity. Convergent validity was assessed by evaluating the correlation between the Thai HHI and the Rosenberg Self-Esteem Scale (RSES) using Spearman's correlation coefficient. We hypothesized that the Thai HHI would be positively correlated with the RSES since a previous study found that people with higher levels of self-esteem had higher levels of hope.[16] The RSES designed to measure self-esteem consists of 10 items. Responses are rated using a 4-point Likert scale that ranges from 1 to 4 (1 = strongly disagree, 2 = disagree, 3 = agree, 4 = strongly agree), with a total possible score ranging from 10 to 40. Higher scores indicate higher levels of self-esteem. The RSES was translated to Thai and was evaluated for its psychometric properties which revealed good validity and reliability.[17]

Discriminant validity was evaluated by analyzing for correlation between the Thai HHI and the Patient Health Questionnaire-9 (PHQ-9) using Spearman's correlation coefficient. We hypothesized that the Thai HHI would be negatively correlated with the PHQ-9 because a previous study reported that people who have higher levels of hope are less likely to be affected by depression.[18] The PHQ-9, designed to screen for depression, consists of 9 items. A 4-point Likert scale (0 to 3) is used to answer each question (0 = not at all, 1 = several days, 2 = more than half of days, 4 = almost every day), and the total score ranges from 0 to 27. A higher score indicates a more severe degree of depression. The Thai version of the PHQ-9 was validated for its psychometric properties, which showed good validity and reliability.[19]

Reliability

Reliability was evaluated by internal consistency and test-retest reliability. Internal consistency reliability of the translated instrument was assessed by defining the consistency of each question using Cronbach's alpha. Test-retest reliability was evaluated by re-administering the Thai HHI to 40 of the same 70 patients that took the Thai HHI one week earlier. The questions on the retest were the same as those on the first test, but the order of the questions was changed to prevent the carry-over effect.

Sample size calculation

The sample size was calculated using data from a study by Chan et al. which is the research group that created the Chinese version of the HHI.[10] The sample size was calculated using the following variables: descriptive study with a type 1 error of 0.05, a type 2 error of 0.1, and an add-on of 10% to compensate for dropouts for any cause. The estimated number of participants for the validity and reliability tests were 70 and 40, respectively.

Statistical analysis

CVI was calculated to evaluate content validity; Spearman's correlation coefficient was used to assess convergent and discriminant construct validity; Cronbach's alpha was used to evaluate internal consistency; and, intraclass correlation coefficient was used to measure test-retest reliability.

Range of construct validity[20]

Size of correlation	Interpretation
.90 to 1.00 (-0.90 to -1.00)	Very high positive (negative) correlation
.70 to .90 (-0.70 to -0.90)	High positive (negative) correlation
.50 to .70 (-0.50 to -0.70)	Moderate positive (negative) correlation
.30 to .50 (-0.30 to -0.50)	Low positive (negative) correlation
.00 to .30 (0.00 to -0.30)	Negligible correlation

Range of internal consistency[21]

Cronbach's alpha	Internal consistency
$0.9 \leq \alpha$	Excellent
$0.8 \leq \alpha < 0.9$	Good
$0.7 \leq \alpha < 0.8$	Acceptable
$0.6 \leq \alpha < 0.7$	Questionable
$0.5 \leq \alpha < 0.6$	Poor
$\alpha < 0.5$	Unacceptable

Range of intraclass correlation coefficient[22]

Range of Intraclass correlation coefficient	Interpretation
< 0.50	Poor
0.50 ≤ ICC < 0.75	Moderate
0.75 ≤ ICC < 0.90	Good
≥ 0.90	Excellent

Results

Seventy stroke patients who attended the Department of Rehabilitation Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University during December 2017 to August 2018 were enrolled in this study. The demographic and clinical characteristics of study patients are shown in Table 1.

Concerning validity, five experts were asked to judge the content validity of the Thai HHI. All experts gave all questions the highest score except for question number 3, which one expert gave a score of 2 out of 4 (low relevance). Nevertheless, when all scores from all experts were combined for question 3, an acceptable content validity index (CVI) of 0.80 was calculated. The overall content validity of the Thai HHI found to be high with a CVI of 0.983 (Table 2).

For convergent validity, the Spearman's correlation coefficient between the Thai HHI and the RSES was 0.563 ($p < 0.01$), which indicates significant moderate positive correlation between the Thai HHI and the RSES (Table 3).

The correlation between the Thai HHI and the PHQ-9 was analyzed in order to define the discriminant validity. The Spearman's correlation coefficient between these two tests

Table 1. Demographic data of 70 participants

Variable	
Age (year)[2]	63.4 (11.4)
Sex[1]	
Male	42 (60)
Female	28 (40)
Underlying disease[1*]	
Hypertension	50 (71.4)
Dyslipidemia	32 (45.7)
Diabetes mellitus	19 (27.1)
Coronary artery disease	11 (15.7)
Prior stroke	2 (2.9)
Onset of stroke[1]	
≤ 6 months	13 (18.6)
> 6 months -1 year	11 (15.7)
> 1 year - 5 years	28 (40.0)
> 5 years - 10 years	11 (15.7)
> 10 years	7 (10.0)
Hemiparesis side[1]	
Left	35 (50.0)
Right	33 (47.1)
Bilateral	2 (2.9)
Dominant hand[1]	
Left	11 (15.7)
Right	59 (84.3)
Recent stroke type[1]	
Ischemic	46 (65.7)
Hemorrhagic	24 (34.3)
Education[1]	
Below high school	27 (38.6)
High school	18 (25.7)
Bachelor degree	16 (22.9)
Above bachelor degree	9 (12.9)
Marital status[1]	
Single	15 (21.4)
Married	49 (70.0)
Divorced	6 (8.6)

[1]Number (%), [2] mean (SD)

*Some participants had more than one underlying diseases

Table 2. Content validity of the Thai HHI among 5 experts

Question No.	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	No. in agreement	CVI
1	√	√	√	√	√	5	1.00
2	√	√	√	√	√	5	1.00
3	√	√	√	√	x	4	0.80
4	√	√	√	√	√	5	1.00
5	√	√	√	√	√	5	1.00
6	√	√	√	√	√	5	1.00
7	√	√	√	√	√	5	1.00
8	√	√	√	√	√	5	1.00
9	√	√	√	√	√	5	1.00
10	√	√	√	√	√	5	1.00
11	√	√	√	√	√	5	1.00
12	√	√	√	√	√	5	1.00
Total	1.00	1.00	1.00	1.00	0.917		0.983

HHI, Herth Hope Index; CVI, content validity index

√ indicated scores 3-4 of 4 points rating scale (acceptable), X indicated scores 1-2 0f 4 points rating scale (unacceptable)

Table 3. Convergent validity of the Thai HHI compared to RSES

		Thai HHI	RSES
Spearman's	Correlation coefficient	1.000	0.563
Correlation coefficient	*p*-value	-	< 0.001

HHI, Herth Hope Index; RSES, Rosenberg self-esteem scale

Table 4. Discriminant validity of the Thai HHI compared to PHQ-9

		Thai HHI	PHQ-9
Spearman's	Correlation coefficient	1.000	-0.545
Correlation coefficient	*p*-value	-	< 0.001

HHI, Herth Hope Index; PHQ-9, Patient health questionnaire-9

Table 5. Internal consistency of the Thai version HHI, presented with Cronbach's alpha coefficient

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
1. I have a positive outlook toward life.	33.00	11.217	.552	.460	.773
2. I have short and/or long-range goals.	33.13	10.751	.474	.414	.775
3. I feel all alone.	33.07	10.212	.446	.445	.781
4. I can see possibilities in the midst of difficulties.	33.09	10.717	.573	.504	.767
5. I have a faith that gives me comfort.	33.01	11.493	.278	.273	.794
6. I feel scared about my future.	33.63	11.164	.192	.474	.817
7. I can recall happy/joyful times.	32.83	11.275	.379	.474	.784
8. I have deep inner strength.	32.81	10.356	.630	.601	.760
9. I am able to give and receive caring/love.	32.93	11.198	.498	.449	.776
10. I have a sense of direction.	33.16	10.917	.402	.315	.783
11. I believe that each day has potential.	33.04	11.143	.544	.561	.773
12. I feel my life has value and worth.	32.93	10.531	.594	.617	.764

HHI, Herth Hope Index

was 0.545 ($p < 0.01$), which indicates significant moderate negative correlation between the Thai HHI and the PHQ-9 (Table 4).

The Thai HHI was found to have acceptable internal consistency with a Cronbach's alpha of 0.794. Analysis of each question was performed in order to define the Cronbach's alpha when that question was deleted. All deletions of individual questions yielded a lower Cronbach's alpha except for the deletion of question number 6, which yielded a higher Cronbach's alpha (0.817). The internal consistency for each question is given in Table 5.

The Thai HHI was re-administered to 40 of the 70 patients who took the test one week earlier in order to assess test-retest reliability. The order of the questions on the retest was different from the order on the first test to reduce the carry-over effect. The intraclass correlation coefficient of

Table 6. Test-retest reliability of the Thai version HHI, presented with intraclass correlation coefficient

		95% confidence interval		F Test with true value			
	Intraclass Correlation	Lower bound	Upper bound	Value	df1	df2	Sig
Average	0.776	.584	.880	4.467	41	41	< 0.01

0.776 (Table 6) indicated that the test-retest reliability of the Thai HHI is good.

Discussion

Every question in the Thai HHI has a content validity index ≥ 80% and an overall content validity index of 0.983, which indicates good content validity.

Concerning construct validity, the Spearman's correlation coefficient between the Thai HHI and the RSES showed r = 0.563, which is defined as a moderate positive correlation (0.50-0.70).[20] The Spearman's correlation coefficient between the Thai HHI and the PHQ-9 revealed a moderate negative correlation (r = -0.545). This finding supports our hypothesis, and corresponds with the findings of prior studies.[16,17] When we compared our findings with the findings of studies that translated the HHI into Chinese, Portuguese, German, and Italian, our results have the same moderate correlation. However, direct comparison with the exact same test could not be performed due to language-related limitations. The Chinese study compared the Chinese HHI with the RSES and the Hamilton Depression Scale, which is similar to the PHQ-9 depression screening tool that we used in our study. Our study showed the Thai HHI to have higher both convergent validity (r = 0.563 vs. r = 0.40) and higher discriminant validity (-0.545 vs. -0.40) than the Chinese HHI (both respectively).

The Cronbach's alpha for the Thai HHI was found to be 0.794, which is defined as acceptable internal consistency (0.7-0.8).[21] However, when compared with other studies, the Thai HHI was shown to have acceptable internal consistency, whereas the other studies showed good internal consistency. Importantly, when question number 6 was deleted, the Cronbach's alpha increased to 0.817, which increases the internal consistency rating for the Thai HHI from acceptable to good (0.8-0.9).[21] A further study with question number 6 reevaluated and retranslated is recommended so that the Thai HHI will have higher internal consistency.

The intraclass correlation coefficient of the test-retest reliability of the Thai HHI was 0.776, which is rated as good (0.75-0.90).[22] When compared with other studies, our study has higher test-retest reliability than the Portuguese and the Italian studies (good vs. moderate), and has the same level of test-retest reliability with the Chinese and the German studies (good). However, when compared with the original version of the HHI, the Thai HHI has a lower intraclass correlation coefficient (0.776 vs. 0.91, respectively). Nonetheless, the original study only had 20 participants in the test-retest group and the order of the questions was the same on both the first test and the retest, so it is possible that their finding was somehow influenced by the carry-over effect.

The limitations of this study include the fact that we did not perform criterion validity due to the lack of a standard test for determining hope level in Thai population, and that only stroke patients were studied, which could limit the generalizability of our findings to other patient populations. In addition, we did not conduct our study according to guidelines for the process of cross-cultural adaptation of self-report measures because we were unable to find two native English speakers who are both fluent in Thai, instead we performed our research according to protocol by Suraseranivongse S.[23]

In conclusion, the Thai HHI was found to have good to moderate psychometric properties as evidenced by good content validity, moderate construct validity, acceptable internal consistency, and good test-retest reliability. These findings suggest that the Thai HHI can be used to evaluate hope among Thai stroke patients.

Disclosure

All authors declare no personal or professional conflicts of interest relating to any aspect of this study.

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Appendix: Thai version of the Herth Hope Index

	ไม่เห็นด้วยอย่างยิ่ง	ไม่เห็นด้วย	เห็นด้วย	เห็นด้วยอย่างยิ่ง
1. ฉันมีมุมมองที่ดีเกี่ยวกับชีวิตของฉัน				
2. ฉันมีเป้าหมายในการดำเนินชีวิต				
3. ฉันรู้สึกโดดเดี่ยว				
4. ฉันมองเห็นทางออกสำหรับปัญหาต่าง ๆ ในชีวิต				
5. ฉันมีที่ยึดเหนี่ยวทางจิตใจ				
6. ฉันรู้สึกกังวลเกี่ยวกับอนาคตของฉัน				
7. ฉันยังจดจำช่วงเวลาดี ๆ ในชีวิตได้				
8. จิตใจของฉันยังเข้มแข็งอยู่				
9. ฉันยังสามารถให้และได้รับความห่วงใยแก่ผู้อื่น				
10. ฉันรู้ว่าชีวิตฉันกำลังดำเนินไปในทิศทางใด				
11. ฉันเชื่อว่าทุก ๆ วันมีความหมาย				
12. ฉันรู้สึกว่าชีวิตของฉันมีคุณค่าและมีความหมาย				

Original Article

Effect of Vojta Therapy on Balance and Walking of Community Dwelling Chronic Stroke Patients

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ABSTRACT

Objectives: To evaluate effect of Vojta Therapy on balance and walking of community dwelling chronic stroke patients.
Study design: Single group clinical trial with pre and post test.
Setting: VojtaTherapy clinic, Division of Physical Therapy, Department of Rehabilitation Medicine, Trang Hospital.
Subjects: Community dwelling chronic stroke patients with abnormal gait referred to the VojtaTherapy clinic.
Methods: Every participant did a timed up and go test (TUGT) immediately before and after the VojtaTherapy. Techniques were chosen according to response of patients with 30 minutes per session. Treatment and assessment were repeated once a week for three weeks.
Results: Twenty chronic stroke patients with average age of 63.1 (SD = 13.23) years and average duration after stroke of 58.35 (SD = 52.83) months were enrolled into the study. The median TUGT scores of the first, second and third pre-treatment were 28, 22 and 19.5 respectively. Friedman test demonstrated a significant difference ($p < 0.001$). Median TUGT Score of the first, second, and third post treatment TUGT score were 22.5, 18 and 18.5 respectively. Wilcoxon test showed significant difference of pre versus post treatments in everysessions ($p < 0.0001$).
Conclusion: Once a week of VojtaTherapy for three weeks can improve walking in community dwelling chronic stroke patients.

Keywords: stroke, hemiplegia, balance, walk test, rehabilitation

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Introduction

Stroke is the most common cause of neurological disability in adult.[1] Walking limitation is the number one concern of stroke patients and family.[2] There are many methods for balance and walking rehabilitation as group or individual training or therapies.[3,4] These include the use of resistive exercise,[5] treadmill training,[6] robot assisted gait training,[7] task-oriented circuit class,[8] virtual reality,[9] whole body vibration,[10] orthosis,[11] electrical stimulation[12] etc. However, several chronic stroke patients still have poor balance and walking limitation. This significantly reduce quality of life and increase risk of falling.[14] Falling rate in chronic stroke patients was reported 0.88 falls per person per year.[15] This is almost triple of the falling rate in community dwelling normal elderly persons.[16] There is a need to search for a novel and perhaps more effective form of therapy.

"Vojta Therapy" also known as "reflex locomotion therapy" was invented in the 60's by Prof. Václav Vojta.[17] It was proposed that facilitation of reflex creeping and reflex rolling motor pattern through specific positioning of body segments and manual compression of contact or "trigger zones" could improve automatic postural control and other aspects of motor functions. The application of Vojta Therapy does not require complicated and expensive high technological equipment. Previous research showed that Vojta Therapy can improve balance and walking in cerebral palsy children,[18] and elderly persons.[19] It is expected that Vojta Therapy may significantly improve trunk control and gait ability when applied to early subacute stroke patients.[20] However, there has never been a research study of the effect of Vojta Therapy on gait and balance of chronic stroke patients. There are many ways to measure change of balance ability,[21] or gait function,[22] Timed Up and Go Test (TUGT) is perhaps one of the simplest timed walk tests which is proven to be valid and reliable for balance and gait function assessment in chronic stroke patient.[23]

Therefore, the goal of this study was to demonstrate immediate effect of Vojta Therapy on TUGT score in chronic community dwelling stroke patients.

Methods

Participants

All stroke patients with chronic hemiparesis (at least 6 months) who were referred to the VojtaTherapy clinic at Trang Hospital during the months of August until October 2019 were invited to participated in this study and gave informed consent.

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Inclusion criteria

- Ability to adequately understand and cooperate to the purpose of the study
- Medically stable
- Ability to walk independently for at least 20 meters with/or without gait aid

Exclusion criteria

- Unwillingness to attend every session of the therapy and assessment appointment through the whole study period, at the hospital for Vojta Therapy and gait assessment.

Steps of the study

Each patient visited the hospital once a week for three consecutive weeks. Balance and gait were assessed with timed up-and-go (TUGT) test before and after each therapy session. The therapy was delivered by the first author who is certified physiotherapist for adult Vojta Therapy by the International Vojta Society. During the therapy each patient was positioned in one of the three standard starting positions and received manual pressure point stimulation according to the method of Vojta Therapy.[17] The positioning of the limbs, spinal alignment, direction and force of pressure acting on the trigger zone, number and location of trigger zone to use, were constantly adjusted to maintain optimal response. Patients were not required to voluntarily contract muscles or try to do any active movement, but they should not sleep during the therapy. Between the therapy sessions, they were advised to do normal daily activities as they usually did but no additional or new exercise was recommended.

Immediately before and after each therapy session, patients were instructed to sit on a steady standard size chair with back rest but no arm support which was placed facing a 3 meters walkway. The assessing therapist who was not the same person as the treating therapist, gave verbal instruction to the patient that after the signal "go!" he/she should stand up, walk to the opposite end of the 3 meters walkway, turn around and walk back toward the chair, and turn to sit down in the chair without any pause. Touching the chair was prohibited but gait aids such as a cane or walker were allowed. They were also instructed to walk at a fastest speed in which they felt steady and secured. A stopwatch was used to measure the time in seconds used.

Statistical analysis

Descriptive statistic was used for demographic data. Friedman test was used to demonstrate change through the three pre-therapy TUGT score. Wilcoxon test was used to demonstrate difference between pre versus post therapy score of each session. Statistic calculation were made with MedCalc Statistical Software version 19.1 (MedCalc Software by, Ostend, Belgium; https://www.medcalc.org; 2019)

Results

Twenty chronic stroke patients, 15 males and 5 females, were included in the study. Average (SD was 63.1 (13.23) years. Average (SD) duration after stroke was 58.35 (52.83) months. Average (SD) weight, height and BMI were 61.8 (12.59) kg, 163.1 (7.40) centimeters and 23.1 (3.77) Kg/m^2, respectively. Fifteen patients had right hemiparesis and the rest had left hemiparesis. There were 9 ischemic and 11 hemorrhagic stroke cases. There were no dropouts. And data of individual subjects can be found in table 1.

Average and median TUGT score (time used in seconds) which were obtained before and after each of the three therapy sessions can be seen in table 2. The median TUGT scores of the first, second and third pretreatment TUGT were 28, 22 and 19.50 seconds respectively. Friedman test demonstrated a significant difference of these three values at *p* value 0.001.

The median TUGT Scores of the first, second, and third post treatment TUGT were 22.50, 18 and 18.50 seconds respectively. Wilcoxon test showed significant difference of pre versus post treatment in everysessions at *p* value, 0.0001

Graphical representation of individual patients' TUGT scores is shown in figure 1. There was no case which the score became worst immediately after therapy. Out of these 20 cases 19 cases in the first,16 cases in the second, and 19 case in the third therapy session showed improvement of TUGT scores immediately after the therapy.

Discussion

The immediate pre and post therapy changes of TUGT scores, despite no active therapeutic exercise of any kind, are interesting. There was no worsening of TUGT scores after therapy. This is probably because through the stimulation of "reflex locomotion" motor patterns, Vojta Therapy might facilitate a more effective automatic postural regulation.[17-20] When looking at the average score after one session and the score before the next session, after one week pause with no intervention at all (Table 1), the effects of therapy appear to be somewhat maintained during the pause between the end of one session and the next pre-session assessment.

Repeated stimulation resulted in significant continuous improvement of TUGT scores. During each session of Vojta Therapy several combinations of "trigger zone" compression plus a set of specific body positioning is maintained for up to 25 minutes. This, in combination with an isometric resistance applied to the head to stop any reflex induced rotation of the head, could lead to temporal and spatial summation of intensive non-nociceptive proprioceptive and tactile afferent signals. It is well known that such a prolonged facilitation could result in a long-lasting hyperexcitable state of the nervous system which is known as "long term potentiation".[24,25]

Table 1. Demographic data and individual timed up and go test (TUGT) scores (in seconds) of each participant

Case No.	Age	Sex	Effected side	Duration in (months)	TUG Pre 1	TUG Post 1	TUG Pre 2	TUG Post 2	TUG Pre 3	TUG Popst 3
1	33	Male	Rt.	15	18	15	16	15	15	13
2	76	Male	Rt.	88	24	23	22	20	22	21
3	55	Female	Lt.	15	40	40	41	35	37	32
4	58	Male	Rt.	29	47	37	43	34	41	34
5	66	Male	Rt.	49	39	31	30	29	33	31
6	55	Male	Lt.	107	10	9	9	9	9	8
7	65	Male	Lt.	204	43	38	42	36	42	33
8	78	Male	Rt.	102	17	16	15	15	15	13
9	80	Male	Rt.	34	23	20	14	12	14	13
10	66	Male	Lt.	9	26	20	26	18	20	19
11	77	Female	Rt.	8	30	24	18	16	19	18
12	80	Male	Rt.	26	21	12	12	12	12	10
13	73	Male	Rt.	137	41	39	36	34	36	33
14	45	Female	Rt.	11	23	21	19	18	17	16
15	55	Male	Lt.	30	41	31	29	28	34	29
16	54	Male	Rt.	139	38	22	25	18	23	19
17	51	Male	Rt.	17	32	25	22	18	17	15
18	76	Male	Rt.	42	16	13	13	12	13	11
19	69	Female	Rt.	39	97	76	65	54	56	50
20	50	Female	Rt.	66	12	10	10	10	9	9

Table 2. Timed up and go test (TUGT) scores (in seconds) of three pre and post Vojta Therapy sessions

	TUGT Pre 1	TUGT Post 1	TUGT Pre 2	TUGT Post 2	TUGT Pre 3	TUGT Post 3
Sample size	20	20	20	20	20	20
Minimum	10	9	9	9	9	8
Maximum	97	76	65	54	56	50
Average (SD)	28.00 (18.96)	22.50 (15.28)	22.00 (14.19)	18.00 (11.64)	19.50 (13.08)	18.50 (11.20)
Median	28	22.50	22	18	19.50	18.50
Interquartile range	21.33 to 39.83	16.678 to 31.00	15.16 to 29.83	15.00 to 28.83	15.00 to 33.83	13.00 to 30.66
Hodges-Lehmann median difference	-5.00		-3.00		-2.50	
95% Confidence interval of the difference	-8.00 to -3.00		-5.00 to -1.00		-4.00 to -1.50	
Number of cases with improved score after each therapy session	19		16		19	
Wilcoxon test	$p < 0.0001$		$p < 0.0001$		$p < 0.0001$	
Friedman test[a]			$p < 0.0001$			

[a]Comparing Pre 1 TUGT, Pre 2 TUGT and Pre 3 TUGT

In this study all patients had stroke longer than 6 months after stroke. No instruction was given for the patient to do any kind of exercise at home. Therefore, these reductions of the time required to complete the TUGT test were not likely to be the result of spontaneous recovery, un-prescribed active gait training, or even placebo effects. The difference of average TUGT scores between the first and the last assessment in this study were 9.50 seconds, this was larger than 3.4 second which is the minimal clinically important difference (MCID) level of TUGT established in adult population with back pain.[26] But small sample size and the lack of control group necessitate a future randomized control study with adequate sample size is warranted.

The authors had strictly adhered to the standard TUGT test procedure. All measurements were made once without repetition. No averaging was applied because repeated timed walking would necessitate patient to walk totally 6 laps per session and as such fatigue of the patient could potentially compromise the reliability of test score. For these reasons, the reliability of TUGT score in this study can be expected to be acceptable.

Despite of the short-term improvement of gait speed and balance, a prospective randomized control study is needed to confirm the result. Further study should assess not only short term but also longer-term gait and balance outcome. They could as well study the effect of different therapy intensity in term of therapy frequency and duration.

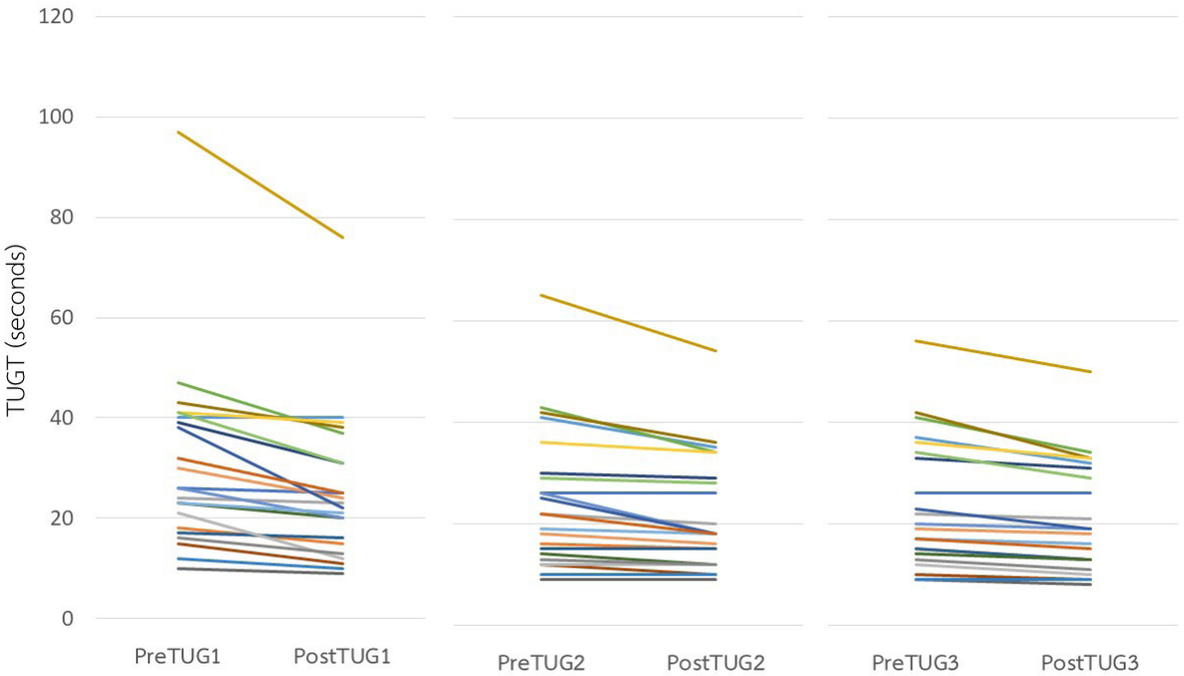

Figure 1. Individual TUGT scores of all subjects before and after each weekly Vojta Therapy sessions.

The maintenance of increased TUGT score in the period after cessation of stimulation is another interesting research question. Since there has been no study comparing the effects of combining Vojta therapy and exercise-based gait and balance training programs, a research that study the effects of the combination of Vojta Therapy plus other gait training method such as body weight supported treadmill training or other balance training protocol could be carried out. It would be interesting to see if such combination brings greater or faster recovery.

In conclusion, Once a week of 30 minutes session of Vojta Therapy for three weeks could significantly improve walking measured with the time up and go test in chronic stroke patients.

Disclosure

Watcharin Tayati, Niranya Chompunuch and Assistant Professor Parit Wongphaet declare no conflict of interest of any kind.

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Original Article

Prevalence of Complementary and Alternative Medicine Used by Stroke Patients in Siriraj Hospital, Thailand

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ABSTRACT

Objectives: To study the prevalence of complementary and alternative medicine (CAM) use and related factors among stroke patients in Siriraj Hospital.
Study design: Cross-sectional descriptive study.
Setting: Inpatient and outpatient of the Departments of Internal Medicine and Rehabilitation Medicine, Siriraj Hospital.
Subjects: Stroke patients (at least 3 months after onset), age at least 18 years.
Methods: Data collected by questionnaire-based study on stroke patients or their relatives.
Results: Three hundred and nine stroke patients were recruited, 59.2% were male. Mean age was 65.2 (SD 12.3) years. The prevalence of CAM use in stroke patients was 40.8%. The most common CAM used was Thai massage (56.3%) followed by acupuncture (44.4%), traditional Thai herb and medication (36.5%) and traditional Chinese herb and medicine (15.9%). The main reasons for CAM used were muscle strength improvement (58.7%), controlling spasticity (41.3%), improving walking ability (37.3%), and pain reduction (25.4%). Treatments with CAM started from suggestions from families or friends (58.7%) and physicians and healthcare professions (23.8%). The total cost per month of CAM use that was less than 1,000 baht was 40.5%. Complication rate was 16.7%. Ecchymosis or bruise was the most common complication. Regarding satisfaction rate, CAM users rated extremely satisfied, satisfied and neutral 19.0%, 48.4% and 27.0%, respectively.
Conclusion: About 40% of stroke patients used CAM. The frequent CAM treatments chosen were traditional Thai and Chinese medicine suggested by their relatives and friends. Though, there were some complications, stroke patients were still satisfied with CAM.

Keywords: complementary medicine, alternative medicine, poststroke, prevalence, Thai traditional medicine

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Introduction

Stroke is a common health problem in the world, including Thailand. It is the leading cause of death and one of the top five causes of disability-adjusted life years in Thailand.[1] Though acute stroke treatment had been advanced and improved, stroke survivors still faced with impairments and disabilities such as weakness, numbness, mobility and communication limitations. Rehabilitation program during early and intensive post-acute phase is aimed at reducing impairments and disability. After completion of medical rehabilitation program, impairments and disability may remain and some stroke survivors seek complementary and alternative medicine (CAM) to solve their remaining problems.[2,3]

Complementary and alternative medicine (CAM) means a broad set of health care practices that is not part of conventional medicine and is not fully integrated into the dominant health care system.[4] In Thailand, the examples of common CAM treatments are massage, exercise, herbals and acupuncture.[3] The main reasons of using CAM in Thailand are pain treatment and relaxation. The Thai National policy aimed to develop, promote and set standards of the Thai traditional and alternative medicine in the country. So the Department of Thai Traditional and Alternative Medicine was established in the Ministry of Public Health. Thereafter, Thai traditional medicine (TTM) clinics have been established in over 80% of the public hospitals.[5] Several types of CAM treatment such as TTM, Thai massage, traditional Chinese medicine (TCM), acupuncture used by stroke survivors had been reported in Thailand.[6] The prevalence of CAM used in stroke patients in India was 36.3%[7] but the prevalence in Thailand was not known. Hence, this study was performed to report the prevalence of CAM use and related factors among stroke patients.

Methods

This cross-sectional descriptive study was conducted at Siriraj Hospital-Thailand's largest university-based center (Bangkok, Thailand). The protocol for this study was approved by the Siriraj Institutional Review Board (SIRB), Faculty of Medicine Siriraj Hospital, Mahidol University (Si 728/2558(EC4)). Stroke patients at outpatient clinic and inpatient wards of Rehabilitation Medicine and Internal Medicine Departments were invited to participate in the study. All

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participants provided informed consent before joining the study.

Participants

Inclusion criteria

- Age more than 18 years old
- Onset >= 3 months
- Normal consciousness and able to complete the paper-and-pencil questionnaire or caregiver could be a proxy.

Exclusion criteria

- Non-Thai nationality
- Inability to communicate

Participants completed the questionnaires which included demographic data, stroke characteristics and complementary and alternative medicine use.

Sample size calculation was based on the prevalence of Pandian JD study[7] at 95% confidence interval and 5.5% allowable error. The calculated sample size was 289. The oversample by 5% was 305.

Statistical analysis

Predictive analytics software (PASW) statistics version 18.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Descriptive statistics were used for subject characteristics. Unpaired t-test was used to compare quantitative data while Chi-square test was used for qualitative data. Statistical significance was set at < 0.05.

Results

Table 1 and 2 show participants' characteristics and comorbidities. Table 3 shows stroke types, related symptoms, and history of rehabilitation program. In total, 309 stroke patients agreed to participate in the study. Participants had a mean age of 65.2 (SD 12.3) years. There were 183 males (59.2%) and 126 females (40.8%). Duration post stroke was 43.6 (SD 50.4) months. The total number of CAM user was 126, so the overall prevalence was 40.8%. There was no statistically significant difference between CAM and non-CAM users in almost all aspects. However, most patients with hypertension used CAM (Table 2) (p = 0.012). Regarding stroke and its related problems, patients with either ischemic stroke or hemorrhagic stroke (p = 0.025), spasticity (p < 0.001) and constipation (p < 0.017) were more likely to use CAM (Table 3) while those without weakness (p < 0.001) were the

Table 1. Demographic data of participants and comparison between CAM and non CAM users

		Total (n=309)	CAM user (n=126)	Non CAM user (n=183)	*p*-value
Sex[1]	Male	183 (59.2)	80 (63.5)	103 (56.3)	0.239
	Female	126 (40.8)	46 (36.5)	80 (43.7)	
Age (year)[2]		65.2 (12.3)	64.0 (11.7)	66.1 (12.6)	0.141
Religion[1]	Buddhism	303 (98.1)	124 (98.4)	179 (97.8)	1.000
	Others	6 (1.9)	2 (1.6)	4 (2.2)	
Education[1]	No education	15 (4.9)	7 (5.6)	8 (4.4)	0.731
	Elementary	104 (33.7)	40 (31.7)	64 (35.0)	
	Secondary	86 (27.8)	33 (26.2)	53 (29.0)	
	Higher education	96 (31.1)	43 (34.1)	53 (29.0)	
Career[1]	No career	145 (46.9)	61 (48.4)	84 (45.9)	0.983
	State officer	24 (7.8)	10 (7.9)	14 (7.7)	
	Retired officer	54 (17.5)	21 (16.7)	33 (18.0)	
	Others	82 (26.5)	34 (27.0)	48 (26.2)	
Income[1]	Yes	128 (41.4)	51 (40.5)	77 (42.1)	0.906
	No	176 (57.0)	72 (57.1)	104 (56.8)	
Family's income (Baht)[1]	< 10,000	67 (21.7)	24 (19.0)	43 (23.5)	0.462
	10,001-100,000	198 (64.1)	87 (69.0)	111 (60.7)	
	> 100,000	19 (6.1)	7 (6.5)	12 (6.6)	
Birthplace[1]	Bangkok	223 (72.2)	91 (72.2)	132 (72.1)	0.917
	Central region	42 (13.6)	16 (12.7)	26 (14.2)	
	Others	40 (12.9)	17 (13.5)	23 (12.6)	
Caregiver[1]	No	49 (15.9)	16 (12.7)	33 (18.0)	0.267
	Yes	260 (84.1)	110 (87.3)	150 (82.0)	
	Relative	200 (64.7)	86 (68.3)	114 (62.3)	0.333
	Hired caregiver	34 (11.0)	11 (8.7)	23 (12.6)	0.356
Smoking[1]	Smoker	8 (2.6)	4 (3.2)	4 (2.2)	0.337
	Non-smoker	217 (70.2)	83 (65.9)	134 (73.2)	
	Ex-smoker	83 (26.9)	39 (30.9)	44 (24.0)	
Healthcare insurance[1]	Universal coverage	118 (38.2)	50 (39.7)	68 (37.1)	0.777
	Civil service welfare	134 (43.4)	50 (39.7)	84 (45.9)	
	Social security for employee	31 (10.0)	14 (11.1)	17 (9.3)	
	Others	23 (7.4)	10 (7.9)	13 (7.1)	

CAM, complementary and alternative medicine; [1]number (%), [2]mean (SD)

Table 2. Underlying diseases of participants

	Total (n=309)	CAM user (n=126)	Non CAM user (n=183)	*p*-value
Diabetes mellitus	92 (29.8)	34 (27.0)	58 (31.7)	0.448
Hypertension	215 (69.5)	98 (77.8)	117 (63.9)	0.012*
Dyslipidemia	120 (38.8)	48 (38.1)	72 (39.3)	0.906
Liver disease	3 (1.0)	0 (0.0)	3 (1.6)	0.273
Gout	16 (5.2)	4 (3.2)	12 (6.6)	0.296
Ischemic heart disease	30 (9.7)	10 (7.9)	20 (10.9)	0.438
Chronic obstructive pulmonary disease	3 (1.0)	1 (0.8)	2 (1.1)	1.000
Asthma	2 (0.6)	0 (0.0)	2 (1.1)	0.515
Peripheral vascular disease	37 (12.0)	10 (7.9)	27 (14.8)	0.077
Chronic kidney disease	10 (3.2)	1 (0.8)	9 (4.9)	0.052
Osteoarthritis	14 (4.5)	6 (4.8)	8 (4.4)	1.000
Depression	11 (3.6)	4 (3.2)	7 (3.8)	1.000
Benign prostatic hypertrophy	13 (4.2)	8 (6.3)	5 (2.7)	0.152
Others	51 (16.5)	21 (16.7)	30 (16.4)	1.000

Number (%); * $p < 0.05$ indicates statistical significance

Table 3. Stroke, its related consequences and treatment of participants

		Total (n=309)	CAM user (n=126)	Non CAM user (n=183)	*p*-value
Type of stroke[1]	Either ischemic or hemorrhagic	285 (92.2)	122 (96.8)	163 (89.1)	0.025*
	Both ischemic and hemorrhagic	22 (7.1)	4 (3.2)	18 (9.8)	
Recurrent stroke[1]	Yes	42 (13.6)	14 (11.1)	28 (15.3)	0.312
	No	261 (84.5)	112 (88.9)	149 (81.4)	
Weakness[1]	Yes	289 (93.5)	126 (100)	163 (89.1)	< 0.001*
	No	20 (6.5)	0 (0)	20 (10.9)	
Duration of stroke (months)[2]		43.6 (50.4)	40.8 (45.5)	45.5 (53.5)	0.412
Side of weakness[1]	Right	140 (45.3)	63 (50.0)	77 (42.1)	0.290
	Left	130 (42.1)	58 (46.0)	72 (39.3)	
	Both	19 (6.1)	5 (4.0)	14 (7.7)	
Neglect[1]	Yes	86 (27.8)	34 (27.0)	52 (28.4)	0.897
	No	220 (71.2)	90 (71.4)	130 (71.0)	
Swallowing function[1]	Can do	290 (93.9)	122 (96.8)	168 (91.8)	0.137
	Need help	18 (5.8)	4 (3.2)	14 (7.7)	
Communication[1]	Communicable	281 (90.9)	117 (92.9)	164 (89.6)	0.421
	Uncommunicable	28 (9.1)	9 (7.1)	19 (10.4)	
Spasticity[1]	Yes	186 (60.2)	93 (73.8)	93 (50.8)	< 0.001*
	No	121 (39.2)	33 (26.2)	88 (48.1)	
Bladder incontinence[1]	Controlled	259 (83.8)	109 (86.5)	150 (82.0)	0.190
	Cannot control	45 (14.6)	14 (11.1)	31 (16.9)	
Bowel incontinence[1]	Controlled	251 (81.2)	102 (81.0)	149 (81.5)	0.149
	Cannot control	36 (11.7)	10 (7.9)	26 (14.2)	
Constipation[1]	Yes	24 (7.8)	15 (11.9)	9 (4.9)	0.030*
	No	285 (92.2)	111 (88.1)	174 (95.1)	
Pain[1]	Yes	120 (38.8)	56 (44.4)	64 (35.0)	0.092
	No	175 (56.6)	64 (50.8)	111 (60.7)	
BADLs[1]	Independent	122 (39.5)	48 (38.1)	74 (40.4)	0.773
	Partially independent	148 (47.9)	61 (48.4)	87 (47.5)	
	Dependent	37 (12.0)	17 (13.5)	20 (10.9)	
Walking[1]	Ambulator	222 (71.8)	90 (71.4)	132 (72.1)	0.897
	Non- ambulator	86 (27.8)	36 (28.6)	50 (27.3)	
Main treatment[1]	Surgery	48 (15.5)	16 (12.7)	32 (17.5)	0.268
	Antiplatelet	208 (67.3)	88 (69.8)	120 (65.6)	0.461
	Tracheostomy	9 (2.9)	3 (2.4)	6 (3.3)	0.743
	Others	35 (11.3)	13 (10.3)	22 (12.0)	0.717
Rehabilitation program[1]	Yes	263 (85.1)[#]	120 (95.2)	143 (78.1)	< 0.001*
	At hospital	188 (60.8)	88 (69.8)	100 (54.6)	0.009*
	At home	138 (44.7)	58 (46.0)	80 (43.7)	0.727
	No	44 (14.2)[#]	5 (4.0)	39(21.3)	

BADL, basic activities of daily living; [1]number (%), [2]mean (SD); * $p < 0.05$ indicates statistical significance; [#]two missing data

non-CAM user. Patients with a history of receiving rehabilitation program tended to be a CAM user (Table 3) ($p < 0.001$).

Figure 1 shows the types of CAM used. The most common types of CAM used were Thai massage (56.3%), acupuncture (44.4%) and traditional Thai herb and medication (36.5%). Most CAM users used 1-3 types of CAM. The average number of CAM type used was 1.96 (range 1-10). Among the CAM users, there were 54 (42.9%) using one type, 41 (32.5%) using two types and 23 (18.2%) using three types of CAM.

Figure 2 shows the reasons for using CAM. The top three most common reasons were muscle strength improvement, spasticity reduction, and walking ability improvement whereas health conditions significantly related to CAM use were spasticity and constipation as shown in Table 4. The majority of CAM users got information about CAM from friends or relatives (58.7%), doctors or health care providers (23.8%), other people (14.3%), media (television and newspaper) (11.9%), internet (4.8%) and personal belief (3.4%). The monthly cost of CAM therapy was less than 1000 baht (40.5%), between 1,001-5,000 baht (38.9%), between 5,001-10,000 baht (7.1%), between 10,001-30,000 baht (4.8%) and over 30,000 baht (2.4%). In addition, 16.7% of CAM users experienced complications such as bruises (23.8%) and edema (9.5%). The CAM users rated as satisfied (48.4%), very satisfied (19.0%), neutral (27.0%) and unsatisfied (4.8%).

Discussion

The prevalence of CAM users among stroke survivors in this study was 40.8% which fell in the range of the previously reported rates, 26.5%-67%.[7-11] The difference in prevalence rate may be attributed to post-stroke duration, variety of CAM, accessibility to CAM, cost of therapy, reimbursement system and belief including knowledge of traditional medicine of each country or area. Thailand is the country which

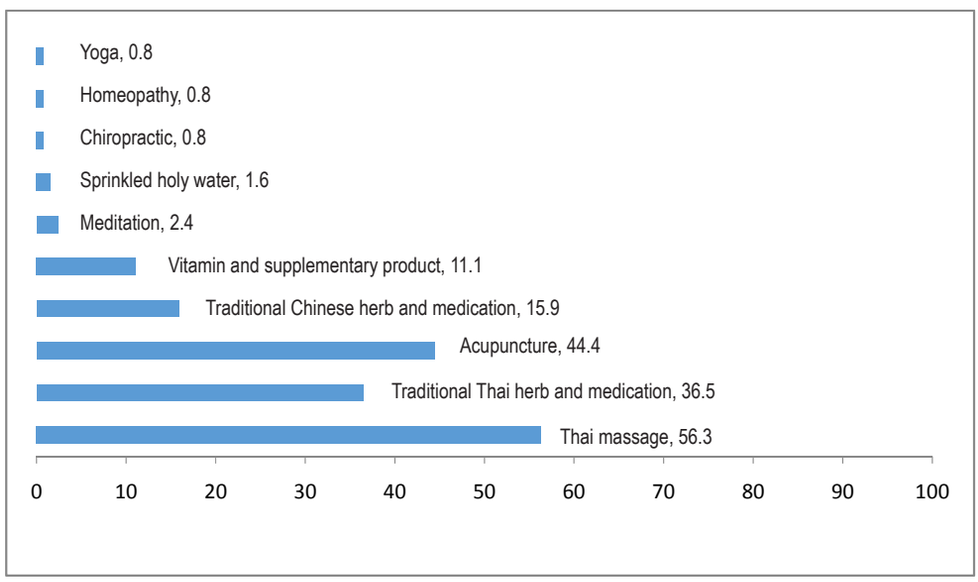

Figure 1. Types of CAM used in percentage

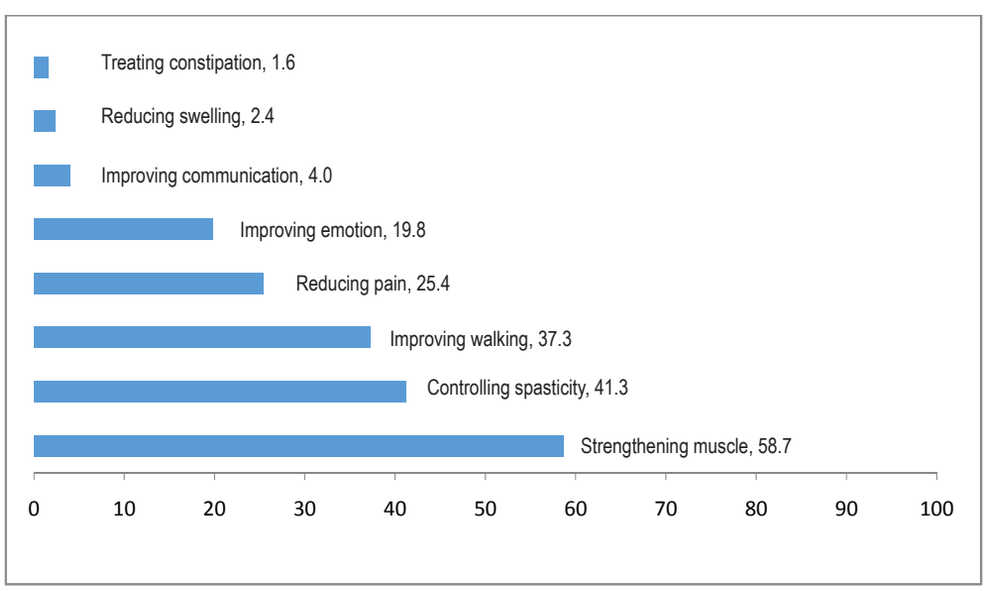

Figure 2. Reasons of using CAM in percentage

Table 4. Types of CAM used for muscle strengthening, improving walking, controlling spasticity and treating constipation

CAM Type	Strengthening muscle	Improving walking	Controlling spasticity	Treating constipation
Thai Massage	34 (45.9)	27 (57.4)	54 (58.1)	10 (66.7)
Traditional Thai herb and medication	30 (40.5)	24 (51.1)	34 (36.6)	6 (40.0)
Acupuncture	43 (58.1)	21 (44.7)	44 (47.3)	9 (60.0)
Chinese massage	3 (4.1)	-	3 (3.2)	-
Traditional Chinese herb and medication	15 (20.3)	7 (14.9)	16 (17.2)	1 (6.7)
Vitamin and supplement	7 (9.5)	6 (12.8)	8 (8.6)	-
Meditation	3 (4.1)	2 (4.3)	1 (1.1)	-
Sprinkled holy water	1 (1.4)	-	2 (2.2)	-
Chiropractic	1 (1.4)	1 (2.1)	1 (1.1)	-
Homeopathy	1 (1.4)	1 (2.1)	1 (1.1)	-
Total	74 (100.0)	47 (100.0)	93 (100.0)	15 (100.0)

Number (%)

has variety of culture. Thai population is composed mainly of Thai ethnic and Chinese ethnic. This is why the most common types of CAM used were Thai massage (56.3%), acupuncture (44.4%), traditional Thai herb and medication (36.5%) and traditional Chinese herb and medicine (15.9%). The finding that showed massage was the most frequently used CAM was consistent with the previous report by Kadir in Malaysia.[10] Acupuncture, part of traditional Chinese medicine, was also popular like the study of Shah in the United States of America.[9] In our study, about 90% of CAM users used 1-3 types of CAM while 40% used only one type of CAM.

About comorbidities, our study revealed that those with hypertension were likely to be CAM users, same as the previous research from India.[7] Moreover, some with chronic kidney disease (CKD) used CAM, this indicated that they were not aware of the potential toxicity of herbs prescribed. Therefore, healthcare providers should be aware of non-prescription herbal medications and warn those with CKD to avoid toxicity.

Conditions that were significantly related to CAM users were spasticity and constipation. Spasticity is a common consequence of stroke and usually impairs functional outcome. Constipation is another health condition seldom mentioned. Top five reasons for using CAM were strengthening muscle, controlling spasticity, improving walking ability, reducing pain and improving emotion. These suggest that stroke patients suffer from both physical and psychological problems and need holistic approach. Controlling spasticity, strengthening muscle power and improving walking are aimed at correcting motor impairments. Sorted by descending order, Thai massage, acupuncture and traditional Thai herb and medication were CAM frequently used in spasticity (Table 4). Constipation was reported to be a common gastrointestinal problem in stroke survivors, about 20-30%.[12-14] Its incidence was high during rehabilitation phase, 48-79%.[15,16] In our study, constipation was found to be a significant health condition leading to using CAM but its percentage in our study was only 7.5%, rather low compared to the previous reports,[12-16] suggesting that constipation might be neglected but requires treatment.

Interesting findings from our study, 85% of stroke patients received rehabilitation program and nearly all (95%) having a hospital-based rehabilitation (95%) tended to be CAM users. They usually had more impairment that required inpatient rehabilitation service. However, length of hospital stay was usually short and some degrees of impairments/disabilities remained at discharge which might not meet stroke survivors' satisfaction. Therefore, they seek other treatments including CAM to improve their conditions. Moreover, a low monthly cost of CAM treatment may be one important factor for high prevalence of CAM users. Regarding healthcare insurance in Thailand, over 80% of participants in our study were under universal coverage and civil welfare schemes which provide free health services including TTM and acupuncture. And, this might be another reason of choosing CAM. Another aspect is that friends or relatives had more influence than doctors or health care providers in choosing CAM treatments. But considering about the potential growth of social media and internet, the social media and internet might have more roles in the future.

Complications from CAM used in our study were only minor such as bruise and edema. Bruise was most commonly found and corresponded with the most common CAM used, Thai massage and acupuncture. In addition, stroke survivors usually receive antiplatelet medication and minor trauma could cause bruise. However, the study did not explore about the cause of edema. And this should be the point of interest to explore more in future CAM research especially in patients with cardiac, renal and or hepatic impairment who are prone to develop edema.

There are limitations of this study. It was done in a university hospital; hence, the results might not be generalizable to stroke survivors in other regions of the country. Satisfaction in CAM was asked but how much improvement after receiving CAM was not explored.

In conclusion, the prevalence of CAM use among Thai stroke patients was about 40%. The most common types of CAM used were Thai massage, acupuncture, traditional Thai and Chinese herbs and medications. Significant

related factors of CAM use were spasticity and constipation. These problems should be considered as essential problems among stroke patients.

Disclosure

The authors report no conflicts of interest.

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Original Article

Long-term Follow-up of Spinal Cord Injured Patients with Vesicoureteral Reflux

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ABSTRACT

Objectives: to investigate the management of VUR, outcomes after treatment and factors associated with VUR outcomes in SCI patients.

Study design: Retrospective data collection

Setting: Maharat Nakhon Ratchasima Hospital

Subjects: Spinal cord injured patients admitted to the Rehabilitation ward between August 2008 and July 2019.

Methods: The medical records of 59 spinal cord injured (SCI) patients with 81 vesicoureteral reflexes (VUR) admitted to our hospital between August 2008 and July 2019 with minimum one-year follow-up were reviewed retrospectively. General demographics, urological information, including bladder management, medications, urodynamic studies, eGFR, UTI, calculi and imaging, including hydronephrosis, bladder deformity and VUR grading, were investigated. Grading of VUR during follow-up were compared to the initial assessment and classified into good (transient or improved) vs poor (stable or progress) outcomes. Bivariate analysis was performed to examine an association between urological variables and good or poor outcomes.

Results: The majority of VUR (83%) developed within 4 years after SCI. Before VUR was detected, only 23.7% of the patients received antimuscarinic medication and the most common bladder management was indwelling catheterization (69.5%). Management post-VUR included indwelling catheterization (83.1%), antimuscarinics (98.3%) and antibiotics (72.7%). VUR outcomes were noted to be transient in 23.7%, improved in 30.5%, stable in 18.6%, and progressive in 27.1%. One patient had eGFR that revealed CKD stage 5 which needed hemodialysis. Three patients had impaired renal function assessed by renal scan. Follow-up VUR was categorized into 2 groups (good vs poor outcomes). Patients with low bladder compliance showed a significant association with poor outcome. High detrusor pressure (Pdet > 40 cmH_2O) tended to have poor outcome but did not reach statistical significance. Indwelling catheterization and antibiotic prophylaxis for management of VUR did not show a significant difference in outcomes.

Conclusion: VUR remains an important complication in SCI-patients, leading to upper urinary tract deterioration. About half of VUR patients improved after conservative treatment. Bladder compliance was a factor associated with VUR outcome. Indwelling catheterization or antibiotic prophylaxis did not prevent progression of VUR. Early urological management and regular urological evaluation should be performed in SCI patients.

Keywords: spinal cord injuries, vesico-ureteral reflux, hydronephrosis, urodynamics, long-term outcome

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Introduction

Vesicoureteral refluxes (VUR) is one of the complications in spinal cord injured (SCI) patients with neurogenic lower urinary tract dysfunction (NLUTD) leading to upper urinary tract (UUT) deterioration. The etiology of VUR in NLUTD is not well estabished, however several studies have purposed the etiology of VUR as a combination of recurrent urinary tract infection (UTI), sustained high detrusor pressure, sacculation associated with the ureteric orifice[1] and neurogenic dysfunction of vesico-ureteric junction and trigone.[2] The management of VUR is usually complex and individualized.[3] Several studies reported the use of antibiotic prophylaxis[4,5] and indwelling catheterization for management of VUR.[6,7] However, some studies have shown antibiotic prophylaxis[8,9] and catheter[6,7] does not protect the kidney from damage. In Thailand, the prevalence of VUR was 11-24%.[10-12] with conflicting management. In our sevice, many patients with VUR were treated with indwelling catheterization and antibiotic prophylaxis but many of them still had VUR progression, pyuria and UTI. The objective of this study was to investigate the management of VUR, outcomes after treatment and factors associated with VUR outcomes in SCI patients.

Methods

We retrospectively reviewed the electronic medical records and imaging results of all SCI with VUR admitted to the Rehabilitation Ward, Maharat Nakhon Ratchasima

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Hospital between August 2008 and July 2019. The yearly urological check-up protocol in our hospital consists of imaging including ultrasonography, intravenous pyelogram (IVP), cystography or voiding cystourethrography (VCUG), laboratory tests including serum creatinine, urinalysis and urodynamics or cystometry. The protocol can be adapted as necessary due to each individual's condition. Data from the initial detection of VUR to the last follow-up were studied. Because the urological check-up protocol in our hospital is yearly, patients with follow-up time of less than one year were excluded. The data from each check-up were divided into 3 parts which were general demographics, urological, and imaging data.

The general demographics including gender, age at onset, level of injury, completeness and cause of spinal cord injury, time interval from SCI to VUR, age at VUR and ambulatory level were recorded. The previous study stated that injury at T10-L2, where the sympathetic intermediolateral nuclei that mediate sphincter relaxation during voiding are located, is associated with the highest incidence of VUR.[13] The authors categorized level of injury into 3 groups: cervical to thoracic 9, thoracic 10 to lumbar 2 and lumbar 3 to sacral. The ambulatory level was classified into ambulatory (score of 3 or greater) and non ambulatory (score less than 3) according to the Mobility for Moderate Distances subscale of the Spinal Cord Independence Measure version III (SCIM III).[14]

The urological data, including type of bladder management: indwelling catheterization, clean intermittent catheterization (CIC), voluntary voiding with continence, triggered reflex voiding with incontinence and voiding plus CIC; antimuscarinic medication used; a history of UTI and upper tract calculi (renal and ureteric calculi), were investigated. Urodynamics or cystometry were performed in some patients. The parameters including bladder compliance, maximum cystometric capacity and detrusor pressure were recorded. Bladder compliance was defined by dividing the change in volume by the change in detrusor pressure, where < 20 mL/cmH_2O considers low bladder compliance.[15] Bladder capacity less than 200 mL was identified as small bladder capacity.[16] Detrusor pressure more than 40 cmH_2O at filling phase was defined as high detrusor pressure (Pdet > 40).[17] Renal functions were evaluated using estimated glomerular filtration rate (eGFR) calculated from CKD-EPI equation and classified into chronic kidney disease (CKD) staging 1-5.[18] Impaired renal function was also identified by renal scan or small kidney from ultrasound.

The imaging data including hydronephrosis, bladder deformity, VUR side (unilateral or bilateral) and grading of VUR were assessed by radiologists. International reflux committee study criteria to grade the reflux were used.[19] Hydronephrosis was detected from ultrasonography or IVP whereas VUR was detected from voiding cystourethrography (VCUG) or cystography. Bladder deformity was classified into 4 grades (grade 0 to 3) according to Ogawa T's classification.[20] For statistical analysis, bladder deformity was grouped into low (grade 0-1) and high grade (grade 2-3) deformity.

The urological data and imagings were examined at every check-up. Grading of VUR at final follow-up was compared to the initial VUR and classified into 4 levels; transient if VUR disappeared by the next evaluation; improved if VUR improved in grading or from bilateral to unilateral; stable if no change in grade of VUR; and progressive if grading of VUR worsened or changed from unilateral to bilateral. Hydronephrosis and bladder deformity were compared and classified into 3 levels; improved, stable, and progressive. VUR at follow-up was defined into good and poor outcomes for statistical analysis. A good outcome was achieved when follow-up VUR was transient or improved. A poor outcome was identified when follow-up VUR was stable or progressive.

Data were analysed using descriptive statistics for demographic and urological data. Bivariate analysis was performed to examine an association between urological variables and good or poor outcomes, using Student's t-test, Fisher's exact test, Chi-square and Mann-Whitney U test, as appropriate. $p < 0.05$ was considered to indicate significance.

Remark: The present study was approved by the Ethics Committee of Maharat Nakhon Ratchasima Hospital (No. 084/2019)

Results

Sixty-three SCI patients had VUR but 4 patients were excluded due to no follow-up VUR data for comparison. Fifty-nine SCI patients with 81 renal units of VUR were evaluated. The majority of VUR (83%) developed within 4 years after SCI. The median time interval from SCI to VUR was 19 months (range, 2-180). The mean age at the onset of SCI and VUR were 37.8 years (range, 3-75) and 40.4 years (range, 7-77) respectively. Eighty-six percent were males. Thirty-seven percent of the patients had SCI at cervical to T9, 42% T10 to L2 and 20% L3 to sacral level. Sixty-six percent had complete lesion, and 73% of injuries were caused by trauma. There were 22% who could walk for a moderate distance. The clinical characteristics of the studied population are shown in Table 1. Of 59 patients, 39 (75%) had urodynamic/cystometry results. Just about half of this group (51.3%) had Pdet > 40, 74.4% had low bladder compliance and 43.6% had small bladder capacity (< 200 mL). Eighty-five percent had a history of UTI and 3.4 percent had upper tract calculi. Eleven patients (18.6%) had impaired renal function. Three patients were assessed by renal scan and 8 patients were assessed by ultrasound. CKD staging from eGFR are shown in Table 1.

The urological data of the patients at which first VUR was detected are shown in Table 2. The most common bladder management was indwelling catheterization (69.5%) followed by triggered reflex voiding with incontinence (20.3%) and voiding plus CIC (10.2%). Antimuscarinics were prescribed to 23.7% of the patients. The reflux was bilateral in 22

Table 1. Clinical characteristics of the patient population (n=59)

Characteristics	Value
Mean age at onset of SCI (years)[1]	37.8 (17.9)
Mean age at onset of VUR (years)[1]	40.4 (17.7)
Time interval from SCI to VUR (months)[2]	19 (10-37, 2-180)
Gender: male[3]	51 (86.4)
Level of spinal cord injury[3]	
Cervical - T9	22 (37.3)
T10 - L2	25 (42.4)
L3 - Sacral	12 (20.3)
Complete lesion[3]	39 (66.1)
Cause of spinal cord injury: Trauma[3]	43 (72.9)
Ambulatory level: ambulatory[3]	13 (22.0)
Urodynamics data[3]	
Pdet > 40 cmH_2O (n=39)	20 (51.3)
Low bladder compliance (n=39)	29 (74.4)
Cystometric capacity < 200 mL (n=39)	17 (43.6)
UTI[3]	50 (84.8)
Upper tract calculi[3]	2 (3.4)
eGFR[2]	112 (92-131, 7-169)
CKD staging[3]	
Stage 1	45 (76.3)
Stage 2	6 (10.2)
Stage 3	6 (10.2)
Stage 4	1 (1.7)
Stage 5	1 (1.7)
Impaired renal function[3]	11 (18.6)

T, thoracic; L, lumbar; VUR, vesicoureteral reflux; UTI, urinary tract infection; eGFR, estimated glomerular filtration rate; CKD, chronic kidney disease
[1]Mean (SD); [2]median (IQR, range); [3]number (%)

Table 2. Urological data of the patient population at first VUR detection

Characteristics	Value
Bladder management before VUR[1]	
Triggered reflex voiding with incontinence	12 (20.3)
Void + CIC	6 (10.2)
Indwelling catheterization	41 (69.5)
Antimuscarinics[1]	14 (23.7)
VUR on initial investigation[1]	33 (55.9)
VUR side[1]	
Unilateral	37 (62.7)
Bilateral	22 (37.3)
Grading of VUR[1] (n=81 units)	
Grade I	19 (23.5)
Grade II	12 (14.8)
Grade III	40 (49.4)
Grade IV	6 (7.4)
Grade V	4 (4.9)
Bladder deformity[1]	
Grade 0-1	37 (62.7)
Grade 2-3	22 (37.3)
Hydronephrosis[1]	15 (25.4)

CIC, clean intermittent catheterization; VUR, vesicoureteral reflux
[1]Number (%)

(37.3%) and unilateral in 37 patients (62.7%). Thirty-three patients (56%) had VUR on initial investigations; 25% had hydronephrosis.

The urological data of post VUR are shown in Table 3. After VUR was detected, there were 16 patients (27.12%) who had their bladder management changed. Indwelling catheterization was the most common form of bladder management and increased when compared to when VUR was first detected (69.5% to 83.1%). Suprapubic catheterization was performed in one patient. Almost all patients (98.3%) received antimuscarinics and 73% received antibiotic prophylaxis as treatment for VUR. The time interval from the first VUR to the last follow-up was 33 months (range 12-108). On follow-up, VUR had improved in 54% (23.7% transient, and 30.5% improved) and had not improved in 46% (18.6% stable, and 27.1% progressive). However, hydronephrosis and bladder deformity improved only 13.6% and 20.7% respectively. A focus on UUT deterioration from CKD stage 3-5 and abnormal renal scan, reveals there were 11 patients who had UUT deterioration. Eight patients (72.7%) used indwelling catheterization in this impaired renal function group. About half of the patients who had impaired renal function had transient or improvement of VUR on follow-up whereas almost all of the patients were stable and progressive on ultrasound and bladder deformity. Two patients died (1 from UTI septic shock and 1 from pulmonary tuberculosis), and 1 patient required hemodialysis. One patient who had CKD stage 5 and was on hemodialysis used an indwelling catheter for bladder management. He had VUR on his first urological evaluation at 10 months after SCI and then VUR had disappeared on the next evaluation. But the ultrasound showed progression from normal renal calyx to hydronephrosis and bladder

Table 3. Urological data of post VUR

Characteristics	Value
Bladder management post VUR[1]	
Voluntary voiding with continence	1 (1.7)
Triggered reflex voiding with incontinence	5 (8.5)
Void + CIC	4 (6.8)
Indwelling catheterization	49 (83.1)
Medication post VUR[1]	
Antimuscarinic	58 (98.3)
Antibiotic prophylaxis	43 (72.7)
VUR onlast follow-up[1]	
Transient	14 (23.7)
Improved	18 (30.5)
Stable	11 (18.6)
Progressive	16 (27.1)
Hydronephrosis on last follow-up[1]	
Improved	8 (13.6)
Stable	38 (64.4)
Progressive	13 (22.0)
Bladder deformity on last follow-up[1] (n=58)	
Improved	12 (20.7)
Stable	32 (55.2)
Progressive	14 (24.1)
Time interval from 1st VUR to last follow-up[2] (month)	33 (19-64, 12-108)

CIC, clean intermittent catheterization; VUR, vesicoureteral reflux
[1]Number (%); [2]median (IQR, range)

deformity progressed from grade 1 to 3.

Follow-up VUR was categorized into 2 groups (good vs poor outcomes). Bivariate associations between variables and outcomes of VUR are shown in Table 4. Patients with low bladder compliance showed significant association with poor outcome. High detrusor pressure (Pdet > 40 cmH_2O)

Table 4. Bivariate associations with outcomes of VUR

Factors	Good outcomes (n=32)	Poor outcomes (n=27)	*p*-value
Age at onset of SCI[1]	35.1 (17.4)	40.9 (18.2)	0.22
Age at onset of VUR[1]	37.25 (17.33)	44.04 (17.65)	0.14
Gender[2]			0.61
Male	27 (84.4)	24 (88.9)	
Female	5 (15.6)	3 (11.1)	
Level of spinal cord injury[2]			
Cervical-T9	12 (37.5)	10 (37.0)	0.58
T10-L2	15 (46.9)	10 (37.0)	
L3-Sacral	5 (15.6)	7 (25.9)	
Completeness of lesion[2]			
Incomplete	8 (25)	12 (44.4)	0.12
Complete	24 (75)	15 (55.6)	
Ambulatory[2]			
Yes	7 (21.9)	6 (22.2)	0.97
No	25 (78.1)	21 (77.8)	
Time interval from SCI to VUR[3]	13.5 (10-34.5)	25 (7-44)	0.48
Duration of follow-up[3]	34 (19-63)	26 (18-66)	0.64
Bladder management before VUR[2]			
Triggered reflex voiding with incontinence	6 (18.8)	6 (22.2)	0.91
Void + CIC	3 (9.4)	3 (11.1)	
Indwelling catheterization	23 (71.9)	18 (66.7)	
Antimuscarinic medication[2]			
Yes	6 (18.8)	8 (29.6)	0.33
No	26 (81.3)	19 (70.4)	
UTI[2]			
Yes	27 (84.4)	23 (85.2)	0.93
No	5 (15.6)	4 (14.8)	
Upper tract calculi[2]			
Yes	2 (6.3)	0	0.19
No	31 (93.8)	27 (100)	
Pdet > 40 cmH_2O[2]	n=19	n=20	
Yes	8 (42.1)	14 (70)	0.08
No	11 (57.9)	6 (30)	
Low bladder compliance[2]	n=19	n=20	
Yes	11 (57.9)	18 (90)	0.02*
No	8 (42.1)	2 (10)	
Cystometric capacity < 200 mL[2]	n=19	n=20	
Yes	7 (36.8)	10 (50)	0.41
No	12 (63.2)	10 (50)	
Hydronephrosis[2]			
Yes	7 (21.9)	8 (29.6)	0.5
No	25 (78.1)	19 (70.4)	
VUR side[2]			
Unilateral	17 (53.1)	20 (74.1)	0.1
Bilateral	15 (46.9)	7 (25.9)	
VUR grading[2]			
Grade I	6 (18.8)	7 (25.9)	0.8
Grade II	5 (15.6)	3 (11.1)	
Grade III	16 (50)	13 (48.2)	
Grade IV	2 (6.3)	3 (11.1)	
Grade V	3 (9.4)	1 (3.7)	

VUR vesicoureteral reflux; CIC, clean intermittent catheterization; UTI, urinary tract infection

[1]Mean (SD), [2]number (%), [3]median (IQR); * statistic significance

Table 4. Bivariate associations with outcomes of VUR (continuted)

Factors	Good outcomes (n=32)	Poor outcomes (n=27)	*p*-value
Bladder deformity[2]	n=31	n=27	
Low grade (grade 0-1)	20 (64.52)	16 (59.26)	0.68
High grade (grade 2-3)	11 (35.48)	11 (40.74)	
Bladder management post VUR[2]			
Voluntary voiding with continence	1 (3.1)	0 (0)	0.33
Triggered reflex voiding with incontinence	1 (3.1)	4 (14.8)	
Void + CIC	2 (6.3)	2 (7.4)	
Indwelling or suprapubic catheterization	28 (87.5)	21 (77.8)	
Antimuscarinic medication after VUR[2]			
Yes	31 (96.9)	27 (100)	0.35
No	1 (3.1)	0	
Antibiotic prophylaxis after VUR[2]			
Yes	23 (71.9)	20 (74.1)	0.85
No	9 (28.1)	7 (25.9)	

VUR vesicoureteral reflux; CIC, clean intermittent catheterization; UTI, urinary tract infection
[1]Mean (SD), [2]number (%), [3]median (IQR)

tends to have poor outcome but does not reach statistical significance. Indwelling catheterization and antibiotic prophylaxis to manage VUR did not show significant difference in outcomes. Focusing on 18 patients who did not use indwelling catheterization before VUR was detected, 12 cases used indwelling catheterization and 6 cases used the same methods after VUR was detected. In the group that changed to indwelling catheterization, there were 6 patients with good outcomes and 6 patients with poor outcomes. In the group that used the same methods, there were 3 patients who had good outcomes and 3 patients who had poor outcomes. Forty-five patients who did not receive antimuscarinics before VUR was detected; 44 patients were prescribed this medication after VUR was detected. There were 25 patients who had good outcomes and 19 patients who had poor outcomes.

Discussion

VUR is one of the most common urological complications following SCI which may lead to upper urinary tract (UUT) deterioration. In Thailand, the prevalence of VUR has been reported at 11-24%.[10-12] In this study, almost all cases of VUR developed within 4 years, consistent with previous studies.[6,7,10,11] However, it could be as short as only 2 months after SCI or as long as 15 years.The Canadian Urological Association guideline recommended that urological evaluation of a patients with a newly acquired SCI should occur within 3-6 months of SCI.[21] The median time interval from SCI to VUR in this study was 19 months (IQR 10-37). Half of the patients had VUR on initial urological evaluation. Early urological management and regular urological evaluation should be performed in SCI patients.

Bladder management in our SCI patients before VUR was diagnosed consisted mainly of indwelling catheterization (69.5%) and triggered reflex voiding with incontinence (20.3%). Indwelling catheterization could not prevent VUR and may instead be the cause of VUR. After VUR was diagnosed, bladder management was switched to indwelling catheterization (83.1%). But it could not prevent VUR progression, which was consistent with previous studies.[6,7] Five patients with VUR used triggered reflex voiding with incontinence and 4 patients used voiding plus CIC. No significant correlation between type of bladder management and VUR outcome was found in this study. Improper bladder management and late urological evaluation in post-acute SCI rehabilitation service remain the problem. It can be challenging to have early urological evaluation and switch the patients from indwelling catheterization and triggered reflex voiding with incontinence to CIC.

Antibiotic prophylaxis was a common means of management for VUR in this study (72.7%); patients with VUR have a high risk of UTI.[22] However, there is still a lack of evidence for its efficacy in adults with SCI. Research in pediatrics, for which there is an extensive body of research in continuous antibiotic prophylaxis, still shows conflicting results.[4,5,8,9] In this study, no association was found between antibiotic prophylaxis and VUR outcome consistent with a previous study in Thailand.[10] Antimuscarinics were prescribed for only 23.7% of cases at the time VUR was diagnosed; but most patients (98.3%) received some after that. We could not find any effect of antimuscarinics on VUR outcome in bivariate analysis.

Detrusor overactivity and bladder compliance were associated with UUT deterioration in many studies.[13,17,23,24] However, in the present study showed that only half ofVUR patients had detrusor overactivity (NDO) (Pdet > 40 cmH_2O), 74.4% had low compliance, and 43.6% had low bladder capacity (< 200 mL). The etiology of VUR in SCI patients ramains unclear. However, there are two etiologies of VUR in SCI patients: primary and secondary.[25] Primay reflux is a congenital anomaly of the ureterovesical junction. One recent study showed 11 of 15 SCI patients with VUR had

congenital displaced ureteral orifices.[25] Secondary reflux is secondary to bladder deformity and loss of bladder compliance leading to anatomic changes, resulting in lack of support of the posterior bladder wall musculature. In this study, no single etiology of VUR was found. We tried to invesigate the factors affecting the outcome of VUR after management. Bladder compliance is the only one factor which had a statistically significant association with the outcome of VUR on long-term follow-up. As mentioned before, there is no single etiology. The keys to improving VUR outcomes are to maintain low detrusor pressure, preservation of adequate bladder capacity and compliance[26] and prevention of recurrent UTI.[22,26]

VUR after conservative management resulted in good outcomes in half of the patients without causing damage to the UUT; this was consistent with a previous study.[22] Poor VUR outcome was not directly associated with UUT deterioration or impared renal function. Less than 20% of VUR patients had impaired renal function, and it did not correlate with VUR progression. The patient who had CKD stage 5 and who was on hemodialysis developed VUR on the first urological check-up and had no VUR on the next evaluation. The results also showed that about half of the patients who had impaired renal function had transient or improvement of VUR on follow-up. Whereas, almost all of the patients were stable and progressive on ultrasound and bladder deformity. We could not clearly explain these findings. Accurate detection of VUR depends on the radiologist, consistent with a previous study, which found that the grading system of VUR varies among doctors especially in middle grades (grade III and IV).[27] The technique of refilling the contracted bladder with contrast medium in SCI patients may be one of the reasons. Because no antireflux surgery was performed in this SCI population, we could not discuss about its efficacy or complications. Previous studies showed good results after surgery.[6,22] However, Wu CQ reported that secondary VUR in NLUTD is less likely to be cured with antireflux surgery independent of technique or surgical approach.[26]

There is a sparse consensus on the urological evaluations in SCI patients.[28] Previous studies recommended yearly ultrasound of upper and lower urinary tract which has a good sensitivity for diagnosing upper tract problems and stones. It is a useful, noninvasive, has no radiation exposure, and is a cost-effective method for routine and long-term follow-up.[28] Bladder deformity and trabeculation from VCUG or cystography were associated with UUT deterioration in previous studies.[12,20] In this study, we found that VUR and hydronephrosis or bladder deformity did not correlate well in all patients. About half of SCI patients with impaired renal function showed VUR improvement on follow-up, the same patients also had worse hydronephrosis and bladder deformity. Not only should the grading of VUR be focused, the shape and trabeculation of bladder and hydronephrosis should be included in urological investigations in SCI patients with VUR. Urodynamic study gives a useful information for proper bladder management and medication. It should be performed at the time of initial evaluation and repeated as appropriate.[21] We did not perform urodynamics in every SCI patients with NLUTD but in recent years the rate of urodynamics/cystometry has been increased in our department. Urodynamics/cystometry was performed in 75% of patients in this study compared to 37.4% in the previous research at the same hospital.[10] Level of SCI, completeness of lesion, ambulatory level did not predict VUR development[10] or progression. Every SCI with NLUTD should have a regular urological check-up to detect early UUT deterioration and ensure proper management.[28-30]

There were some limitations of this study. Firstly, no UTI frequency, urinalysis, or pathogens were recorded. Because UTI is an important factor correlated with VUR and may be a cause of VUR,[22,26] more details of UTI should be investigated in future researches. Secondly, the small number of patients means comparisons between the 2 groups could not reach statistical significance or may not be reliable. Thirdly, urodynamics/cystometry was not performed in the same period that VUR was detected and not every patient had results; it may be interfered with data analysis. Lastly, this study included patients with at least one year follow-up, some of them only had data from two urological check-ups for comparison. A longer follow-up period of is suggested in the future.

In conclusion, VUR remains an important complication in SCI patients, leading to UUT deterioration. About half of VUR were improved after conservative treatment. Bladder compliance was a factor associated with VUR outcome. Indwelling catheterization or antibiotic prophylaxis did not prevent progression of VUR. Early urological management and regular urological evaluation should be performed in SCI patients.

Disclosure

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วัตถุประสงค์ (กรรมการสมาคม)

1. ส่งเสริมวิชาการ, การวิจัย, การค้นคว้า, การแลกเปลี่ยนความรู้กับสาขาวิชาที่เกี่ยวข้อง
2. เผยแพร่ความรู้วิชาเวชศาสตร์ฟื้นฟูแก่แพทย์, บุคลากรทางการแพทย์และประชาชนทั่วไป
3. ส่งเสริมให้มีจริยธรรมและความสามัคคีอันดีในกลุ่มแพทย์และบุคลากรอื่นที่ปฏิบัติงานด้านเวชศาสตร์ฟื้นฟู
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5. สนับสนุนและธำรงไว้ซึ่งชื่อเสียงเกียรติคุณของสมาชิกและสาขาวิชาชีพนี้
6. ไม่เกี่ยวข้องกับการเมือง
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