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Content

Assistive Devices/Technology

In medical rehabilitation, there are main three principles: restoration, compensation and adaptation. Whenever neuro-musculoskeletal or movement function is impaired, it should be restored, generally with exercise therapy. When a part of the body has impaired function, one should learn how to use a remained good/normal part to compensate the lost function e.g. using the left hand instead of the impaired right hand for self-care activities. And, when a body part is amputated e.g. a limb loss, an artificial limb is prescribed and an amputee is trained how to use a prosthesis to perform both basic and instrumental activities of daily living.

The World Health Organization has emphasized the importance of assistive device/technology such as a prosthesis or an orthosis; whether acquired commercially, modified or customized, it is used to increase, maintain or help a person to perform a task or activity. According to the Community-based Rehabilitation (CBR) which is a strategy within general community development for rehabilitation, equalization of opportunities, poverty reduction, and social inclusion of people with disabilities, an assistive device/technology is a necessary product mentioned in the CBR matrix. Prostheses and orthoses are counted as assistive devices/technology that those with disabilities need to improve their performance. However, PO services are limited in the ASEAN economic community and researches on PO have been seldomly published in this Journal.

In Thailand, the Sirindhorn School of Prosthetics and Orthotics was established in 2002 and later certified by the International Society of Prosthetists and Orthotists (ISPO). The school has produced a certain number of certified prosthetists and orthotists (CPO) who provide PO services not only in Thailand but also in other low to middle income countries in Asia. For continuous improvement, service effectiveness and efficiency should be monitored, evaluated and reported. A study from Sirindhorn School of PO about relationship between service provision and the use of trans-tibial prostheses is published in this issue. Moreover, the Prosthetic Profile of the Amputee (PPA), a common measurement tool used in prosthetic services and research, was translated into Thai, and validity and reliability of the Thai version of the PPA is also published in this issue.

Besides prostheses, orthoses are commonly prescribed by rehabilitation physicians (physiatrists). Nowadays, commercially prefabricated orthoses provide easier access for those who need them. In this issue, there are two interesting articles on orthoses. One is a study on effectiveness of prefabricated silicone toe separator on hallux valgus, and the other study is the effect of obesity on thoracolumbar flexion control of Jewett Hyperextension brace. These two articles point out factors related to effectiveness and limitation of prefabricated orthoses. A proper size of an orthosis should be properly selected to make a person accept and use it without inducing complications. Moreover, another interesting article is about a school screening program for scoliosis. With such screening, one could early detect those who need a proper spinal orthosis and exercise; and, a brief educational video does improve correct knowledge about scoliosis among pupils at school.

The above-mentioned articles published in this issue remind us that rehabilitation physicians' role is not only to restore functions but also to prevent impairment and disability that may occur if not early detected or treated properly. And one of rehabilitation treatment which can be used/prescribed to improve functions is an assistive device/technology.

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Editor, ASEAN J Rehabil Med

Original Article

Validity and Reliability of the Thai version of the Prosthetic Profile of the Amputee (PPA)

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ABSTRACT

Objectives: To test psychometric properties in terms of validity and reliability of the Thai version of the Prosthetic Profile of the Amputee (PPA).

Study design: Descriptive cross-sectional design.

Setting: Outpatient prosthetic service of the Department of Rehabilitation Medicine at Siriraj Hospital, Suratthani Hospital, Songklanagarind Hospital and Maharaj Nakhonratchasima Hospital.

Subjects: Three hundred and twenty-one unilateral lower-extremity amputees who used prostheses were recruited for questionnaire interview.

Methods: The original PPA questionnaire was asked for permission from the developer to be translated into Thai. A forward/backward translation was done by two different groups of one physiatrist and one translator. Both English versions were approved consistency by an American prosthetist. A group of content expert composed of one physiatrist specialized in prosthetics, two prosthetists and one amputee verified the final version. After that the amputees were enrolled and interviewed with the PPA, Thai version. The data from the PPA, Thai version were tested for construct validity, and discrimination type, in the Locomotor Capability Index (LCI) domain by comparing scores between transfemoral and transtibial groups, and comparing scores between groups in other domains. The test-retest reliability of other domains was also analyzed.

Results: The PPA-Thai version has test-retest reliability when tested in some domains such as percentage of locomotor activity, walking distance with the prostheses, walking attention, self-care activities, and acceptance to amputation. In terms of construct validity, and discrimination type, the LCI domain has ability to discriminate amputees with regard to compliance with prosthetic use, walking distance, walking attention, limitation of walking; however, the LCI domain had no evidence of discrimination between transtibial and transfemoral amputees' walking ability.

Conclusion: The Thai version of the Prosthetic Profile of the Amputee (PPA) has test-retest reliability, and the Locomotor Capability Index (LCI) domain has discrimination validity to differentiate amputees with different ambulation levels but not with levels of amputation.

Keywords: amputee, prostheses, locomotion, reliability, validity

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Introduction

Lower-extremity amputation is a common condition bringing patients to rehabilitation service. Common causes of amputation are traumatic injury and peripheral vascular disease. The rehabilitation program requires multidisciplinary approach including medical management, physical exercise and prosthetic prescription to achieve highest functionality.[1] The prosthetic service should start from pre-amputation period, but most of care usually begins after amputation when the wound is completely healed. Prosthetic management requires information regarding to patients' profile such as underlying medical conditions, physical conditioning, previous functional level and careers which amputees need to return to.[2] However, we had never had collected proper data-base of our amputees and their prosthetic uses. In order to develop such database, information such as amputees' background, functional performance, and quality of life, should be collected.[3]

The Prosthetic Profile of the Amputee (PPA) questionnaire established in 1994 is a common measurement tool used in prosthetic service and research.[4] This questionnaire could be completed in 30 minutes.[5] The questionnaire consists of 44 questions divided into 6 domains: 1) physical condition, 2) prosthesis, 3) prosthetic use, 4) environment, 5) leisure activities and 6) general information. In the domain of prosthetic use, there is a subset of locomotion capability index (LCI) which consists of 14 questions[4,5] describing mobility skills with prostheses inside and outside the house. Seven questions are basic mobility skills while the other seven questions are advanced mobility skills. Each question is rated as unable, able with help, able with supervision and able to do the activity alone. The LCI total score is 42. To test construct validity and convergence type, "prosthetic use" of the PPA questionnaire was compared with "ability to do

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daily function" of the Reintegration to Normal Living (RNL) questionnaire and found moderate convergence of these two questionnaires (r = 0.56, $p < 0.01$).[4] And when comparing "perceptions of self" in the RNL to "acceptance of amputation and prosthesis" in the environment domain of the PPA, somewhat good convergence (r = 0.64, $p < 0.01$) was found. In terms of reliability testing, the PPA had excellent test-retest reliability and the intraclass coefficient was 0.92 ($p < 0.001$).[5]

Regarding the locomotor capability index (LCI) which is a subset of the prosthetic use domain in the PPA questionnaire, it consists of 2 groups of 7 questions measuring basic and advance mobility.[4] The intraclass coefficient of the LCI was 0.80 ($p < 0.001$)[4,5] and had good internal consistency with Cronbach alpha of 0.95.[4,5]

In terms of concurrent validity testing, the LCI was compared to the Functional Independence Measurement (FIM) and the Amputee Activity Score (AAS), and there was concurrent validity (X2 = 57.28, $p < 0.01$).[5] Regarding test-retest reliability, the LCI had excellent reliability (intraclass coefficient = 0.80).[5] It takes 5 minutes to complete the LCI subset questions.[6]

According to the above-mentioned, we decided to use the PPA questionnaire to provide a comprehensive database to improve our prosthetic service and to decrease cost of prosthetic management. However, this questionnaire is in English and must be translated into Thai, adapted and tested for psychometric properties. The objective of this study was to estimate test-retest reliability of the Thai version of the PPA questionnaire and to evaluate validity in the LCI domain of the PPA in terms of discrimination property.

Methods

This study was conducted at 4 outpatient amputee clinics at Siriraj Hospital, Surattani Hospital, Songklanakarind Hospital and Maharaj Nakhonratchasima Hospital. All are tertiary care hospitals providing prosthetic service to amputees. This study protocol was approved by the Ethical Committee of Faculty of Medicine Siriraj Hospital. Every parti-cipant had to complete a written-informed consent before completing the questionnaire. To be noted, this study used the same questionnaire as another study titled "Factors affecting returning to work of unilateral lower-extremity amputees who receiving prostheses".

Participants

Unilateral lower-extremity amputees with below-knee, knee or above-knee amputation, who visited outpatient clinics for maintenance or prosthesis replacement, were invited to the study. Nurses at the clinic gave them information for a written consent. Inclusion and exclusion criteria were as follows:

Inclusion criteria: at least 18-year old, using their prostheses for at least one year, working or studying before amputation, being able to understand and speak Thai.

Exclusion criteria: congenital limb deficiency, medical conditions causing weakness of any extremities which interfering with putting on or walking with the prostheses, other unstable medical conditions such as cancer, uncontrolled cardiac diseases that disturbing functions; active psychiatric conditions, and communication problems.

Based on the study of William C. Miller, et al,[7] the mean LCI score in the transtibial amputee group was 26 and in the transfemoral amputee group was 23, the standard deviation was 8, and the difference between LCI scores was 3. Using nQuery Advisor version 7.0, a calculated sample size per group was 113 which would have 80% power to detect a difference in means of 3 assuming that the common standard deviation is 8 using a 0.05 two-sided significance level. And to prevent incomplete data collection, 30% of cases were reserved, and the total number of cases collected was 322.

For test-retest reliability, based on the aforementioned study,[7] a calculated sample size was 51, when an expected intraclass correlation was 0.8 and a two-sided 95% confidence interval computed using a large sample normal approximation for an intraclass correlation based on 2 intra-raters that extended about 0.1 from the observed intraclass correlation. A total number of amputees were approximated up to 60 in total or 30 cases per group.

Study protocol

Before translation, the researchers asked for permission from the developer of the PPA questionnaire.[4] Then the original PPA written in English was translated into Thai by an experienced physiatrist and a professional translator. And a back-translation into English was performed by another professional translator and a physiatrist. The back-translated version and the original English version were then compared and approved by an American native speaker prosthetist that both versions were compatible.

A committee of one physiatrist specialized in prosthetics, two prosthetists and one amputee reviewed the Thai version and provided one change in content to match with the Thai culture[8] i.e., "walking for one block of building" to be "walking for a distance between two adjacent bus stops".

The enrolled amputees were then interviewed by physiatrists, prosthetists or rehabilitation nurses to complete the PPA, Thai version. All interviewers were trained to interview with the questionnaire. For test-retest reliability, 30 amputees from each group, the transtibial and the transfemoral groups, were selected by simple randomization, and interviewed again two weeks after the first interview. Those who could not return to a hospital for a face-to-face interview would be interviewed by telephone by the same interviewer.

Statistical analysis

Descriptive data such as demographic data are presented as mean (standard deviation, SD) or median and inter-quartile

range and Cohen effect size. For discrimination test, this validity was analyzed with unpaired t-test (normality), Mann-Whitney U-test (non-normality), and analysis of covariance by using age and causes of amputation as covariate. Regarding test-retest reliability, intraclass correlation coefficient was applied for total score evaluation, while Cohen Kappa was used in case of binary data (nominal scale) and weighted Kappa was used for ordinal data (ordinal scale). P-value less than 0.05 was considered statistically significant. All data analyses were performed using SPSS Statistics version 18.0 (SPSS Inc., Chicago, IL, USA).

Results

The total numbers of amputees recruited in this study was 312 (Table 1) but 308 reported causes of amputation.

Test-retest reliability

According to incomplete data, only 11 questionnaires from each group were analyzed for test-retest reliability. Parts of the PPA questionnaire were selected for the test including LCI domain, daily-activity questions and self-acceptance of amputation and self-acceptance of prostheses questions. The acceptance questions were 1-5 score rating which presented as numbers of participants rating in each score. For LCI domain alone, the ICC was 0.904 and the 95% CI was between 0.769-0.960. The test-retest reliability of all tested parts is shown in Table 2.

Discrimination test

The LCI subset has14 questions with a total score of 42. This subset was selected for discrimination testing between the transfemoral (above-knee) amputees and the transtibial (below-knee) amputees. The result showed no statistical difference between both groups as shown in table 3. When considering 7 advanced mobilities (pick up an object from the floor when you are standing up with your prosthesis, get up from the floor if you fell, walk outside on uneven ground, walk outside in inclement weather, go upstairs without a hand-rail, go downstairs without a hand-rail, and walk while carrying an object), in the LCI subset, the score of these activities was evaluated for the discrimination, and there was no statistical

Table 1. Demographic data of all 312 participants

	All	AK	BK	*p*-value
Number[1]	312	101 (32.4)	211 (67.6)	
Mean age[2]	45.8 (15.1)	42.5 (14.7)	47.4 (15.1)	0.007
Sex[1]				
Male	239 (76.6)	87 (86.1)	152 (72)	0.006
Female	73 (23.4)	14 (13.9)	59 (28)	
Onset since amputation[3]	0.4 [0.25, 0.75]	0.5 [0.25, 1.0]	0.4 [0.25, 0.67]	0.329
Causes of amputation*	308	100	208	
Traumatic cause[1]		85 (85.0)	132 (63.5)	< 0.001
Non-traumatic cause[1]		15 (15.0)	76 (36.5)	

*Total number of causes of amputation was 308
[1]Number (%), [2]mean (SD),[3]median [P25, P75]
AK, above-knee amputation; BK, below-knee amputation

Table 2. Test-retest reliability of the PPA questionnaire of 22 participants.

	Test	Retest	reliability coefficients	*p*-value
LCI sum score[1] (n=42)	40.1 (5.0)	40.9 (3.3)	0.90[I]	< 0.001
Sitting time ≥ 50% of a day[2]	9 (40.9)	10 (45.4)	0.68[K]	< 0.001
Sitting time of a day[3] 0%/25%/50%/75%/100%	3/10/5/4/0	3/9/5/5/0	0.66[KW]	< 0.001
Standing or walking time ≥ 50% of a day[2]	18 (81.8)	17 (77.3)	0.74[K]	< 0.001
Standing or walking time of a day[3] 0%/25%/50%/75%/100%	0/4/5/11/2	0/5/5/9/3	0.69[KW]	< 0.001
Walking distance with prostheses[3] Unlimited/1-bus stop/less than 1-bus stop	20/2/0	18/2/2	0.63[K]	< 0.001
Automaticity of gait[3] Automatic/attention	15/5	13/7	0.53[K]	0.015
Activity with help score[1] (total score = 16)	15.9 (0.3)	16.0 (0.0)	n/a	
Acceptance of amputation scores[3] (total score = 5) 1/2/3/4/5	0/0/1/1/20	0/1/3/1/17	0.40[KW]	0.006
Acceptance of prostheses score[3] (total score =5) 1/2/3/4/5	0/0/0/2/20	0/0/2/4/16	0.33[KW]	0.016

[1]Mean (SD), [2]number (%), [3]number; n/a, not applicable
I, Intraclass correlation coefficient; K, cohen kappa; KW, weighted kappa

difference between both the two groups as shown in Table 3.

Because of baseline difference between the two groups of amputees, the transtibial group had older in age and higher in numbers of non-traumatic cases. The unpaired t-test and analysis of covariance were applied by using age and causes of amputation as covariate. The mean difference between groups is shown in Table 4.

Regarding compliance, using the prostheses for 8 hours or more was considered as good compliance. There were 302 questionnaires which completed data on compliance. After analyzing the data comparing the LCI sub-score of the less-than 8-hour (poor compliance) group with that of the 8-hour or more (good compliance) group, we found the former had lower LCI score than the latter significantly as shown in Table 5.

When dividing prosthetic users into unlimited community ambulators and limited community ambulators, the group that reported unlimited walking nonstop outside had LCI total score higher than the group that reported limitation of walking distance significantly as shown in Table 6.

Table 3. Locomotion capability index (LCI) scores and levels of amputation (n=312)

	AK (n=101)	BK (n=211)	*p*-value
Total LCI score	38.7 (5.8)	38.7 (6.7)	0.857
Advanced capability score in the LCI	18.5 (3.9)	18.6 (4.2)	0.756

Mean (SD)
AK, above-knee (transfemoral) amputees; BK, below-knee (transtibial) amputees

When considering those who were able to walk automatically comparing with the ones walking with attention, it was found that the automatic ambulators had LCI total score higher than those walking with attention significantly as shown in Table 7.

Discussion

The Thai version of PPA was developed and tested for psychometric properties in terms of discrimination test and test-retest reliability. It revealed that the translated questionnaire has discrimination property when comparing the LCI score between those with good and those with poor prosthetic compliance. In terms of non-stop walking distance those walking without limitation had higher LCI score than those walking with limitation. In the same way the LCI score of those walking automatically was higher significantly then those walking with attention.

The LCI score is a subset of the prosthetic use domain in the PPA questionnaire. It represents walking ability of the amputees and consists of basic and advanced ambulation scores. According to our study, the LCI cannot discriminate the groups of transtibial and transfemoral amputees as both groups had comparable total scores, like a result from the study of Gauthier-Gagnon et al.; however, their study showed better in advanced mobility score in the transtibial group[9] that was different from our study. Our advanced score seemed higher in the transtibial group than in the transfemoral group but was not statistically significant. This

Table 4. The advanced capability score in the locomotion capability index (LCI)

	BK	AK	Mean difference (BK-AK)	Mean difference* (BK-AK)
Advanced score in the LCI	18.65 (4.23)	18.57 (3.84)	0.06 (-0.92 to 1.030)	0.93 (-0.001 to 1.86)
p-value			0.912	0.0502*

Mean (SD); *adjusted age and causes of amputation
AK, above-knee (transfemoral) amputees; BK, below-knee (transtibial) amputee

Table 5. The locomotion capability index (LCI) score and use of prostheses of 302 participants

	Wearing < 8 hr (n=8)	Wearing ≥ 8 hr (n=254)	*p*-value
LCI score	33.7 (9.7)	39.8 (4.4)	< 0.001*

Mean (SD), *Independent t test

Table 6. The locomotion capability index (LCI) score and non-stop walking distance of 299 participants

LCI score	Non-stop walking distance		*p*-value	Effect size	*p*-value
	Unlimited (n=199)	Limited (n=100)			
LCI score	40.4 (4.3)	35.0 (8.3)	< 0.001*	< 0.001*	0.82

Mean (SD), *Independent t test

Table 7. The locomotion capability index (LCI) score and automaticity of gait of 293 participants

	Walk automatically (n=170)	Walk with attention (n=123)	*p*-value
LCI score	40.9 (2.9)	35.7 (7.9)	< 0.001*

Mean (SD), *Independent t test

might be from higher non-traumatic causes, more advanced age and female predominance in our transtibial group. For this reason, these factors had to be adjusted; however, there was no statistical significance (p = 0.0502). The discrimination property seemed more suitable to be tested with ambulatory functional level, not with the level of amputation. Level of amputation is a part of physical function that is usually affected by other factors such as physical health.

The PPA, Thai version had good test-retest reliability when testing the prosthetic use domain such as the LCI subset duration of activities, walking distance with prostheses, automaticity of gait, self-care activities and the significant others' acceptance of amputation. The retest had done in 2 weeks apart unlike the original version that performed in 4 weeks' duration. The 2-week duration is considered short enough to remain the same functional status and long enough to prevent the carry-over effects.[5] The original version had good repeatability and enough sensitivity to change. They performed test-retest reliability testing in more aspects than our study, such as percentage of displacement indoors and outdoors, factual information, accessibility to service, donning the prostheses, automatism of walking, walking distance, walking limitation, reason for disuse, satisfaction, adaptation to amputation, and family acceptation. But our test covered only some domains of the PPA questionnaire and revealed reliability.

In conclusion, the Thai version of the prosthetic profile of the amputee (PPA) questionnaire has test-retest reliability and has discrimination validity to differentiate amputees with different locomotion abilities with the prosthesis (so called locomotion capability index, LCI); however, it has no ability to differentiate amputees in terms of levels of amputation.

Disclosure

The authors declare no conflicts of interest regarding any aspects of the study.

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Original Article

Relationship between Service Provision and the Use of Trans-tibial Prostheses: a Study from Sirindhorn School of Prosthetics and Orthotics in Thailand

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ABSTRACT

Objectives: To study servicing factors related to the use of trans-tibial prosthesis.

Study design: Retrospective study.

Setting: Sirindhorn School of Prosthetics and Orthotics, Faculty of Medicine Siriraj Hospital

Subjects: Amputees who received trans-tibial prostheses and completed follow-up during May 2019 to February 2020

Methods: The data collection was done by reviewing the participants' medical records and follow-up forms. The data of the participants and of the most recent prosthesis which had been used for at least one month was retrieved. The participants were divided into daily-user and non-daily-user groups.

Results: There were 44 participants. The median age was 56 years. The most common cause of amputation was trauma (40.9%). Most of them had underlying disease (68.2%) and had problems after receiving the prosthesis (68.2%). Twenty-nine participants (65.9%) used the prosthesis every day. Comparing between the two groups, statistically significant difference was found for receiving the prosthesis from less experienced prosthetists and less time from casting to fitting day. (p = 0.026 and 0.006, respectively). The only factor affecting the every-day use of prosthesis was the time from casting to fitting day (odd ratio = 5.4, 95% CI 1.3-22.7). The cut-off duration for casting to fitting day was 21 days.

Conclusion: Most of the amputees who received the tran-stibial prosthesis from Sirindhorn School of Prosthetics and Orthotics used the prosthesis every day. The only factor affecting the everyday use of prosthesis is the time from casting to fitting day. The cut-off duration for casting to fitting day was 21 days.

Keywords: leg prosthesis, artificial limb, amputees

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Introduction

In 2012 there were 1,478,662 persons with disability in Thailand. Of those,13,562 disabled had to use prostheses. Trans-tibial prosthesis accounted for the most proportion at 61%[1] which was near the number from Australia at 63.6%[2] and Vietnam at 65.5%.[3] Nowadays, there should be more demand for trans-tibial prosthesis due to the increased number of the disabled of the whole country.[4] The conditions in need of trans-tibial prosthesis could be acquired trans-tibial or below-knee amputation or congenital limb deficiency. The process of providing a trans-tibial prosthesis starts from a doctor's prescription, mostly a rehabilitation doctor (physiatrist) or an orthopaedic doctor (orthopedist). Then, an amputee will be re-assessed by a prosthetist and casted for a model stump. The prosthetist will rectify and assemble every component into alignment before appointing the patient to fit the prosthesis and deliver it. A follow-up is usually done at one to four weeks' time.

There have been less prosthetics studies from developing countries and lesser about prosthetic services provision. Quantity is usually used as a measure. In 2005, Jensen JS and colleagues developed and tested a set of quality benchmarks for trans-tibial prosthesis in developing countries.[5] They used the components made of polypropylene and assembly system from the International Committee of the Red Cross (ICRC). Based on their results, the International Society for Prosthetics and Orthotics (ISPO) established user-relevant measures as percentage of non-user, discomfort, pain, and user's satisfaction. For technical measures, good socket fit, malalignment, insufficient craftmanship, and replacement were included. There are many studies reported the factors related to usage, functional outcomes, satisfaction, and quality of life. van Brakel WH and colleagues reported that causes of amputation, servicing center, type of the components, and problems after receiving the prothesis were related to satisfaction.[3] In addition, living environment, gait aids, type of prosthesis, a spare prosthesis, good socket fit, need for replacement, and patient's satisfaction were related to usage.[3] Pohjolainen T and Alaranta H reported age and level of amputation as predictive factors for walkability.[6] In Thailand, Pumpitakkul reported the time after surgery to

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prosthesis fitting but not the relationship of it to usage.[7] Thirapatarapong W and Dajpratham P reported the use of prosthesis and factors related to the use but not included technical measures, not specific to trans-tibial prosthesis, and the center of service.[8] Ananub K reported the duration of manufacturing time for both trans-femoral and trans-tibial prosthesis.[9] To the authors' knowledge, there was no research studying prosthesis service and servicing factors related to the use of prosthesis, reported from a school of prosthetics and orthotics in Thailand.

Sirindhorn School of Prosthetics and Orthotics (SSPO), Faculty of Medicine Siriraj Hospital, Mahidol University is the only prosthetics and orthotics school in Thailand. There are about 130 to 160 trans-tibial prostheses delivered each year. Making a trans-tibial prosthesis requires a lot of resources including money, time, and manpower. The cost of a trans-tibial prosthesis is about 30,000 Baht and it takes about four weeks or more for production. To ensure the resources are not wasted and the amputees do benefit from the prostheses, identifying and improving significant factors are worth considering. The aim of the present study was to identify servicing outcomes and factors related to the use of prostheses.

Methods

The present study was approved by Siriraj Institutional Review Board (SIRB), Faculty of Medicine Siriraj Hospital, Mahidol University, reference number 348/2563(IRB4), certification number 415/2020.

Participants

Amputees received trans-tibial prosthesis from the Sirindhorn School of Prosthetics and Orthotics, Faculty of Medicine Siriraj Hospital, Mahidol University during May 2019 - February 2020.

Inclusion criteria were having K-level K1-K4, receiving the prosthesis and completing follow-up appointments, and using the current prosthesis for at least one month after the delivery

Exclusion criteria were having incomplete information in the medical record or SSPO follow-up form and prostheses made by students.

Sample size calculation

A study done by Jensen JS reported the percentage of trans-tibial prostheses use of 93%.[5] 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), 25 participants were required. Due to the nature of study design, 20% of drop-off was estimated. The recruited sample size should be at least 30 subjects in total.

Study protocol

The SSPO follow-up forms were reviewed to exclude duplication and cases served by students. Information retrieved from the follow-up forms and the medical records without identifiable information were collected and recorded into an encrypted digital file only. Information retrieved from medical records were age, gender, cause of amputation, side of amputation, underlying disease/condition, stump length, stump complication, expected K-level, servicing prosthetist, number of the previous prostheses, designs of the previous and the current prostheses, dates of each provision process, and physical therapy received.

From the follow-up form, date of follow-up, number of days in a week that the prosthesis was used, problems reported by the patients, and comments and adjustments by prosthetist, were identified and recorded.

Definitions

Weakness was defined if either stated in the medical records or motor power grade less than 5 in any muscle of the lower extremities.

Component change of the current prosthesis was defined as a change of any prosthetic component from the previous prothesis.

First-time user was an amputee whose current prosthesis was the first one.

Stump length was classified by the ratio of the stump length to the sound leg length or the calculated length if the amputee had bilateral amputation. The stump is short if its length is shorter than 30% and medium if it is 30%-66%.

The servicing prosthetist who had experience more than or equal to 3 years was classified as senior and who had less was classified as junior.

Doctor check was referred to a physiatrist who involved at the fitting and/or the delivering processes.

Physical therapy received was classified as pre- or post- by date of delivery.

Problems were classified as pain or discomfort.

For the causes of the problems socket misfit and mal-alignment, were derived from the doctors' or the prosthetists' notes. Unexpected component degradation was defined as any degradation or a problem of any component with manufacturing defect. Insufficient craftmanship was defined if the prosthesis needed a minor adjustment such as smoothing of the socket brim, and not classified into any of the socket misfit, malalignment, nor unexpected component degradation. Disease natural course was defined if the stump shrank during the very first period after amputation. Patient's misunderstanding was defined if problems occurred from the patient's misunderstanding of how to don/doff the prosthesis or how to take care the stump.

Remaking was defined if the prosthetist decided to recast the socket.

Statistical analysis

Statistical analyses were performed with the Statistical Package for Social Sciences (SPSS Inc, Chicago, IL, USA)

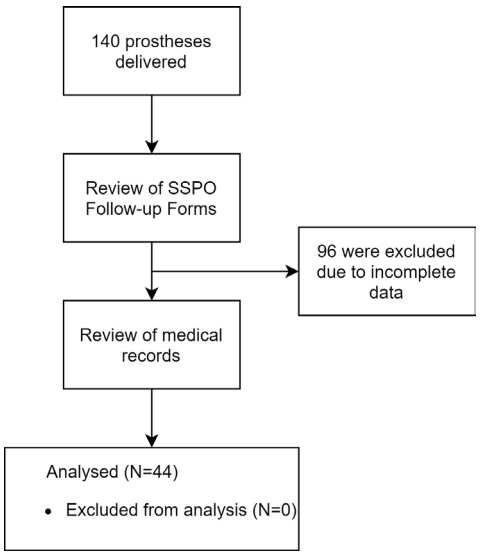

Figure 1. Flow diagram of the study

version 18.0. A *p*-value of less than 0.05 was considered a statistically significant difference.

For the main outcome, the use of prosthesis, the participants were divided into daily-user and non-daily-user groups. The number of the participants who used the prothesis for 0, 1-3, and 4-6 days a week were combined to non-daily-user group. For the variable causes of amputation, the causes other than trauma were combined into non-trauma. The participants who had no previous prosthesis before the prosthesis under review were classified as first-time users. The servicing prosthetists who had experience more than three years were classified as senior, and those who had less as junior. The duration from surgery to prescription date was used only for the first-time users.

Demographic data was shown in frequency table as counts and percentage. Kolmogorov–Smirnov test was used to test normality of the continuous data. Means, inter-quartile range (IQ), and 95% confidence intervals (95%CI) as summary measures for normally-distributed and median, minimum, and maximum for non-normally-distributed data were used.

Unpaired t-test and Mann–Whitney test were used to analyze the differences of quantitative data with normal distribution and non-normal distribution, respectively. Fisher's exact test and Pearson's chi-squared test were performed to analyze the differences of categorical data. Multiple logistic regression analysis was used to find associations between possible variables and the main outcome. The resulting odds ratios (OR) show the amplitude of association, OR more than 1 indicates the increased likelihood of daily use and OR less than 1 indicates the decreased likelihood. To find cut-off value, receiver operating characteristic (ROC) analysis was used and the point where the sensitivity and specificity of the test are equal was selected.

Results

Ninety-six patients were excluded, hence there were 44 participants in total; the median age was 56 (range 2-82) and 28 were men (63.6%) (Table 1). Almost all needed only one prosthesis (88.6%). The majority of the participants had underlying disease (68.2%) such as diabetes, vascular diseases, or else. Around half of the participants had at least one of stump complications (54.5%) prior to the study either stump pain, skin hypersensitivity, stump volume fluctuation, wound, or contracture. Of all available stump length data, medium length was commonly found (55.56%). Community ambulation (K-level 2 and 3) was mostly expected (81.8%). About one-third were prosthesis first-time users. Around two-third had the same current prosthesis designs as the previous one. The numbers of prostheses made by junior and senior

Table 1. Characteristics of all 44 participants

Variables	Frequency	Percentage
Age[1]	56	(2, 82)
Gender		
Male	28	63.6
Female	16	36.4
Causes of amputation or limb loss		
N/A	1	2.3
Trauma	18	40.9
Vascular	8	18.2
Cancer	2	4.5
Congenital	3	6.8
Infection	12	27.3
First-time user	15	34.1
Underlying diseases*		
None	14	31.8
Diabetes mellitus	15	34.1
Vascular	11	25
Others	23	52.3
Bilateral amputation	5	11.4
Expected K-level		
1	7	15.9
2	15	34.1
3	21	47.7
4	1	2.3
Stump length		
N/A	8	18.2
Medium	20	45.5
Short	16	36.4
Weakness	7	15.9
Stump complications*		
None	20	45.5
Scar adhesion	1	2.3
Hypersensitivity	6	13.6
Volume fluctuation	3	6.8
Pain	16	36.4
Wound	6	13.6
Contracture	5	11.4

[1]Median (min, max); N/A, not available

*Some participants had more than one underlying disease or stump complication

certified prosthetists were equal. About one-third of the prostheses were checked by physiatrists on the fitting date. Around forty percent received physical therapy. For the first-time users, the mean duration from the date of surgery to the date of protheses prescription was 228 (interquartile range 89, 322) days. For all participants, the mean durations of prescription-to-casting, casting-to-fitting, and fitting-to delivery were 53, 22, and 20 days, respectively. (Table 2.)

After receiving the prostheses, 68.2% had prosthesis-related problems; discomfort (50%) and pain (27.3%). The causes of the problems were socket misfit (31.8%), malalignment (13.6%), insufficient craftmanship (15.9%), unexpected degradation of the component (4.5%), natural course of the disease (6.8%), and patient's misunderstanding (9.1%). These required remaking in 4.5% and revisiting (by the end of data collection) in 29.5% of all participants. (Table 2.)

Regarding the use of prosthesis, there were 29 (65.9%) daily users. Comparing between daily and non-daily users, the daily users statistically significantly received the prosthesis from junior prosthetists and had less time between casting and fitting (p = 0.026 and 0.006, respectively). (Table 3) When using multivariate logistic regression analysis, the only factor associated with daily use of the prosthesis was duration between casting and fitting day. Those who waited between these two processes less than 21 days had 5.4 times more chance to use the prosthesis every day than who waited for longer (odds ratio = 5.4, 95% CI 1.3-22.7). (Table 4.)

Discussion

There was no consensus yet at which level of usage the patient should be defined as user. Some other studies used the number of hours per day to categorize users.[3,8] The present study included patients with expected K-level from K1 to K4 and as high as around one-third of them used the prostheses for the first time (34.1%) in particular. With these regards, it seemed unusual to expect equal time per day between the first-timer and the experienced users or K1 and K4 users. Therefore, the present study used number of days a week to categorize the participants. The result shows high rate of prosthesis use especially in every-day category as 65.9%. This finding was correlated well with such of other studies because trans-tibial amputation itself is one of the factors predicting successful prosthetic rehabilitation.[3,8] Comparing daily-users to non-daily-users, there was no statistically significant difference for causes of amputation, underlying diseases, prior stump complications, component change from the previous prosthesis, physical therapy prior or after the casting, and even problems after receiving the prosthesis. Other studies also found the same trend for some variables but for the others perhaps due to participant's demographic heterogeneity. The present study involved more ageing people (median age = 56 years) who had at

Table 2. Characteristics of the prostheses and the service provision

Variable	Frequency	Percentage
Socket		
PTB	13	29.5
PTB + thigh corset	1	2.3
PTB-SC	29	65.9
TSB	1	2.3
Liner		
Foam	36	81.8
Silicone	5	11.4
Silicone with Foam	3	6.8
Suspension		
Self-suspension	25	56.8
Sleeve	2	4.5
Supra-patella cuff	15	34.1
Thigh corset	2	4.5
Shank		
Endoskeletal	31	70.5
Exoskeletal	13	29.5
Foot		
SACH	34	77.3
Single-axis	7	15.9
Dynamic	3	6.8
Change of component from the previous prosthesis		
N/A	1	2.3
Yes	12	27.3
No	31	70.5
Servicing prosthetist		
Senior	25	56.8
Junior	19	43.2
Doctor check	17	38.6
Physical therapy*		
None	27	61.4
Pre	8	18.2
Post	16	36.4
Duration(days)[1]		
Surgery to prescription**	228	(89, 322)
Prescription to casting	53	(28.3, 84.5)
Casting to fitting	22	(16, 24)
Fitting to delivery	20	(6.25, 25.3)
Using-days per week		
0	2	4.5
1-3	4	9.1
4-6	9	20.5
7	29	65.9
Prosthesis-related problems*		
None	14	31.8
Discomfort	22	50
Pain	12	27.3
Causes of problems		
Socket misfit	14	31.8
Malalignment	6	13.6
Insufficient craftmanship	7	15.9
Unexpected component degradation	2	4.5
Disease natural course	3	6.8
Patient's misunderstanding	4	9.1
Remaking	2	4.5
Number of revisiting for prosthetic services		
1 time	5	11.4
2 times	5	11.4
3 times	2	4.5
5 times	1	2.3

[1]Mean (interquartile range); *Some participants have both pre-delivery and post-delivery physical therapy or have more than one problem
**N = 15; N/A, not available; PTB, patellar tendon bearing; SC, supracondylar; TSB, total-surface-bearing; SACH, solid ankle cushion heel

Table 3. Comparisons of participants' characteristics between daily-users and non-daily users

Variables	Daily-users (n=29)	Non-daily-users (n=15)	*p*-value
Age[1]	59 (43, 66)	56 (53, 62)	0.88[a]
Gender[2]			
Male	17 (58.6)	11 (73.3)	0.34[b]
Causes[2]			
Trauma	12 (66.7)	6 (33)	0.37[b]
First-time user[2]			
Yes	9 (31)	6 (40)	0.6[b]
Underlying disease[2,*]			
None	11 (37.9)	3 (20)	0.31[c]
Diabetes mellitus	9 (31)	6 (40)	0.55[b]
Vascular	7 (24.1)	4 (26.7)	1[c]
Others	14 (48.3)	9 (60)	0.46[b]
Bilateral amputation[2]			
Yes	2 (6.9)	3 (20)	0.3[c]
Expected K-level[2]			0.82[b]
1	4 (13.8)	3 (20)	
2	12 (41.4)	3 (20)	
3	12 (41.4)	9 (60)	
4	1 (3.4)	0 (0)	
Stump length[2]	(n=23)	(n=13)	0.88[b]
Medium	13 (56.5)	7 (53.8)	
Short	10 (43.5)	6 (46.2)	
Lower limb weakness[2]	6 (20.7)	1 (6.7)	0.393[c]
Stump complications[2]			
Yes	15 (51.7)	9 (60)	0.6[b]
Change of component from the previous prosthesis[2]			
Yes	9 (31)	3 (20)	0.534[b]
Servicing prosthetist[2]			
Senior	13 (44.8)	12 (80)	0.03[b]
Junior	16 (55.2)	3 (20)	
Doctor check[2]			
Yes	13 (4.8)	4 (26.7)	0.24[b]
Physical therapy[2,*]			
None	18 (62.1)	9 (60)	0.89[b]
Pre-delivery	5 (17.2)	3 (20)	1[c]
Post-delivery	10 (34.5)	6 (40)	0.456[b]
Duration (days)[1]			
Surgery to prescription[**]	127 (101, 147)	217 (89, 348)	0.72[a]
Prescription to casting	46 (33, 85)	29 (21, 44)	0.13[a]
Casting to fitting	17 (15, 20)	24 (19, 28)	0.01[a]
Fitting to delivery	12 (7, 26)	8 (5.5, 19)	0.35[a]
Casting to fitting duration (days)[1,2]	17 (15, 20)	24 (19, 28)	0.01
> 21 days	7 (24.1)	10 (66.7)	0.01[b]
< 21 days	22 (75.9)	5 (33)	
Prostheses-related problems[2,*]			
None	10 (34.5)	4 (26.7)	0.74[b]
Discomfort	13 (44.8)	9 (60)	0.34[b]
Pain	7 (24.1)	5 (33.3)	0.72[c]
Causes of prostheses-related problems[2,*]			
Socket misfit	8 (27.6)	6 (40)	0.5[c]
Malalignment	4 (13.8)	2 (13.3)	1[c]
Insufficient craftmanship	7 (24.1)	0 (0)	0.08[c]
Unexpected component degradation	1 (3.4)	1 (6.7)	1[c]
Disease natural course	3 (10.3)	0 (0)	0.5[c]
Patient's misunderstanding	0 (0)	4 (26.7)	0.01[c]
Remaking[2]			
Number of revisiting[2]	1(3.4)	1(6.7)	1[c]
0 time	21 (72.4)	10 (66.7)	0.37[b]
1 time	3 (10.3)	2 (13.3)	
2 times	4 (13.8)	1 (6.7)	
3 times	1 (3.4)	1 (6.7)	
5 times	0 (0)	1 (6.7)	

[1]Median (interquartile range); [2]mean (interquartile range); [a]Mann-Whitney test; [b]Pearson Chi-Square; [c]Fisher's Exact test
[*]Some participants had more than one underlying disease, problem and the cause of the problem, or received both pre-delivery and post-delivery physical therapy; [**]n=15

Table 4. Factors associated to prosthesis daily-use

Variables	Crude OR (95% CI)	Adjusted OR (95% CI)	*p*-value
Servicing prosthetist			
Senior	1.0	1.0	0.075
Junior	4.9 (1.1-21.2)	4.1 (0.9-19.5)	
Casting to fitting duration			
> 21 days	1.0	1.0	0.020
< 21 days	6.3 (1.6-25)	5.4 (1.3-22.7)	

OR, Odds ratio; CI, Confident interval
p-value from Enter method, Binary Logistic Regression Analysis

least one underlying disease (68.2%). Two variables found statistically significant difference were servicing prosthetist being less experienced (junior) and less duration from casting to fitting day.

For servicing prosthetists, the authors categorized prosthetists who had been working for more than 3 years by the time of the study as senior and who had less as junior. Because making a prosthesis requires skills and experience,[10-12] the authors also hypothesized the prostheses made by more experienced prosthetist would give better outcomes, translated to more frequently used. The result turned out vice versa. Subgroup analysis comparing junior and senior prosthetists was done. Even though, statistical signi-ficance was not found for the conditions of the participants and the problems after receiving the prosthesis, there was a trend in different causes of amputation and the duration the prosthetists spent in each process. The senior prosthetists served more non-trauma cases and spent more time in each process. These two factors might indicate the cases served by the senior prosthetists were more complicated than those by the junior, however, is not the extent of the present study.

For casting to fitting duration, this was the only factor related to the daily use of the prosthesis after multivariate logistic regression analysis. Socket fit has long been widely known as one of the most significant factors contributed to prosthesis use level and satisfaction.[5,13-19] Although, socket misfit was found not statistically significant in the present study (p = 0.5). Less waiting time after casting can be transferred to less chance of condition changes either the stump or the other parts of the body and also expectation of the users.[20,21] The present study found cut-off value for this variable was 21 days. By achieving appointing the patient for fitting in less than 21 days from the casting date increases 5.4 times likelihood the patient will use the prosthesis daily than those who cannot. From the authors' opinion, this cut-off duration is sensible especially in the first-time user because this duration is within the period which the stump loses its volume the greatest.[22] Moreover, it is possible by most of the prosthesis service centers even in secondary hospital.[9,23]These technical processes management should be paid more attention on for the best to the patients.

In contrary, the high use rate found in the present study, which is a patient-reported outcome, is not concur with the technical-assessed problems (discomfort, pain; p = 0.34, 0.72 respectively). There is possibility the present study might have a bias toward daily user group. The authors hypothesize three possible factors. First, the participants included must completed following-up. Those who did not use the prostheses might refuse the follow-up. Second, a trans-tibial prosthesis costs high amount of money if self-paid. Considering Thailand is a middle-to-high income country and a prosthesis is covered by the disabled rights, the participants might accept a level of problems in exchange to be given it for free.[24] Third, even with high rate of problems found, there were quite low rate of remaking (4.5%) and patient revisiting (29.1%) which were less than some other studies.[5,13] This reflects the problems could be minor and not related to daily-use (p = 1, 0.37 respectively).

To our knowledge, the present study is the first study in Thailand reporting the prosthesis use and relating factors with regard to technical variables. Thirapatarapong W. and Dajpratham P. reported the use of all type of prostheses as high as 82.1% and the factors related to the use; less diabetes mellitus, being younger at the time of amputation, employed status, satisfaction to good wearing comfort, a trans-tibial level of amputation, and undergoing particular etiologies of amputation such as congenital problem or blast injury.[8] All those are patient-related outcomes. Since the study was a postal survey, assessing technical and follow-up information could be difficult. To improve the quality of the devices provided and service, another aspect of information which is specific to a type of device and servicing center might avail.

ISPO established quality benchmark for trans-tibial prostheses in low-income countries in 2005.[5] The technical performance demands were set for good socket fit at 60±10%, misalignment at 15±10%, insufficient craftsmanship at 10±10%, and requirements for socket change at 10±10%. Comparing to those of the present study were 68.2% (100 – socket misfit%), 13.6%, 15.9%, 4.5% respectively, all were within ranges. These are comparable to the result W. Van Brakel reported of good socket fit at 61%, poor alignment at 11.4%, and socket replacement at 7.4%.[3] In another aspect, the patient compliance demands were set for discomfort at 10±10%, pain at 10±10%, and non-users at 5±5%. Pain and discomfort in the present study were found far more than the benchmark ranges and in other studies.[3,5,13] These two measures are quite difficult to compare since they are patient-reported outcomes. The present study set pain and discomfort as a result of any technical problems, not only reported by the participants. Observed from the results of the other studies, the numbers of reported pain and discomfort were not equal to those of problems found.[3,13] Different inclusion measure is suspected. For non-user outcome, only two participants (4.5%) reported as non-users which is within the benchmark range.

The present study had some limitations. Because of the retrospective study in nature, the completeness of data was the major limitation. Only around one-third were recruited despite many delivered prostheses. Number of participants was also a limitation. Although the number of recruited participants met the calculated sample size, more number could show more outcomes related to the use. In Thailand, every registered amputee is given a prosthesis for free every one-year period. All the participants used the disabled right. If the recruiting period is more than a year, the authors expected some amputees who come more than once. Because of the this, the nature of the study, and the COVID-19 situation during the time of study, not so many participants were recruited. Lastly, the present study focuses more on service provision and technical outcomes. There were other patient-reported outcomes reported elsewhere but not included in the present study such as user's satisfaction, the environment the prosthesis is used, walking aid use, spare prosthesis, age at time of amputation, employment status, and wearing comfort. In addition, functional capability, participation, and quality of life are all important and parts of reflecting further benefit of prostheses.[25-29] These factors should be encouraged to be included in future study and clinical assessment.

In conclusion, most patients used the prosthesis every day regardless to the problems occurred. Problems were found in the majority of the devices provided but the consequences were minor. The only factor related to the every-day prosthesis use was the duration from casting to fitting day. Cut-off duration from casting to fitting day was 21 days.

Disclosure

The authors declare no conflict of interest of any kind.

Acknowledgments

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Original Article

Effectiveness of Prefabricated Silicone Toe Separator on Hallux Valgus

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ABSTRACT

Objectives: To determine effectiveness of a prefabricated silicone toe separator to decrease hallux valgus angle (HVA) |and hallux pain, and also investigate possible complications, compliance, and users' satisfaction.

Study design: Prospective cohort analytical study design

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

Subjects: Forty patients with hallux valgus deformity at moderate level (HVA 20°- 40°) were recruited from February to March 2019.

Methods: The participants were asked to wear a prescribed prefabricated silicone toe separator in proper shoes 6 hours a day for 12 months, and continue their current medication and treatment regimen. They had to record the duration of wearing the toe separator and complications in a logbook on a weekly basis. Follow-up pain numeric rating scale (pain NRS) and HVA measured from radiography were evaluated at 6 months, and 12 months after receiving the device.

Results: Thirty-eight participants returned for follow-up at a 6-month and 33 participants continued until the end of the study. Based on per protocol and intention to treat analyses, the results showed no progression of HVA. Pain at the 1st metatarsophalangeal joint decreased with a statistically significant difference ($p < 0.001$) at 12 months. Nearly 60% of participants had minor complications. The common complication was discomfort at the 1st web space.

Conclusion: Wearing a prefabricated silicone toe separator in proper shoes for a year in patients with a moderate degree of hallux valgus could prevent the progression of hallux valgus angle and decrease hallux pain without serious complications.

Keywords: hallux, hallux valgus, pain, orthotic device, foot

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Introduction

Hallux valgus is a common forefoot deformity described as a static subluxation of the first metatarsophalangeal (MTP) joint, characterized by lateral deviation of the great toe and medial deviation of the first metatarsal bone.(1) Intrinsic factors include age,(2) female,(3-4) pes planus,(5-6) tightness of the Achilles tendon,(7) degenerative joint disease at the first MTP joint,(6) ligamentous laxity,(8) and first-ray hypermobility.(9) A family history is a major risk factor of the disease.(10,11) Extrinsic factors include shoe-wearing behaviors,(12) and wearing ill-fitting shoes.(13-15) A heel height of 6 cm or above could also be related to hallux valgus formation.(16) In addition, hallux valgus is associated with excessive walking and weight-bearing.(17)

Goals of treatments for those with hallux pain and progression of hallux deformity are symptomatic pain relief and correction or prevention of the progression of hallux deformity. Conservative treatments relieve patients' symptoms, reduce operative rates and potential operative complications.(10) However, conservative treatments cannot reverse hallux valgus deformity,(18) but decrease progression of disease.(19,20) The conservative treatments include well-fitting shoes with a wide and deep toe box,(21) and foot orthoses.(22) Additional options are soft tissue stretching and muscle strengthening/ retraining exercises, and also therapeutic cold modality.(22) Various orthoses, such as insoles, hallux valgus strap, and toe separators, have been prescribed.(23) Previous literatures reported the effectiveness of a total contact insole with fixed toe separator in relieving pain,(19,20) and improving toe alignment and walking ability.(19)

Our previous study revealed that wearing a custom-mold room temperature vulcanizing (RTV) silicone toe separator for a year decreased the hallux valgus angle (HVA) and hallux pain in patients who had a moderate degree of hallux valgus.(24) In general practice, this orthotic device has to be prescribed by a physician and made by an orthotist. This makes it difficult for patients to access to the treatment. For convenience, many physicians prefer to prescribe prefabricated orthotic devices with acceptable prices. However, there are no studies reporting effectiveness of a prefabricated silicone toe separator to decrease the HVA progression. Therefore,

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the primary objective of this study was to determine the effectiveness of the prefabricated silicone toe separator in decreasing the HVA progression in individuals diagnosed with hallux valgus. In addition, this study would also monitor hallux pain (pain of the great toe), related complications, patient's compliance and satisfaction with the prefabricated silicone toe separator.

Methods

The study protocol was reviewed and approved by the Institutional Review Board at Siriraj Hospital, Bangkok, Thailand (Si597/2018) and supported by the Research Division, Faculty of Medicine Siriraj Hospital, Mahidol University.

Participants

Forty patients who had hallux valgus and visit the Outpatient Foot Clinic, Siriraj Hospital from February to March 2019 were recruited to participate in the study. A physiatrist performed a complete foot examination and provided the clinical diagnosis of hallux valgus.

Inclusion criteria

- Age not less than 18 years old
- A moderate degree of hallux valgus (HVA: 20°- 40°)

Exclusion criteria

- Having foot numbness or foot ulcers
- Having acute inflammation of the first MTP joint
- Having hallux rigidus or hallux limitus
- Continuous usage of any types of toe separator or hallux valgus strap in the past year
- Having silicone allergies
- History of hallux valgus surgery

If the condition presented on both sides, the one with a greater HVA measured with a goniometer was selected.

Sample size calculation

The sample size was determined by using Independent Student's t-test. Sample size calculation was based on the results of a previous study.[24] based on a power of 0.80 to detect a significant difference (5% type I error, $p = 0.05$, two-sided), 33 patients were required for this study. The recruited sample size was 40 subjects with an estimated 20% drop-out. The clinically important difference in HVA was 5°.

Materials

Two different sizes of a prefabricated silicone toe separator (size M and L) (Figure 1) The prefabricated silicone toe separator selected for this study was 00-120 toe retractors, I-M® brand. It is a single unit of a toe separator and made of medical-grade silicone to maximize comfort when used. Size M was selected for those who had a foot length of 22.5-26 cm and size L for a foot length of 26-30 cm.

Study protocol

Once the study was approved, an information sheet with verbal explanation was provided to the patients, and a signed informed consent form was obtained prior to the study. Correspondingly, the participants were recommended to wear a prefabricated silicone toe separator every day for at least 6 hours per day during daytime or nighttime, and recommended to wear proper shoes; i.e. low-heel shoes with a wide-and-deep toe box without termination of current drug use.

To ensure that the device fit properly for each participant, a trial was provided for each participant to wear it and walk for 5 to 10 minutes, and then an appropriate size was prescribed accordingly. The participants were asked to record the duration of wearing the toe separator and complications caused by the device in a log book on a weekly basis. If irritation or discomfort occurred, they were instructed to contact the researcher immediately.

At baseline, demographic data were collected, as well as, average hours of wearing walking shoes, current types of daily-used shoes, side of hallux deformity, duration of hallux valgus, family history, and complications/ problems related to hallux valgus.

The primary outcome measured in this study was the HVA, which was measured with a weight-bearing anteroposterior radiograph (Figure 2).[1] The progress evaluation on HVA was done at baseline, 6-month and 12-month follow-up. The HVA was measured by two well-trained physiatrists who did not assess nor treat the participants. The angles measured by the two assessors were averaged and used for further analyses.

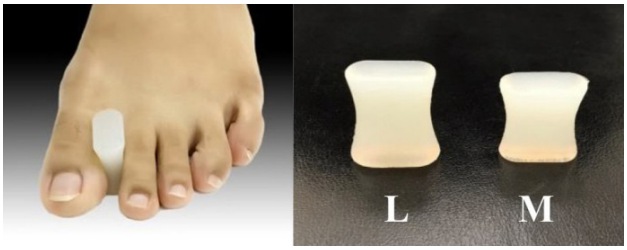

Figure 1. The prefabricated silicone toe separator between the great and the second toes (left), and two different sizes: L (large) and M (medium) (right)

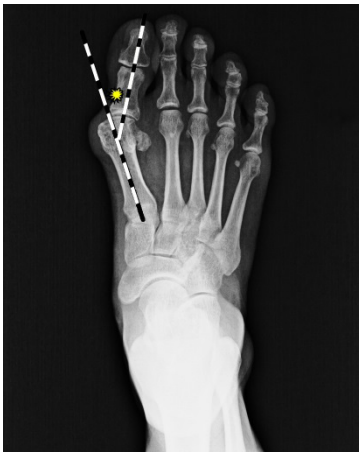

Figure 2. The hallux valgus angle (HVA) measures demonstrated on a weight bearing anteroposterior (AP) radiographs.

The secondary outcomes were hallux pain, compliance, complications related to using the toe separator, and satisfaction. At baseline, 6-month follow-up, and 12-month follow-up, hallux pain experienced within the last 24 hours was scored from 0 (no pain) to 10 (worst pain). Patient compliance was measured with daily usage of the toe separator, which was then averaged as weekly use and recorded in the logbook. Any complications caused by the device such as abrasions or rashes were also recorded. At the end of the study, patient's satisfaction in seven sub-domains - pain reduction, cosmetic appearance of the device, convenience in wearing, maintenance, durability, fitting and overall satisfaction, were recorded. The NRS was scored as 0 (dissatisfaction) to 10 (most satisfaction). Intentions for future use as well as suggestions for improving the quality of the device were also reported.

Statistical analysis

All statistical analyses were performed using PASW Statistics (SPSS) 18.0 (SPSS, Inc., Chicago, IL, USA) and a *p* value of less than 0.05 was considered as statistically significant difference. Age, BMI, HVA and patient compliance in using the prefabricated silicone toe separator (hours/day) were calculated by means and standard deviations (SD). The median (range) was calculated for duration of hallux valgus problem (months), pain at the 1st MTP joint and patient satisfaction (NRS from 0 to 10). Gender, daily activities, current types of daily-used shoes, sides, complications and problems from hallux valgus, results from foot examinations and any complications from the toe separator usage were calculated as a number and percentage. For demographic data, an unpaired t-test and Mann–Whitney test were used to analyze the differences of quantitative data with normal distribution and non-normal distribution, respectively. Additionally, Fisher's exact test and chi-square test were performed to analyze the differences of categorical data. To explore the primary outcome of HVA, as measured in degrees, were reported by both per protocol (PP) and intention-to-treat (ITT) analysis. A repeated-measures analysis of variance (ANOVA) was used to analyze the differences between at baseline, 6-month and 12-month follow-up. To explore the secondary outcomes of hallux pain, compliance, complication, and satisfaction, the Friedman test was performed, and Bonferroni correction for multiple comparisons was used to analyze the difference of the data at baseline, 6-month and 12-month follow-up.

Results

Forty participants enrolled in the study. Thirty-eight and 33 participants returned to follow-up at 6-month and 12-month, respectively. Two participants lost contact at 6-month follow-up. Five participants dropped out at 12-month follow-up, two of them due to pain, one of them due to difficult to transport and two of them lost contact. The characteristic data and foot problems of the participants are shown in Table 1. The majority

Table 1. Demographic data of all 40 participants

Characteristics	
Age (year)[1]	52.3 (13.5)
Gender[2]	
Female	36 (90)
Body mass index (kg/m^2)[1]	23.0 (3.2)
Daily activity/working[2]	
Mostly standing/ walking with shoes wearing	20 (50)
Mostly sitting	17 (42.5)
Mostly standing/ walking with bare feet	3 (7.5)
Current types of daily-used shoes	
Types[2,*]	
Closed toe	24 (60)
Open toe	10 (25)
Wide toe box	26 (65)
Narrow toe box	6 (15)
Shoe height (inch)[2,*]	
< 2	33 (82.5)
≥ 2	2 (5)
Hallux vulgus	
Side[2]	
Right	9 (22.5)
Left	12 (30.0)
Bilateral	19 (47.5)
Duration (month)[3]	120 (6, 840)
Family history[2]	
Yes	23 (57.5)
Complications related to hallux valgus[2,**]	
Pain	
Pain at the 1st metatarsophalangeal joint	18 (45)
Metatarsalgia	10 (25)
Pain at bunion from shoe compression	26 (65)
Friction ulcer at	
Bunion from shoe compression	3 (7.5)
1st web space Maceration at 1st web space	2 (5)
Paronychia	2 (5)
Nail thickening	2 (5)
Callus	1 (2.5)
Toe riding (when wearing shoe)	8 (20)
Shoes-fitting problems	7 (17.5)
Cosmetic problem	18 (45.0)
	17 (42.5)
Foot examination[2, **]	
Tenderness at	
1st metatarsal head	3 (7.5)
2nd-5th metatarsal head	5 (12.5)
Callus at	
Medial side of 1st toe	22 (55)
1st metatarsal head	25 (62.5)
Tip of 2nd-5th toes	3 (7.5)
2nd-5th metatarsal heads	18 (45.0)
Callus at	
Medial side of 1st toe	22 (55)
1st metatarsal head	25 (62.5)
Tip of 2nd-5th toes	3 (7.5)
2nd-5th metatarsal heads	18 (45.0)
Maceration at 1st web space	2 (5)

[1]Mean (SD), [2] number (%), [3]median (min, max)
[*]Some patients wore more than one type of shoes,
[**]Some patients had more than one problem

Table 2. Hallux valgus angle at baseline, 6 and 12-month follow-up

	Per protocol (n=33)		*p*-value	Intention to treat (n=40)		*p*-value
Hallux valgus angle (degrees)	Baseline	29.3 (5.4)	0.846[a]	Baseline	28.7 (5.6)	0.797[a]
	Month 6	29.3 (7.1)		Month 6	28.5 (7.6)	
	Month 12	28.9 (6.9)		Month 12	28.2 (7.5)	

Mean (SD)

[a]*p*-value analyzed by repeated-measure analysis of variance (ANOVA) with the use of Bonferroni correction for multiple comparisons, statistically significant at $p < 0.05$

of the participants were females with a mean age of 52.3 (SD 13.5) years. Half of the patients had hallux valgus on both sides. The duration of hallux valgus was 120 (range 6, 840) months. The present study found that at base line the patients spent their time standing or walking while wearing shoes with an average of 7.9 (SD 4.2) hours per day. The top three most common problems from hallux valgus were pain at bunion from shoe compression (65%), pain at the 1st MTP joint (45%) and shoes-fitting problems (45%). The hallux valgus associated findings were tenderness at the metatarsal head, callus, and skin maceration at the 1st web space.

Primary outcome

The results demonstrated no progression of HVA at baseline, 6-month and 12-month follow-up, and were reported in both PP and ITT analysis as shown in table 2. From the PP analysis, means (SD) of the HVA were 29.3 (5.4) at baseline, 29.3 (7.1) at a 6-month and 28.9 (6.9) at a 12-month follow-up with no statistically significant difference ($p = 0.846$).From the ITT analysis, means (SD) of the HVA were 28.7 (5.6) at baseline, 28.5 (7.6) at a 6-month and 28.2 (7.5) at a 12-month follow-up with no statistically significant difference ($p = 0.797$).

Subgroup analyses were analyzed to evaluate whether factors: the BMI, daily activity, types of daily-used shoes, severity of HVA at baseline and compliance with the device usage, had any effects on the HVA progression. The results showed that the differences of HVA at baseline, 6 months and 12 months after treatment remained no statistical significance.

Secondary outcomes

Based on the PP and the ITT analyses, the result showed a statistically significant decrease in pain at the1st MTP joint at 12-month follow-up when compared with the baseline ($p = 0.001$) as shown in Figure 2, and when compared at 6-month follow-up. However, there was no a statistically significant decrease in pain at 6-month follow-up when compared with the baseline.

Regarding compliance with the usage of prefabricated silicone toe separator, the data from participants' logbook showed that the highest compliance was seen in the first 3 months with mean (SD) of 6.8 (1.8) hours per day and 41.3 (16.0) hours per week. The lowest compliance was in the last 3 months with mean (SD) of 6.5 (1.9) hours per day and only 37.3 (17.7) hours per week.

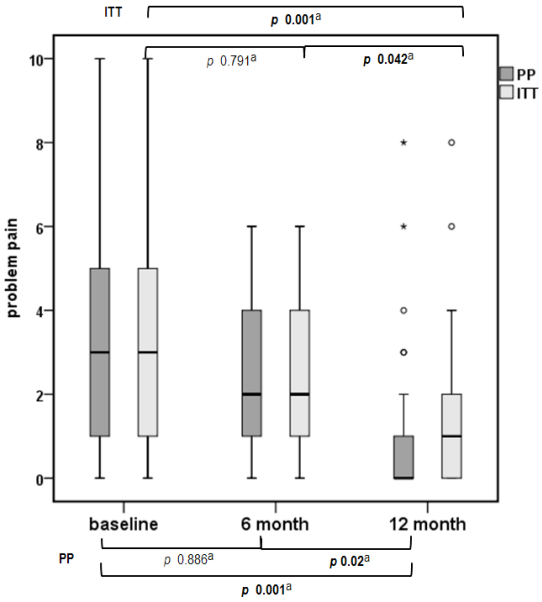

Figure 3. Pain at the 1st metatarsophalangeal joint
Measured by numeric rating scale (0- no pain, 10-the worst pain)
PP, per protocol analysis; ITT, intention to treat analysis
[a]*p*-value analyzed by Friedman test, statistically significant at $p < 0.05$

Table 3 indicates that 14 (42%) of participants had minor complications while using the device. Some patients had more than one complication; however, they did not register them as serious complications. The most common complication reported was discomfort or mild pain at the 1st web space.

The satisfaction scores with the prefabricated silicone toe separator were high in every domain. The median (min, max) satisfaction score of the overall satisfaction was 8 (2, 10). The three subdomains with highest scores were durability, pain reduction and maintenance as shown in table 4. Concerning the intention to use this device in the future, 20 participants (60%) would continue using it, 10 (30.3%) might continue using it and 3 (9.1%) would stop using it due to pain.

Table 3. Complications from using the prefabricated silicone toe separator

Complications	N (%)
No	19 (58)
Yes*	14 (42)
Discomfort or mild pain at the hallux and second toe	13
Rash/ pruritus	2
Metatarsalgia	1

N (%); number of participants = 33
*Some patients had more than one complication

Table 4. Satisfaction with the prefabricated silicone toe separator (n=33)

Categories	Satisfaction score
Pain reduction	8 (0,10)
Cosmetic appearance	7 (0,10)
Convenience	7 (0,10)
Maintenance	8 (6,10)
Durability	9 (4,10)
Fitting	7 (0,10)
Overall satisfaction	8 (2,10)

Median (min, max)
Measured with numeric rating scale (0, dissatisfied; 10, mostly satisfied)

Discussion

Over time, hallux valgus usually progresses to hallux valgus deformity by increasing the HVA because of the instability of the 1st MTP joint. Wearing proper shoes seems not prevent such deformity as our study followed the HVA of those who had a moderate degree of hallux valgus for 12 months and found significantly increased HVA in the control group and but those who used a custom-mold silicone toe separator had the HVA reduction in 6 months.[24] In Thailand, an access to a custom-mold silicone toe separator is limited.

Therefore, in this present study, we focused on evaluating effectiveness of wearing a prefabricated silicone toe separator which is available at drug stores with affordable price, around 250 Baht. We assumed that the custom-mold and the prefabricated silicone toe separators have a similar effect in decreasing the progression of HVA and hallux pain as both allow soft tissues and nerves on the medial and the lateral aspects of the hallux to return to a more anatomical position,[20] thus prevent shortening of the soft tissues on the lateral aspect of the hallux, and overstretching of the soft tissues and the nerves located on the medial aspect, and subsequently reducing the hallux pain.

The results from using the prefabricated silicone toe separator in the present study showed no progression of HVA at 6 and 12 months whereas the previous study revealed that the custom-mold RTV silicone toe separator could reduce the HVA.[24] The reason may be due to the fact that the prefabricated silicone toe separator could not exactly fit each patient's toes. When compared with the custom-mold toe separator,[24] our study showed higher rate of complications (42% vs 20%) especially in discomfort and lower compliance (6.5 vs 7 hours/day, 37.3 vs 45 hours per week). This might be caused by slippage or incorrect position of the device causing shearing force and leading to pain over affected toes in long term use.[24] However, such problems were resolved by decreasing the duration of use or wearing socks. And, thus more than half of the participants intended to continuously use this device.

Although the prefabricated silicone toe separator used in this study could not reduce the HVA but it could effectively reduce hallux pain. In addition, it has some advantages as one could buy it over the counter and it costs less than a custom-mold one.

The present study had some limitations in. as its design was a cohort analytical study and has no control group. For stronger evidence a randomized controlled trial should be conducted.

In conclusion, using a prefabricated silicone toe separator for a year in patients with a moderate degree of hallux valgus could prevent the progression of hallux valgus angle and decrease hallux pain with mild complications.

Disclosure

The authors declared no potential conflicts of interest with respect to the materials used in this research study, authorship, and/or publication of this article.

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Original Article

The Effect of Obesity on Thoracolumbar Flexion Control of Jewett Hyperextension Brace

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ABSTRACT

Objectives: To investigate the effect of obesity on thoracolumbar flexion control of Jewett hyperextension brace.

Study design: Experiment study

Setting: King Chulalongkorn Memorial Hospital, Bangkok, Thailand

Subjects: Fifty healthy volunteers

Methods: Volunteers were stratified into obese and non-obese groups. After wearing the prefabricated Jewett hyperextension brace with adjustment performed by a certified prosthetist orthotist (CPO), the lateral plain TL film was done in a standing upright and in a force, trunk bending against the Jewett brace. The lateral Cobb angles from T9 to L3 were measured and the result was the difference of angle between standing and bending.

Results: The obese group had a significantly higher mean flexion angle than the non-obese group in all positions [in an upright position: 9.73 (SD 6.14) and 3.35 (SD 5.32) degrees, $p < 0.001$; and in the force flexion position: 17.89 (SD 8.09) and 12.80 (SD 6.84) degrees, $p = 0.026$]. The mean bendable angle after applying the brace were 9.45 (SD 5.80) degrees in the non-obese group and 8.13 (SD 6.53) degrees in the obese group and were not statistically different.

Conclusion: Obese volunteers had a significantly higher truncal flexion angle compared with the non-obese groups in all positions. The Jewett brace could control the spinal flexion movement to less than 10 degrees and not significant different between groups.

Keywords: obesity, spine, orthotic devices, brace

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Introduction

Spinal orthoses are externally applied devices that apply force to the spine for the treatment of diseases or spinal conditions. The purposes of spinal orthoses using are spinal motion restriction and stabilizing the affected spinal segments.[1,2]

The thoracolumbar junction is the most likely area where traumatic spine injuries results in vehicle accidents, falls, sports injuries, and other causes.[3] The thoracolumbar orthoses are often used as a part of the treatment consists of many different approaches in the case of conservative management, pre- and post-operative treatments. One the most used thoracolumbar orthoses is the Jewett brace.

Jewett brace is a thoracolumbar hyperextension orthosis. Its function is to limit truncal flexion and helps to reduce the pressure force onto the anterior column of spinal body. The advantages are lightweight and easy to wear, so it is popular in practical use. The principle of spinal control of Jewett brace is 3-point pressure. Two forces from anterior to posterior at sternal pad and pubic pad. Another force from posterior to anterior at lumbar pad. Three pads place on bony landmarks for control spine. For pubic pad, to stabilize pubic bone, the landmark is 1-2 inch above pubic symphysis.

The previous literature about the Jewett brace can be divided into 2 kinds of trials. Those are biomechanical and clinical trials. In biomechanical trials, the main outcomes were force and moment that the orthosis generated and the spinal motion that the orthosis can control, or other physical parameters related to the orthosis. These groups of literature usually recruited normal healthy subject with normal body proportions. Some of the articles indicated that obesity was an exclusion criterion.[2,4] The other group of literature was the clinical trials. These researches explored the clinical outcomes such as spinal pain, disease progression, patient activities, etc.; and the subjects recruited were patients with the spinal problems regardless of the obesity. The results showed little clinical efficacy of spinal orthosis.[5-10] After reviewing literature, it could be concluded that the good biomechanical results of the Jewett brace did not contribute enough to reach a significant clinical outcome. But the authors would want to explore if this assumption results from the different criteria of the subjects regarding the obesity parameters.

The fundamental mechanism of the orthosis is to limit the motion of body segment. The more contact between the

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orthosis and the bony landmark or firm structure of the body, the better in control achieved. The skin and adipose tissues have the property that is soft, smooth, and pliable. They lie between the orthosis and the skeletal landmarks of the body, so the orthosis cannot completely adhere the bone beneath the soft tissue.[11] Obese patients have thicker layer of subcutaneous adipose tissue than non-obese patients that make an increment of the distance between orthosis and bony landmark so the orthosis theoretically cannot completely inhibit spinal motion and may contribute to the failure of conservative treatment by the spinal orthosis. In clinical experience, the authors had observed the difficulty of fitting the suprapubic pad of the Jewett brace in the severe obese patients who had excessive abdominal fat that interferes with the orthosis landmark. So far, there was no study that explored the real biomechanical effect of obesity to spinal motion restriction of the Jewett brace. We hypothesized that obesity might reduce the spinal motion control of the Jewett brace.

Methods

Participants

A stratified sample of fifty adult volunteers (twenty males and thirty females) with varying levels of obesity were recruited. Inclusion criteria were 18-40 years old healthy volunteers who gave a written informed consent before participation. Exclusion criteria were persons with the following: spine conditions or back pain that potentially affect the spine or back motion, neurological condition or balance instability that affect the standing ability or trunk motion, not being able to wear available sizes of Jewett hyperextension brace, and having a contraindication for radiography

After enrollment, the participants who did not meet any of the exclusion criteria were stratified into 5 groups according to the obesity levels using body mass index (BMI) classification by World Health Organization,[12] as follows

BMI < 18.5 kg/m^2	underweight
BMI 18.5-24.9 kg/m^2	normal
BMI 25-29.9 kg/m^2	overweight
BMI 30-34.9 kg/m^2	obese class I
BMI ≥ 35 kg/m^2	obese class II&III

We defined 10 volunteers for each group.

The demographic and anthropometric data that were weight, height, body mass index (BMI), waist circumference, hip circumference, waist/hip ratio and waist/height ratio were recorded. And, we also categorized them into “obese” and “non-obese” groups according to the obesity parameters using multiple criteria as follows:

i. BMI > 25
ii. Waist circumference: (male > 102 cm, female > 88 cm)[13]
iii. Waist/hip ratio: (male > 0.90, female > 0.85)[13]
iv. Waist/Height ratio: (> 0.5)[14,15]

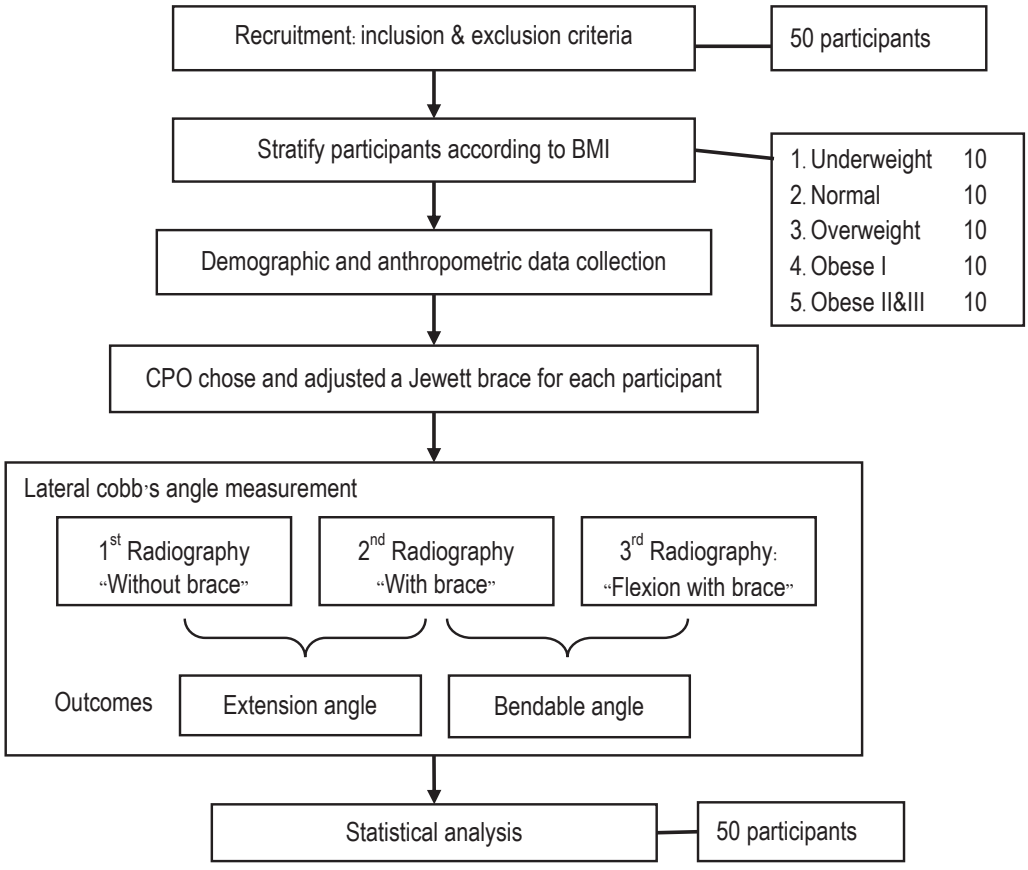

Figure 1. Flow diagram of research protocol
CPO, certified prosthetist-orthotist

Materials

A prefabricated Jewett hyperextension brace was selected for each participant by a certified prosthetist & orthotist (CPO) according to device's size recommendation, and individually adjusted to optimally fit truncal shape and posture without pain or uncomfortable pressure at certain point of contact by the brace.

Outcome measurement

Based on radiography of the thoracolumbar spine lateral view of each participant, the lateral Cobb's angle from T9 to L3 segment defined as the "truncal angle" was measured (Figure 2.) by the authors separately (PY, a physiatrist and NK, a 2nd year resident in training of rehabilitation medicine). This truncal angle was considered as the flexion angle of the spinal segment measured. Thus, the greater value was considered as more flexion posture and lesser value as more extension posture.

Radiographic imaging was recorded in 3 different upright postures as follows:

1. Without brace: participants were standing upright in a comfortable posture without wearing the Jewett brace. This was considered as the baseline truncal angle for each participant.
2. With brace: while wearing the Jewett brace, the participants were advised to standing in a comfortable posture and not resisting the brace. The Jewett brace would theoretically produce more extension forces to the spine, thus create more extension posture. The truncal angle in this posture was expected to be less than the 1st posture.
3. Flexion with brace: the participants were advised to voluntarily bend their trunk as much as possible against the Jewett brace. They were orientated to differentiate the truncal flexion and hip flexion motion and be advised to perform only the truncal flexion, not the hip flexion motion.

Main outcomes

1. Extension angle was defined as the range of motion of the truncal angle from the 1st to the 2nd posture. This angle represented the hyperextension function of the Jewett brace and calculated as follows:

Extension angle = lateral Cobb angle in 1st image - 2nd image

2. Bendable angle was defined as the range of motion of the truncal angles between the 2nd and 3rd posture. This was the angle that participants could still bend their trunk while wearing the brace. This would reflect the efficacy of the brace, the more bendable angle, the less efficacy of the brace in controlling the truncal flexion. The bendable angle was calculated as follows:

Bendable angle = lateral Cobb angle in 3rd image - 2nd image

Statistical analysis

Demographic and anthropometric data were presented with mean and standard deviation (SD). the student T-test and one-way ANOVA were used to compare the spinal motion between male and female groups, and between obese and non-obese groups. The correlation between obesity and flexion control function of Jewett brace was analyzed by using the linear regression model analysis. *P* values less than 0.05 were considered statistically significant. Analysis was done by using SPSS program version 22.

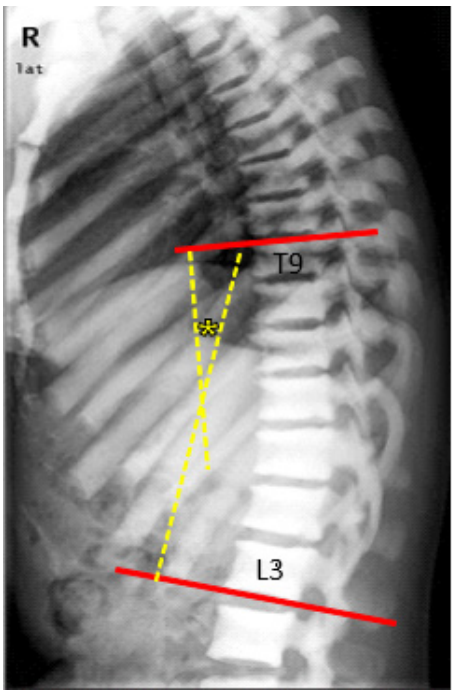

Figure 2. Lateral Cobb angle measurement

Results

The fifty volunteers were recruited between August 2015 to July 2016 and consisted of 20 men (40%) and 30 women (60%). All participants had an average weight of 74.96 kg, height of 163.28 cm and the BMI of 27.74 kg/m^2. More details were shown in Table 1.

Table 1. Demographic and anthropometric data of 50 participants

Parameters	
Age (years)[1]	29.72 (5.60)
Sex[2]	
Male	20 (40)
Female	30 (60)
Anthropometric data[1]	
Weight (kg)	74.96 (27.25)
Height (cm)	163.28 (9.05)
BMI (kg/m^2)	27.74 (8.53)
Waist circumference (cm)	92.24 (20.13)
Hip circumference (cm)	104.64 (15.81)
Waist/hip ratio	0.87 (0.08)
Waist/height ratio	0.56 (0.11)

[1]Mean (SD), [2]number (%)

BMI; body mass index

Comparison of the truncal angles between groups

Radiographic imaging was recorded 3 times as described in the measurement section and the data were shown in Table 2. Male and female groups had the same truncal flexion angle about 9 degrees at baseline and 7 degrees while wearing the Jewett brace. When instructing the participants to flex their trunk while wearing the brace, the male group demonstrated 13.60 degrees of truncal angle, and the female group was 17.33 degrees, and there was not statistically different between the two groups.

In every criterion mentioned-above, we could observe the trend that the non-obese group had a significantly lower degree of truncal flexion than the obese group. The subjects with the BMI < 18.5 kg/m^2 (underweight) had an average truncal angle of 4.6 degrees while the subjects with BMI > 35 kg/m^2 (obesity class II-III) had a truncal angle of 11.5 degrees. (Table 2) These patterns of differences were found in the 1st and the 2nd imaging (without and with the Jewett brace) and reached a statistically significant level at $p < 0.05$. The significant difference in truncal angle was also found in the 3rd imaging (force flexion while wearing the brace) using the BMI and waist circumference criteria but not the waist/hip ratio or waist/height ratio criteria.

Comparison of the extension angle and the bendable angle between groups

Table 3 demonstrates the extension angle representing the hyperextension function. In every obesity criteria classification, the posture of the non-obese group had changed into more degree of extension than in the obese group. But the statistically significant level could only be reached by using the waist circumference criteria which the non-obese group had a 3.57 degree of spinal extension while the obese group had 0.7 degrees of more spinal extension. When wearing the Jewett brace, trunk extension was 2.10 degrees in the male group and 1.97 degrees in the female group, and there was not statistically different between groups.

The bendable angle reflected the limitation in controlling the spinal motion of the Jewett brace. When dividing the participants into groups by the obesity parameters, there was no statistical difference in the bendable angle between groups. The non-obese group had about 9 degrees and the obese group had about 7 to 8 degrees of the bendable angle as shown in Table 3. But when dividing groups according to gender (male/female), there was a statistical difference between groups (p = 0.030) with the bendable angle of 6.35 degrees in males but of 10.20 degree in females. So, females had a more bendable truncal flexion angle of 3.85 degrees than males.

Discussion

Our study demonstrates the objective measurement of the normal subjects' truncal posture regarding the obesity parameters. In the 1st imaging showed the baseline lateral Cobb angle when participants were standing upright and

Table 3. Comparison of the truncal angles between groups classified by gender, BMI, waist circumference, waist/hip ratio and waist/height ratio

Variable	N	1st imaging (without brace)	*p*-value	2nd imaging (with brace)	*p*-value	3rd imaging (flex with brace)	*p*-value
Gender			0.898		0.952		0.104
male	20	9.35 (7.34)		7.25 (6.45)		13.60 (6.00)	
female	30	9.10 (6.27)		7.13 (6.77)		17.33 (8.79)	
5 groups of obesity, classified by BMI (kg/m^2)			0.006*		< 0.001*		0.005*
< 18.5	10	4.60 (5.50)		1.50 (3.89)		12.00 (6.72)	
18.5-24.9	10	8.40 (7.55)		5.20 (6.09)		13.60 (7.23)	
25.0-29.9	10	7.10 (4.04)		4.70 (2.91)		12.40 (5.84)	
30.0-34.9	10	14.40 (5.68)		13.80 (4.85)		22.70 (6.53)	
≥ 35.0	10	11.50 (6.29)		10.70 (6.46)		18.50 (8.62)	
Two groups of obesity, classified by BMI			0.017*		< 0.001*		0.026*
Non-obese	20	6.50 (6.72)		3.35 (5.32)		12.80 (6.84)	
Obese	30	11.00 (6.06)		9.73 (6.14)		17.87 (8.09)	
Waist circumference (cm)			0.033*		< 0.001*		0.030*
Non-obese	23	7.04 (6.50)		3.48 (4.96)		13.22 (6.72)	
Obese	27	11.04 (6.32)		10.33 (6.18)		18.07 (8.33)	
Waist/hip ratio			0.036*		0.004*		0.144
Non-obese	24	7.17 (6.55)		4.50 (5.64)		14.13 (8.10)	
Obese	26	11.08 (6.29)		9.65 (6.50)		17.42 (7.61)	
Waist/height ratio			0.036*		0.004*		0.075
Non-obese	17	6.47 (7.30)		3.59 (5.76)		13.06 (7.14)	
Obese	33	10.61 (5.92)		9.03 (6.27)		17.27 (8.06)	

BMI, body mass index; * $p < 0.05$

Table 3. Comparison of the extension angle and the bendable angle between groups

Variables	N	Extension angle	*p*-value	Bendable angle	*p*-value
Gender			0.914		0.030*
Male	20	2.10 (4.18)		6.35 (5.07)	
Female	30	1.97 (4.28)		10.20 (6.51)	
Five groups of obesity, classified by BMI (kg/m^2)			0.488		0.866
< 18.5	10	3.10 (4.28)		10.50 (6.54)	
18.5-24.9	10	3.20 (4.19)		8.40 (5.08)	
25.0-29.9	10	2.40 (4.55)		7.70 (5.96)	
30.0-34.9	10	0.60 (3.17)		8.90 (6.47)	
≥ 35.0	10	0.80 (4.73)		7.80 (7.67)	
BMI			0.121		0.469
Non-obese	20	3.15 (4.12)		9.45 (5.80)	
Obese	30	1.27 (4.14)		8.13 (6.53)	
Waist circumference (cm)			0.015*		0.262
Non-obese	23	3.57 (4.10)		9.74 (5.71)	
Obese	27	0.70 (3.88)		7.74 (6.59)	
Waist/hip ratio			0.300		0.297
Non-obese	24	2.67 (4.02)		9.63 (6.28)	
Obese	26	1.42 (4.35)		7.77 (6.15)	
Waist/height ratio			0.302		0.514
Non-obese	17	2.88 (4.36)		9.47 (5.97)	
Obese	33	1.58 (4.11)		8.24 (6.39)	

BMI, body mass index; * $p < 0.05$

found the obese persons had a significant more truncal flexion posture. The non-obese group had a baseline truncal angle of 6 to 7 degrees while the obese groups had about 10 to 11 degrees with a statistically different between groups.

When applying a Jewett brace, the brace created mild spinal extension motion described as the extension angle in all groups. Every comparison resulted in a non-statistically significant difference except for the waist circumference criteria that showed the non-obese group had a 3.57 degrees extension significantly more than a 0.70 degree from the obese groups. ($p = 0.015$) Even though it was statistically significant, a 3.57 degree more extension is minimal and could not be considered as a significant change of the spinal alignment in clinical use. We can conclude that the Jewett brace could create a non-clinically significant spinal extension in all participants regardless of obesity.

With the significant different baseline truncal posture between the non-obese and the obese groups, and a non-significant spinal extension created by wearing a Jewett brace, we can conclude that the significant difference of the truncal angle in the 2nd posture (wearing brace) was a result from the different baseline angle, not from wearing the Jewett brace.

When instructed the participant to bend their trunk against the Jewett brace to calculate the bendable angle, there was no statistical difference between the obese and the non-obese groups using every obesity criterion. The bendable angle was in the range of 7 to 10 degrees, and the underweight groups (BMI < 18.5 kg/m^2) had the highest angle of 10.5 degrees. But when compared between genders, the bendable angle in males was significantly lower than in the female group (6.35 vs 10.20 degrees, $p = 0.030$). Though the statistically significant level, it was hard to consider a 4-degree difference between males and females as clinically significant.

The lateral Cobb angle in the 3rd imaging could be interpreted as the most flexion truncal angle that could occur while wearing the Jewett brace. This truncal flexion could happen in daily activities when individuals try to bend down to perform various tasks or activities in daily life. From our data, these truncal angles were significantly higher in the obese groups, based on the BMI or the waist circumference criteria. The obese group had approximately 17 to 18 degrees of truncal flexion angle while the non-obese groups had around 12 to 13 degrees ($p < 0.05$). With the non-significant difference of the bendable angle according to the obesity, the significantly higher flexion angle in the 3rd imaging could be the result from the higher baseline flexion angle in the obese groups.

There is no recommendation or definition of how much restriction of the spinal orthosis is needed to be considered optimal or adequate in clinical use. Theoretically, more flexion spinal alignment will create more loading force on the anterior column of the spinal body, thus contribute or involve with various spinal problems.[16] Future research needs to be performed regarding the correlation between the flexion alignment of the spine and the clinical outcome in spinal pathology.

There is no standard recommendation about how to measure the spinal motion using orthosis. In previous studies,

various methods were used to measure spinal motion such as gross flexion angle using plain film radiography,[17] computed tomography (CT),[18] magnetic resonance imaging (MRI),[19,20] video-fluoroscopy,[2,21] or the motion capture technology. The CT and MRI cannot demonstrate the movement of the spine due to the method required subject in the supine position. The motion capture method requires putting the reflective markers on each spinal process landmarks on the back of the subject which is limited due to the lumbar pad of the Jewett brace. Video-fluoroscope can demonstrate the movement of the spine in real-time, but the process is more complicated compared with plain radiography. The angles of the spine measured in this research did not require a real-time measurement, so the authors used plain radiography as it can demonstrate the spinal morphology and alignment accurately enough for the lateral Cobb's angle measurement.

In conclusion, wearing Jewett brace can minimally produce more extension of the spine about 0.60 to 3.57 degrees, and Jewett brace can limit the spinal movement not to exceed 7-10 degrees of flexion, the bendable angle was not significant difference between the obesity groups. But the obese group's baseline truncal alignment was significantly more in flexion angle than the non-obese group.

Disclosure

The authors declare no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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Original Article

Effects of Instituting a Brief Educational Video and a Short Quiz in the Context of a School Screening Program for Scoliosis

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ABSTRACT

Objectives: To evaluate the effects of administering an educational program about scoliosis and spinal health during a scoliosis school screening. To study prevalence of scoliosis in Thai pupils aged 11-18 years.

Study design: Cross-sectional study.

Setting: Rajavinit Mathayom School, Bangkok, Thailand.

Subjects: Thai pupils aged 11-18 years.

Methods: The data from a scoliosis school screening conducted at a secondary school in Bangkok were retrospectively analyzed. All pupils were asked to complete a 10-True/False quiz about spinal health and watch an educational video about scoliosis. Thereafter they were examined with Adam's forward bending test. A scoliometer was used to measure trunk asymmetry. The pupils with angles of trunk rotation (ATR) greater than or equal to 10º were classified as having scoliosis. Those with ATR between 7º to 9º were classified as at risk and follow up examinations were scheduled for this group. Pupils with ATR less than 7º were classified as normal and required no further re-examination. Then after the back examination, the same quiz was administered a second time in order to assess whether pupils' knowledge has improved.

Results: An average of 69.6% and 84.4% of the questions were answered correctly at the pre and the post tests. The 14.8% increase in the pupils' correct answers after watching the video attains a statistical significance at $p < 0.001$. The three questions that most participants answered incorrectly were about basic pathophysiology, health impact and proper treatments of scoliosis. The prevalence of adolescent idiopathic scoliosis of 2,042 Thai pupils aged 11-18 years was 0.59%. The female to male ratio was 1.1:1.

Conclusion: A brief educational video combined with a short pre- and post-quiz can significantly improve pupils' essential knowledge about idiopathic scoliosis. When screening with the Adam's forward bend test and measuring an angle of trunk rotation with a scoliometer, the prevalence of adolescent idiopathic scoliosis in Thai pupils aged 11-18 years was 0.59%.

Keywords: scoliosis, adolescent, health education, prevalence

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Introduction

Scoliosis is a condition marked with abnormal spinal curvature of greater than 10º Cobb angle in coronal plane radiography.[1] When specific causes such as congenital spinal malformation, neuromuscular disease, and mesenchymal tissue insufficiency are ruled out, a diagnosis of idiopathic scoliosis can be made.[2] Currently, 90% of idiopathic scoliosis cases are present in adolescence, coinciding with the period of maximal growth rate. The global prevalence of adolescent idiopathic scoliosis is 0.47-5.2%. The female to male ratio ranges from 1.5:1-3:1.[2] Without treatment, spinal curves progress and diminish the quality of life.[3] Scoliosis may cause frequent back pain,[3,4] postural instability,[5] and increased expenditure of energy when walking.[6] Those with severe scoliosis experience serious cardiopulmonary problems due to chronic restriction of rib cage expansion.[3,7] Lower self-esteem and depression are other common issues in female patients.[3,8]

According to the 2016 International Scientific Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT),[1] there is growing evidence to support the effectiveness of non-operative treatment for scoliosis patients. These include physiotherapeutic scoliosis-specific exercises (PSSE),[9] and bracing.[10] Failure of conservative treatment and cosmetic concerns are other common reasons for surgery.[3,7] Although surgical correction is an effective treatment that can significantly improve and/or curb curve progression, it is not entirely risk free.[11] There is evidence that patients with scoliosis identified through screening are less likely to need surgery than those who were never screened.[10,12] The most widely accepted screening technique is Adam's forward bend test in which a patient bends forward while an examiner visually checks for any asymmetry in the contour of bilateral paraspinal areas.[10] Visual observation of trunk rotation resulted in 92% sensitivity and 60% specificity.[13] To improve the reliability of the test, the maximal angle of trunk rotation can be measured with a type of inclinometer known as a

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scoliometer.[13] Compared with a Cobb's angle measurement from a spine radiograph, the measurement with a scoliometer method used in the Adam's forward bend test has a 71% sensitivity and 83% specificity in detecting significant spinal curves.[13]

The prevalence was higher (8.91% up to 19.37%) when the diagnosis was based on Adam's forward bend test combined with the scoliometer.[14,15] Interestingly, the female-to-male ratio differed among the various studies performed. In recent studies from 2015 and 2016, the prevalence in females was almost the same as in males (1.7:1 and 0.94:1).[15,16] This contradicts the findings from 1996 which showed a female-to-male ratio of 5:1.[17]

Effective self-management and compliance are necessary for successful scoliosis rehabilitation.[18] Thus, patients need sufficient knowledge about the disease as well as an awareness of diagnostic and treatment options. Nowadays, videos have become an essential learning tool at all levels of education, from kindergarten to university and beyond.[19,20] The availability of targeted and easily understandable videos helps patients manage an ever-increasing number of diseases.[19,20]

In 2019, the Samrong Ruam Jai Foundation initiated a free scoliosis screening program for pupils. It was planned as an ongoing long-term project intended to be made available to increasing numbers of pupils. A five-minute educational video about scoliosis was created for the pupils to watch while waiting for their screening. A quiz designed to assess the pupils' knowledge about idiopathic scoliosis was administered before they watched the video. Then, after completing their back examinations, the pupils repeated the same quiz. The True/False quiz consisted of ten separate statements about scoliosis. The video was carefully constructed to ensure that the pupils would retain the knowledge imparted. Since humans' working memory has a limited capacity for data processing, any informational video should minimize cognitive load, increase engagement and promote active learning. [21] The total length of the video was kept under 6 minutes. Conversational language was used instead of technical jargon. Information was presented in a well-planned sequence so that the concepts followed on logically from one to the next. Distracting visual and audio elements were edited out. Clear audio and/or visual cues were delivered when important information was presented. Images and captions were placed close together to reduce the need for visual scanning. The video purposely included no audio narration. The poor acoustics in the gym where the screening took place were not conducive to an audio presentation.

To our best knowledge, there are no published studies on how educational videos can help adolescent with idiopathic scoliosis to understand the condition better. One objective of this study was to evaluate whether a brief educational video and a short quiz administered twice during a school screening can improve secondary school pupils' knowledge about idiopathic scoliosis. Other objectives were to use retrospective data analysis to estimate the current prevalence of adolescent idiopathic scoliosis in Thai pupils, as well as the female-to-male ratio, and the most common location of maximum deformity.

Methods

The study was conducted after receiving an approval by the ethics committee of Samrong General Hospital, Samut Prakan.

Participants

The pupils at Rajavinit Mathayom School who participated in the Scoliosis School Screening project by Samrong Ruam Jai Foundation in August 2019. Those who were present at the school on the day of screening and whose parents gave informed consent to participate in the screening program, were included in the study.

Study protocol

The pupils' weight and height were measured. Each pupil took a quiz before and after watching a brief educational video about idiopathic scoliosis. They then underwent Adam's forward bending test. During the test, pupils were instructed to bend forward from the hip and waist as far as they comfortably could, while keeping their knees straight. The scoliometer was then placed on the midline, tangentially to the surface of the back.[13] The angles of inclination were read and recorded separately for the upper thoracic, mid thoracic, lower thoracic and lumbar regions.[13] All scoliometers used in this screening were "Baseline" model (Fabrication Enterprises, White Plains, New York, U.S.A.). To ensure their techniques were as consistent as possible, the six physiotherapists who performed the measurements participated in a hands-on practical workshop prior to the start of research.

Notification letters were sent to parents of any pupils who presented with a maximal angle of trunk rotation greater than or equal to 10°. These pupils were offered a free spinal radiography as well as a detailed consultation with a rehabilitation physician regarding appropriate strategies for future management. Those pupils with trunk rotation angles between 7° to 9° received appointments for a 6-month follow-up assessment.

Statistical analysis

Statistical analysis was assessed using the SPSS version 18.0 for Windows. The percentage of correct answers given for each quiz statement was calculated and its statistical significance analyzed with a Chi-square test. The prevalence of spinal rotation was expressed as numerical averages or percentages. Descriptive statistics were used to analyze.

Results

A total of 2,042 pupils (1,057 males and 985 females) participated in this scoliosis school screening. On average 69.6% and 84.4% of the quiz statements were answered correctly at the pre- and the post- tests. Statement numbers 1, 3 and 2 respectively had the highest numbers of incorrect answers. After watching the short educational video, the average scores improved significantly for all 10 statements except statements number 4 and 8. The percentage of pupils who gave correct answers for each statement at the pre- and the post- tests is detailed in Table 1.

The number and percentage of male and female pupils in each age and ATR severity group can be seen in Table 2. Among the pupils who underwent screening, 1,970 (9%), 65 (3.2%), and 12 (0.6%) were classified respectively as normal, at-risk, and having scoliosis. The 14 year-olds were the only age group wherein the difference of curve severity distribution between males and females reached a statistical significance of $p < 0.05$.

Spinal curve type distributions from the 12 pupils with scoliosis and the 65 at-risk are presented in Tables 3 and 4 respectively. Right middle thoracic and left thoraco-lumbar were the most common locations of maximum trunk rotation. The difference in curve types between male ($p = 0.061$) and female pupils ($p = 0.532$) was not statistically significant.

Discussion

This study evaluated the effectiveness of a brief educational video about idiopathic scoliosis during a scoliosis screening at a secondary school. The same short 10-True/

Table 1. Percentage of correct responses of the pretest and the posttest of the True/False quiz about idiopathic scoliosis (n=2,031)

Question	Content of quiz	T/F	Pretest	Posttest	% Change	*p*-value
1	Scoliotic spinal deviation happens in three planes	T	22.4%	64.8%	42.4%	< 0.001
2	Adolescence carries a higher risk than other age groups	T	67.1%	91.2%	24.1%	< 0.001
3	Otherwise healthy persons can develop scoliosis	T	45.1%	84.7%	39.6%	< 0.001
4	Only specialist can detect scoliosis	F	66.1%	61.3%	4.7%	0.002
5	Scoliosis cannot be treated effectively	F	89.6%	93.5%	3.8%	< 0.001
6	Habitually carrying heavy bags on one shoulder does not cause scoliosis	F	87.8%	93.7%	5.9%	< 0.001
7	Prolonged sitting can cause scoliosis	T	74.5%	94.3%	9.9%	< 0.001
8	Tossing and turning a lot during the night cause scoliosis	F	74.7%	75.6%	0.9%	0.561
9	Surgery is one of the treatment options for scoliosis	T	78.6%	89.0%	0.4%	< 0.001
10	Exercising and changing postural habits can ameliorate scoliosis.	T	89.9%	95.8%	5.9%	< 0.001
Average			69.6%	84.4%	14.8%	< 0.001

T, True; F, False

Table 2. Distribution of scoliometer finding by age, sex, and severity of ATR (angle of trunk rotation) classified as normal, at-risk and scoliosis

Age (year)	Male			Female			Total	*p*-value
	Normal	At-risk	Scoliosis	Normal	At-risk	Scoliosis		
11	6 (100)	-	-	2 (100)	-	-	8 (0.4)	-
12	154 (97)	4 (2)	1 (1)	134 (99)	2 (1)	-	29(14.4)	0.690
13	210 (98)	4 (2)	-	183 (96)	8 (4)	-	405(19.8)	0.241
14	213 (99)	2 (1)	1 (1)	176 (94)	9 (5)	3 (1)	404(19.8)	0.022
15	159 (94)	9 (5)	1 (1)	136 (94)	7 (5)	1 (1)	313 (15.3)	1.000
16	148 (95)	6 (4)	1 (1)	143 (96)	4 (3)	1 (1)	303 (14.8)	0.875
17	103 (94)	5 (4)	2 (2)	136 (98)	2 (2)	-	248 (12.1)	0.086
18	25 (89)	3 (11)	-	37 (97)	-	1 (3)	66 (3.2)	0.072
Sum	1,018	33	6	947	32	6	2,042	0.124

Number (%) sorted by age, ATR, and sex
Comparison between age and ATR by using Chi-square test.
p-value analyzed with Chi-square test.

Table 3. Spinal curve types among those with scoliosis (n=12)

Curve type	Right				Left				Bouble	Total	*p*-value
	UT	MT	LT	L	UT	MT	LT	L			
Male	-	2 (33)	-	-	-	-	1 (16)	3 (50)	-	6	0.061
Female	-	6 (100)	-	-	-	-	-	-	-	6	

Number (% sorted by gender)
UT, upper thoracic (T1-T4); MT, middle thoracic (T5-T8); LT, lower thoracic (T9-T12); L, lumbar (L1-L5)

Table 4. Spinal curve types among those at risk of scoliosis (n=65)

Curve type	Right				Left				Bouble	Total	*p*-value
	UT	MT	LT	L	UT	MT	LT	L			
Male	-	8 (24)	2 (6)	-	-	4 (12)	7 (21)	9 (27)	3 (9)	33	0.532
Female	1(3)	14 (44)	3 (9)	1 (3)	-	3 (9)	5 (16)	4 (13)	1 (3)	32	

Number (% sorted by gender)
UT, upper thoracic (T1-T4); MT, middle thoracic (T5-T8); LT, lower thoracic (T9-T12); L, lumbar (L1-L5)

False quiz was administered to the pupils twice: once before watching the video and once afterwards. The average percentage of correct responses after watching the video was 18.4% higher than beforehand. This result indicates that a well-designed and easily understandable educational video helps the pupils have a better understanding of idiopathic scoliosis. Watching the video while waiting for their back examination as well as taking the accompanying before and after quiz, seems to have increased the pupils' level of engagement and active participation in learning. However, these authors speculated that watching such a video and giving the quiz outside the context of school screening could be less effective.

An analysis of the pupils' responses to the True/False quiz suggested areas where the video could be improved. For example, in the quiz given after the video, more students marked the question "Only specialist can detect scoliosis." as TRUE than they had before watching the video. In fact, everyone can and should learn how to look for signs of scoliosis, but only specialists can confirm a diagnosis and suggest a proper treatment plan. The video has been edited to communicate these important points more clearly. And now, the latest Thai version of this video is available online (https://m.facebook.com/story.php?story_fbid=3001864509922087&id=1084082001700357.)

Even after watching the video, approximately a quarter of all students incorrectly answered the True/False statement, "Tossing and turning a lot during the night cause scoliosis." A review of the video script revealed that a correct statement was accidentally omitted in the video. Thus, the video has now been revised to say that idiopathic scoliosis is not caused by sleeping position or other habitual postures. However, once a diagnosis of scoliosis has been made, maintaining correct postures throughout the day can reduce the curve progression.

This study showed the prevalence of scoliosis as detected by angle of trunk rotation of 10° or greater was 0.59% and the prevalence of 7° to 9° trunk rotation was 3.18%. These figures are lower than findings from previous studies using ATR > 10° as scoliosis,[14,17] but the discrepancy is not surprising. The variations in prevalence figures in the different studies are probably related to the small sample sizes. We look forward to accumulating more data from ongoing Samrong Ruam Jai Foundation school screening programs. According to our statistical calculations, a study of 9,508 children will be needed to assess the prevalence of scoliosis in Thailand.

Another interesting finding from the current study is the 1.1 female per 1 male ratio of scoliosis prevalence by sex. This is in line with other studies using ATR > 5° and > 7° as scoliosis in the last decade, which showed 0.94:1 and 1.7:1 female to male ratio.[15,16] But, it is in stark contrast to the 1966 study using ATR > 10° as scoliosis in which the female to male ratio was 5:1.[17] This change of gender ratio might be explained by the increasingly sedentary lifestyle of pupils, especially those who present with less than optimal spinal postural control in the first place. We hypothesized that lack of physical activity can potentially aggravate and perhaps fixate this abnormal habitual spinal curve until the scoliosis worsens and becomes clinically apparent. Traditionally, boys tended to be more physically active than girls which probably explains why the prevalence of scoliosis in males used to be several times lower than in females. We postulate that the longer static sitting times associated with increased use of smartphones and portable computers might contribute to reducing the sex differences found in recent studies. Further investigations should focus on the correlation between physical activity and occurrence of scoliosis.

One compelling theory states that those with inborn subclinical postural control deficit due to small central nervous system lesions may be at higher risk to develop scoliosis.[22,23] Incidence of scoliosis in cerebral palsy correlates with the severity of neurological deficit.[24] Additionally, scoliosis occurs more commonly in conjunction with other existing malformations such as malocclusion[25] and pectus deformity.[26]

This novel combination of brief interactive educational activity in the context of screening that we describe herein has other potential applications beyond early detection of new scoliosis cases. It can also serve to increase awareness and motivate pupils with mild trunk deformity to be more mindful of their posture during daily activities. This in turn has the potential to reduce the progression of the spinal curve. Further follow-up of these pupils from this study are needed to assess the long-term effects of such programs.

Regarding limitation, the current study had a low number of participants and the power of prevalence estimation was 44.9%. According to statistical calculations, a study of 9,508 children will be needed to reveal a more reliable prevalence of scoliosis among adolescent group in Thailand. We look forward to accumulating more data from the ongoing Samrong Ruam Jai Foundation school screening programs. In addition, the revised short video with 10-True/False quiz should be tested to confirm it benefits.

In conclusion, a brief educational video that includes a short pre and post quiz has been shown to significantly improve students' essential knowledge about idiopathic scoliosis. By measuring an angle of rotation with a scoliometer, the prevalence of adolescent idiopathic scoliosis in 2,042 Thai pupils aged 11-18 years was 0.59%. The female to male ratio was 1.1:1.

Disclosure

The researchers have no conflict of interest to declare.

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Original Article

Immediate Effects of High-Frequency Repetitive Transcranial Magnetic Stimulation Combined with Task-Specific Training in Individuals with Parkinson's Disease: a Preliminary Study

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ABSTRACT

Objectives: This study examined the immediate effects of a single-session of high-frequency repetitive transcranial magnetic stimulation (HF-rTMS) combined with task-specific training (TST) on reach-to-grasp (RTG) performance in individuals with Parkinson's disease (PD).
Study design: Matched-pair experimental design
Setting: Motor Control and Neural Plasticity Laboratory, Faculty of Physical Therapy, Mahidol University
Subjects: Twenty patients with mild to moderate severity of PD (Hoehn &Yahr stage I-III) participated in the study.
Methods: Participants were allocated into two groups. The experimental group received HF-rTMS to the left-primary motor cortex (M1) combined with TST of RTG, while the control group received only HF-rTMS to left-M1. Before and immediately post intervention, right-hand RTG performance was measured under no barrier and barrier conditions. Additionally, cortical silent period (CSP) was determined to verify the effects of HF-rTMS.
Results: There were no significant differences between the two groups for both RTG performance and CSP duration. In the control group, there was a significant decrease (p = 0.03) in movement time immediately after HF-rTMS for a barrier condition. Moreover, significant differences in absolute time to maximum aperture (TAmax) (p = 0.04) and temporal transport-grasp coordination (Tmax) (p = 0.04) were observed. A significantly longer CSP in the control group (p = 0.02) confirmed the effects of HF-rTMS. In contrast, the experimental group showed a significant prolonged in TAmax (p = 0.04) and Tmax (p = 0.05).
Conclusion: The findings in the experimental group indicated that the TST of RTG was not sufficient to augment the effects of HF-rTMS that may be the results of the complex task of RTG performance covering the aspect of RTG execution, planning, and transport-grasp coordination.

Keywords: transcranial magnetic stimulation, brain stimulation, bradykinesia, Parkinson's disease, task performance

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Introduction

Recently, the non-invasive brain stimulation technologies have been applied to be an alternative treatment for various neurologic and psychiatric conditions such as stroke, Parkinson's disease (PD) and depression.[1-3] In particular, repeti-tive transcranial magnetic stimulation (rTMS) has been increasingly used in both research and clinic. The rTMS is one of non-invasive brain stimulation technologies that can modulate corticospinal excitability and cortical inhibition in the cerebral cortex by the stimulation through the coil.[2]

Previous studies reported that the cortcospinal excitability and cortical inhibition could improve following a single-session of rTMS over the primary motor area (M1) not only in stroke condition[4] but also in individuals with PD.[2,5] Additionally, the upper extremity function especially reach-to-grasp (RTG) performance could be improved following a single-session rTMS over the M1.[2,4] However, long-term beneficial neuromodulation of rTMS is the limitation of a single-session of rTMS. The improvement of corticospinal excitability and motor performance has been observed following multiple sessions.[6] Alternatively, it has been identified that brain plasticity can be improved when HF-rTMS application precedes task specific-repetitive training (TST). Interestingly, the cortical excitability and the paretic hand performance in stroke were improved by a single-session of rTMS to M1 combined with TST as shown in previous studies.[7,8]

Based on the combined intervention model as applied in people with stroke, the TST was an indirect rehabilitation of the paretic limb following the rTMS primed the neural network that could be called "Bottom up approach".[6-8] This approach required a long period of treatment. The rTMS is considered a "top-down approach"[7] since it is directly applied

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to the central nervous system to reduce motor impairment.[4,5,7] In addition, compared to the former approaches, the rTMS may reduce the duration of treatment.[7] Therefore, if both approaches are combined, they most likely lead to a better motor performance as shown in the previous studies.[7,8] Previous evidence suggested that the specific type of motor training like a real world task led to neural plasticity and changed to the behavior.[7] Therefore, clinicians need to focus the specific motor impairment that is an important for becoming the specific type of motor training in each disorder.

Regarding individuals with PD, bradykinesia is one of the cardinal signs that is slowness of a performed movement.[9] The characteristics of bradykinesia are difficulty initiating and executing movement. Individuals with PD often complain of problems with performing manipulative tasks, in particular RTG performance deficits.[10] The RTG performance deficit is reflected by a longer movement time during RTG performance, a decrease in maximum velocity of the arm, an increase in time spent to decelerate the hand during grasping, a reduction of hand opening, and prolonged time between initiation of hand opening and maximal hand opening.[10] All of these impairments are reflected to the RTG execution and transport-grasp coordination. These impairments are magnified if the RTG task is performed under a barrier condition.[10] In term of RTG execution and transport-grasp coordination deficits, it might be a result of a basal ganglia-thalamocortical pathway deficit in nigrostriatal pathway that led to an increase in inhibitory signaling to the thalamus. Therefore, the thalamus cannot generate an excitatory signal to the M1 and supplementary motor cortices, which are the motor execution and planning areas, respectively.[2,11]

Regarding over inhibitory signaling to the motor cortex, it has been related with changes in cortical inhibition as represented by cortical silent period (CSP) duration. Compared to health people, the CSP duration was found to be shorter and intracortical facilitation reduced in people with PD.[12,13] Recently, it has been shown that high-frequency rTMS or HF-rTMS over M1 improved the CSP duration in individuals with PD. The rTMS application can be divided into two different frequencies including high-frequency and low-frequency. High-frequency rTMS should be referred to stimulus rates of more than 1 Hz. While low-frequency rTMS should be referred to stimulus rates of 1 Hz or less.[14] The HF-rTMS is used to increase corticospinal excitability and could restore the inhibitory system as indexed by the lengthening of CSP post HF-rTMS to M1.[2] In individuals with PD, there were several studies reported the HF-rTMS application could reduce the motor impairment.[2,15,16] In particular, the researchers demonstrated that the thalamocortical pathway deficit in nigrostriatal pathway could be compensated by the HF-rTMS application.[15] The HF-rTMS over M1 could reduce the motor impairment, representing by the improvement of motor part of unified Parkinson' disease rating scale (UPDRS),[5,17] movement time,[5,17] and reaction time.[17]

Additionally, following HF-rTMS to M1, many of the deficits for RTG execution when avoiding a barrier including total movement time (MT), deceleration time (DT), and transport maximum velocity (Vmax) improved. These variables reflect improvement in the transport component of RTG. Additionally, the grasping component was improved following HF-rTMS reflected by increased maximum aperture or hand opening (Amax) and time to maximum hand opening (TAmax).[2]

Taken together, the purpose of this preliminary study was to examine the immediate effects of a single-session of HF-rTMS over left-M1 combined with the TST using the RTG training (experimental group) on RTG performance in people with mild to moderate PD. We hypothesized that the experimental group would show greater improvement in RTG performance compared with the control group who received a single-session of HF-rTMS to left-M1 only. Moreover, we also investigated whether normalizing cortical inhibition is accompanied by improved RTG performance.

Methods

The study was approved by the Siriraj Institutional Review Board and the Mahidol University Institutional Review Board (MU-CIRB 2017/067.2003). This study was registered in the Thai Clinical Trials Registry (TCTR20170202002).

Participants

Individuals with PD were recruited from the Faculty of Medicine Siriraj Hospital and the Faculty of Physical Therapy, Mahidol University. Eligible participants had been diagnosed with idiopathic PD by movement disorders neurologists. All participants were right hand dominant (defined by Edinburgh Handedness Inventory) and were screened for inclusion and exclusion criteria. The inclusion criteria were as follows: (1) age range 40 to 80 years, (2) mild to moderate severity with Hoehn &Yahr (H&Y) stage I-III, (3) more impaired on the right hand dominant as examined by the Unified Parkinson's Disease Rating Scale (UPDRS) part III (motor examination) including items of rigidity, finger taps, hand movements, rapid alternating movements of the hands, tremor at rest, and action tremor of the hands, (4) ability to understand and follow simple commands with greater than 23 on the mini mental state examination (MMSE) Thai version 2002, and (5) ability to sit independently for more than one hour. The exclusion criteria were as follows: (1) contraindication for TMS confirmed by TMS screening questionnaire, (2) severe action or resting tremor with a score greater than or equal to 3 for action, postural, or resting tremor of the hands in the UPDRS part III, (3) severe rigidity with a score greater than or equal to 3 for rigidity of the hands in the UPDRS Part III, (4) ON/OFF medication fluctuations, (5) severe disability from dyskinesia with a score greater than or equal to 3 for dyskinesia in the UPDRS part IV, (6) other neurological and/or musculoskeletal problems affecting arm, hand, or trunk which would interfere with task achievement such as arthritis

in the upper extremity (UE), (7) implanted deep brain stimulation (DBS) or plan to have DBS during the study period, (8) psychiatric illness, alcohol or substance abuse, and (9) poorly controlled depression or anxiety (measured by the Thai Hospital Anxiety and Depression Scale (HADS) (score ≥ 11)). All participants were given a written informed consent and assessed before admittance into this study.

Study protocol

This study was a matched-pair experimental design. All participants were randomized into two groups, using a convenience sampling method (Figure 1). They were matched according to their impairment level and age range (+/-5 years). The experimental group received HF-rTMS over the left-M1 with RTG training while the control group received only HF-rTMS over the left-M1.

Moreover, both groups were assessed for RTG performance and cortical inhibition at baseline (Pre) and immediate post HF-rTMS with RTG training or post HF-rTMS only (Post) (Figure 1). Additionally, all participants were measured by the same evaluator. The evaluator was blinded (a single blinded clinical trial). During participation, they took their medications regularly. To control for medication in function, they were tested at the same time of day.

After evaluation at baseline, all participants in both groups received HF-rTMS over left-M1 at the extensor digitorum communis (EDC) representational area. The HF-rTMS application was produced from Magstim Rapid^2 (Magstim Co., Dyfed, UK) with the figure-of-8 air-cooled coil. The parameters for stimulation were shown in the previous study (Figure 1).[2] Importantly, HF-rTMS application was conducted by the same person to all participants.

After stimulation, the experimental group underwent TST of RTG which involved reaching to grasp a dowel of 1.2 centimeter in diameter. The RTG training was performed for 4 sessions consisting of 30 trials per session. They were allowed to take a rest for 5 minutes between sessions. During the training, the verbal instruction to focus on large amplitude movements was given every other trial to "reach the farthest and to open the hand the widest".

Outcome measures

The RTG performance of the right (more affected) hand was measured with an electromagnetic motion tracking system (Motion Monitor, Innsport, Inc, IL, USA). Three 3D sensors captured the kinematic data. The sampling rate for the three sensors was 100 Hz. A zero-lag Butterworth low-pass filter with a cut-off frequency of 20 Hz was used.[10] The researcher provided verbal instructions to the participants and demonstrated reaching and grasping the dowel with and without the barrier. Tasks were performed from less to more complex as determined previously. Thus, the order of task completion was without barrier condition to with the barrier. Regarding RTG measures protocol, it was shown in the previous study.[2]

All kinematic variables were extracted from each trial using customized automatic computer routines written in MatLab (the Math Works Inc., Natick, MA, USA). The RTG kinematic variables were used to determine the movement execution and visuospatial processing. Movement execution included total movement time (MT), deceleration time (DT), time to maximum aperture (TAmax), transport maximum velocity (Vmax) and maximum aperture or hand opening

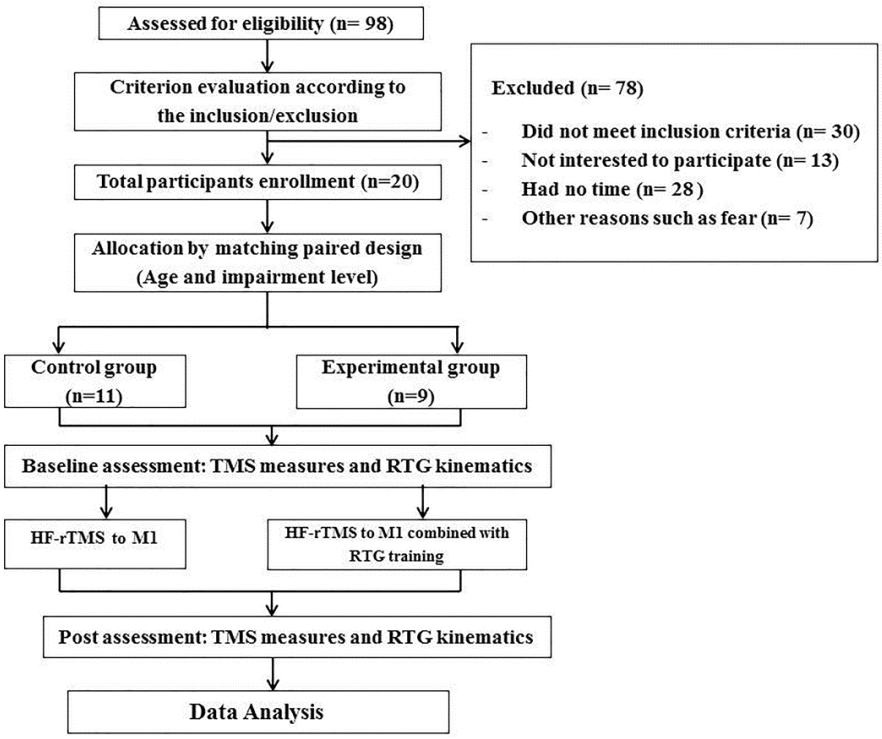

Figure 1. Diagram of the study protocol

(Amax). Visuospatial processing was measured by transport-grasp coordination that was expressed by the cross correlation coefficient (rmax) (spatial coordination) and the associated time lag (Tmax) (temporal coordination) between transport velocity and grasp aperture.[10]

The cortical inhibition was measured by the CSP duration; this is the duration of EMG interruption of voluntary motor activity and was generated using a single-pulse TMS with a figure-of-8 coil. Regarding CSP measures protocol, it was shown in the previous study.[2]

Statistical analysis

Mean and standard deviation was determined for the demographic data and clinical characteristics that were analyzed by descriptive statistics. The average of each variable was analyzed using independent sample t-test or Mann Whitney U-test. All data were analyzed by SPSS for window release 19.0 (IBM, SPSS Inc, Chicago, IL, USA). The Shapiro-Wilk was used to determine normal distribution. As for the differences between the two groups, the independent t-test was used to analyze for the normal distributed data. In contrast, the Mann Whitney U-test was used to test for the non-normalization data. As for the data within each group, paired t-test was used to compare for cortical inhibition and RTG kinematics. In contrast, the Wilcoxon sign rank test was used to compare within each group for non-normally distributed data. The level of significance was set at a probability level equal to or less than 0.05 ($p \leq 0.05$). Effect size was used to quantify the magnitude of change following the stimulation. We calculated the effect size based on the statistical tools that were used in the study including Z score or t score and dividing it by the square root of the sample size per group. The effect size was classified as small (0.2), medium (0.5), and large (0.8).[18]

Results

Twenty individuals with PD who participated in this study were divided into two groups; control (n=11) and experimental (n=9) groups. The characteristics and demographic data are shown in the Table 1. All of the participants were more affected on the right side and their age was between 50-80 years old. In addition, based on UE impairment, participants were identified as H&Y stages I, II, and III with 1, 15, and 4 individuals/stage, respectively. Scores for right UE impairment from the UPDRS-Motor section ranged from 3-18 (total UE score = 24). Additionally, there were no significant differences in age, disease duration, UPDRS UE score, MMSE, HADS scores, and medications ($p > 0.05$) between the two groups (Table 1).

Mean (standard error, SE) of all baseline and post intervention kinematic measures between the two groups for the non-barrier and the barrier conditions are shown in Figure 2 and 3. At baseline, there were no significant differences in any kinematic variables between the two groups. These baseline findings indicates homogeneous participants. The differences in RTG execution are presented in Figure 2 and 3.

No group differences were found in the movement time (MT) and absolute deceleration time (DT) for both conditions. However, the control group demonstrated a significant decrease in MT for the barrier condition ($p = 0.03$) with a medium effect size (ES = 0.53) (Figure 2B). While no significant differences were observed in the experimental group for the non-barrier and barrier conditions (Figure 2A-2B). Additionally, the control group showed a significant decrease in the absolute DT for the barrier condition ($p = 0.03$) with a medium ffect size (ES = 0.56) (Figure 2D), but not found in the experimental group (Figure 2D).

For Transport maximum velocity (Vmax), there were no significant differences between the two groups and within each group for both conditions. However, the control group showed a non-significant increase in Vmax following M1 stimulation only compared to the baseline for both conditions. While, there was no change in the experimental group (Figure 2E-2F).

While no group differences were found in the hand opening or maximum aperture (Amax) and transport to maximum aperture (TAmax) for both conditions. The Amax in the control group showed a near significant increase following

Table 1. Comparison of the characteristics and demographic data

	Control group (n=11) Mean (SD)	Experimental group (n=9) Mean (SD)	*p*-value
Age (years)	66.91 (7.49)	64.44 (8.26)	0.49[a]
Disease duration (years)	9.27 (6.21)	7.44 (4.85)	0.48[a]
UPDRS (III-right UE UE, scores)	12.55 (4.01)	12.89 (2.98)	0.83[a]
Thai-MMSE (scores)	25.73 (1.27)	25.44 (1.42)	0.65[a]
HADS-Anxiety (scores)	3.09 (2.07)	3.11 (2.37)	0.98[a]
HADS-Depression (scores)	4.18 (1.99)	2.56 (1.94)	0.08[a]
Medications			
Levodopa, mg/day	659.09 (267.17)	541.67 (165.36)	0.27[a]
COMT inhibitor, mg/day	475 (95.74)	475 (95.74)	0.73[b]

[a]*p*-value from Independent sample t-test, [b]*p*-value from Mann Whitney test, *significant difference at *p*-value ≤ 0.05
COMT; catechol-O-methyltransferase inhibitor

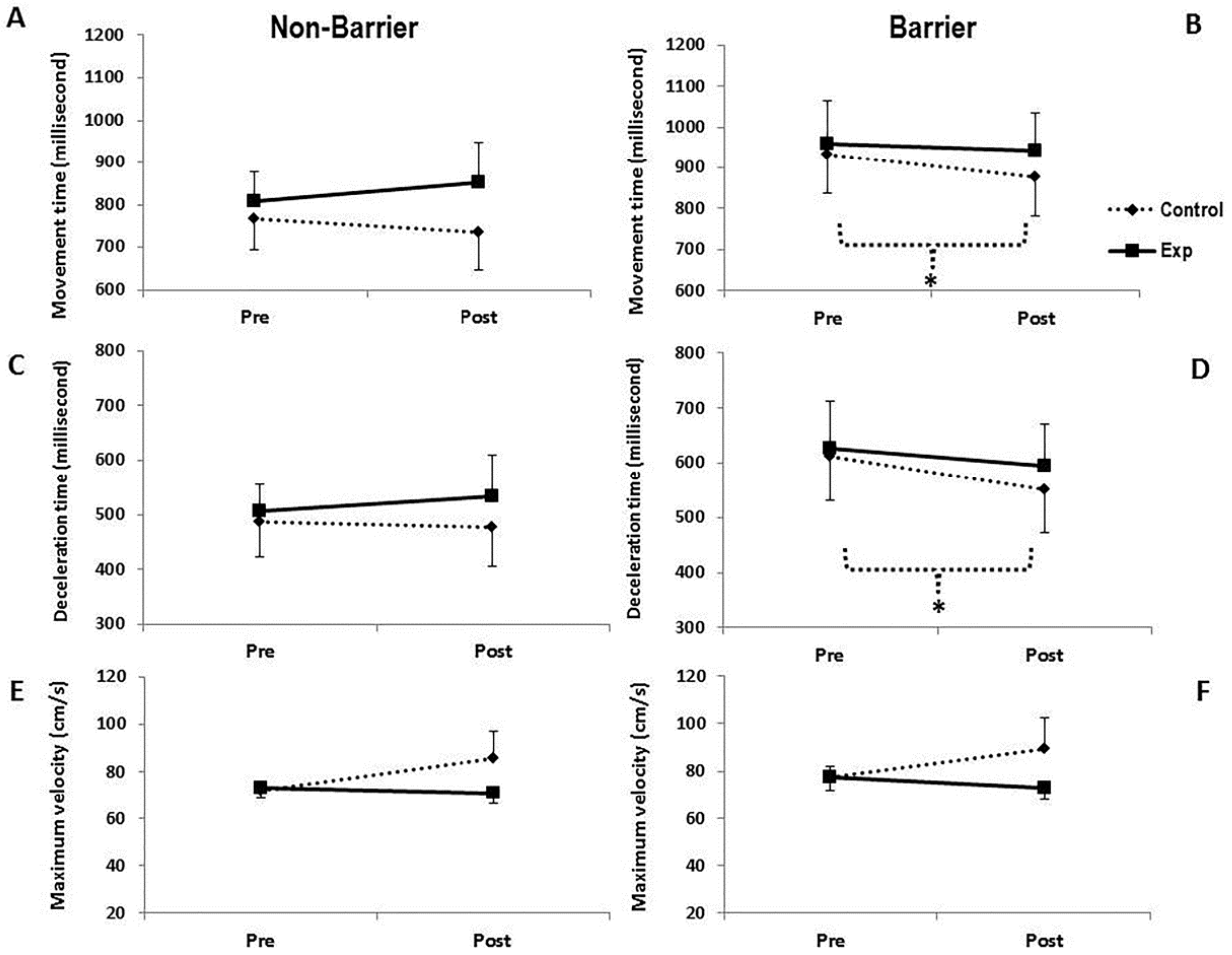

Figure 2. Average (+/-SE) movement time (A and B), absolute deceleration time (C and D), and maximum velocity (E and F) at baseline (pre) and immediately post intervention (post) for the experimental and control groups in non-barrier (left) and barrier (right) conditions

HF-rTMS compared to baseline in the barrier condition (p = 0.06) with a medium effect size (ES = 0.40). In addition, no change was observed in the experimental group. (Non-barrier condition: experimental group pre = 5.23 (0.34) cm/ post = 5.17 (0.54) cm and control group pre = 5.85 (0.52) cm/ post = 5.73 (0.65) cm/Barrier condition: experimental group pre = 4.59 (0.36) cm/post = 4.64 (0.5) cm and control group pre = 4.74 (0.48) cm/post = 5.28 (0.62) cm). Additionally, the control group demonstrated a significant decrease in absolute TAmax in the barrier condition (p = 0.04) with a medium effect size (ES = 0.49) (Figure 3B). In contrast, the experimental group showed a significant longer in TAmax following combined interventions compared to the baseline in the non-barrier condition (p = 0.04) with a large effect size (ES = 0.81) (Figure 3A).

Regarding the temporal coordination or Tmax, there were no group differences for both conditions. However, the control group showed a significant decrease in Tmax compared to the baseline for the barrier condition (p = 0.04) with a medium effect size (ES = 0.50) (Figure 3D). In contrast, the experimental group showed a prolong significant in Tmax compared to the baseline for the non-barrier condition (p = 0.05) with a medium effect size (ES = 0.54) (Figure 3C).

For spatial coordination, there were no significant differences between the two groups and within each group for both conditions. (Non-barrier condition: experimental group pre = 171.77 (23.44) ms/post = 198.45 (31.61) ms and control group pre = 161.7 (23.53) ms/post = 172.65 (22.33) ms /Barrier condition: experimental group pre = 272.71 (37.01) ms/post = 253.95 (34.21) ms and control group pre = 247.07 (29.36) ms / post = 215.32 (26.47) ms).

Regarding the cortical inhibition (TMS measure), it was represented by the CSP duration. There was no significant difference between the two groups. However, there was significant difference between pre and post measurement following the HF-rTMS to M1 (p = 0.02) for the control group, but not in the experimental group who received the HF-rTMS to M1 combined with the RTG training (p 0.11) (Figure 4).

Discussion

This study examined the immediate effects of a single-session HF-rTMS over M1 with task specific-repetitive RTG training (experimental group) on RTG performance in people with PD with mild to moderate upper extremity impairment. Their RTG performance was compared to the control group who was stimulated by HF-rTMS to M1. The findings in the

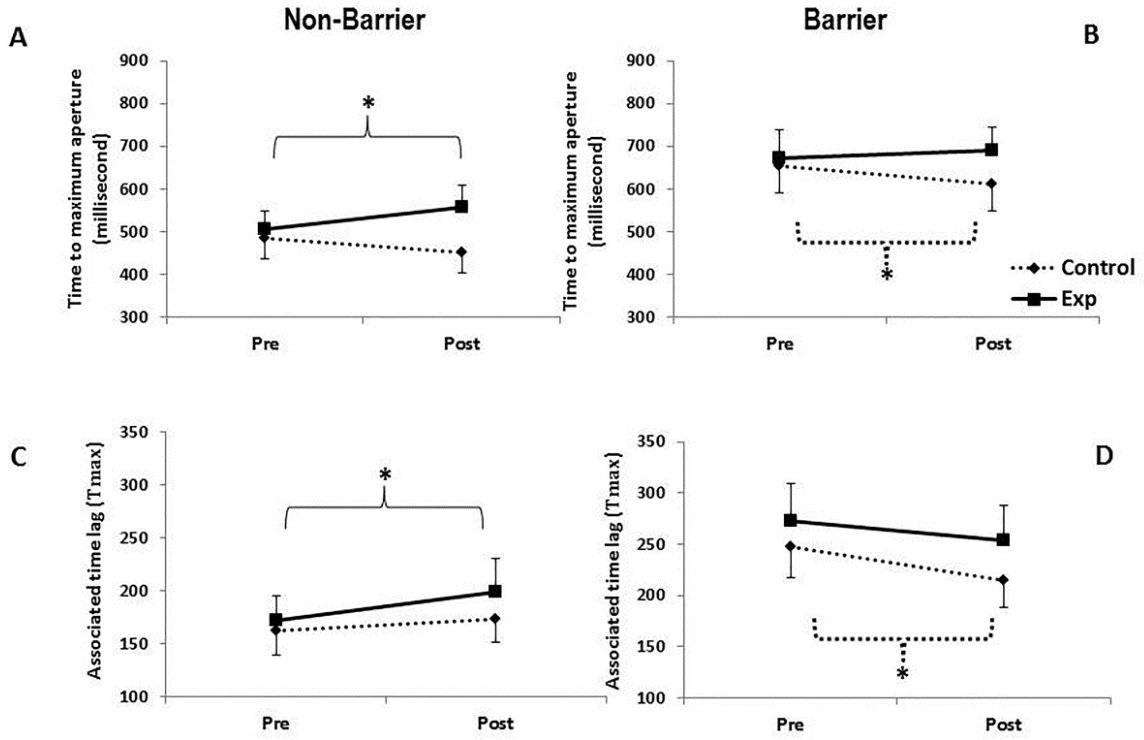

Figure 3. Average (+/-SE) time to maximum aperture (A and B) and associated time lag (C and D) at baseline (pre) and immediately post intervention (post) for the experimental and control groups in non-barrier (left) and barrier (right) conditions

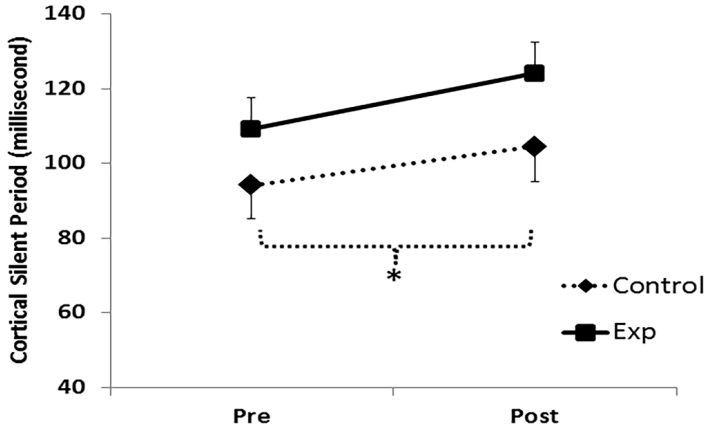

Figure 4. The average (+/-SE) cortical silent period at baseline (pre) and immediately post intervention (post)

control group are consistent with our hypothesis of improvement in RTG performance following HF-rTMS to M1. The HF-rTMS over M1 improved RTG execution with respect to speed as evidenced by decreased MT, DT, and TAmax. Additionally, temporal transport-grasp coordination or Tmax nearly improved following HF-rTMS to M1. In particular, there were significant differences in the barrier condition. These data suggest that HF-rTMS over M1 can directly improve RTG performance, particularly for the most challenging task. Regarding the significant improvement of RTG performance following HF-rTMS to M1, it may be the result of restoration of the inhibitory system by activating dopamine (DA) release through M1 stimulation. From a physiology of HF-rTMS with the parameters used over M1, the previous evidence demonstrated DA release in the striatum was observed following a single-session of stimulation.[2,19,20] The DA release would send back to the nigrostriatal pathway and restored the function between thalamus and motor cortex as evidenced in the previous study.[2] This possible mechanism was verified by an increase in the cortical inhibition as indexed by a significant lengthening of CSP duration seen immediately post HF-rTMS to M1. The finding in the control group was consistent with a previous study.[2]

In the experimental group, the main findings regarding RTG performance is not consistent with our hypothesis because there were no significant improvements following HF-rTMS to M1 combined with RTG training. In addition, a decrease in processing speed based on the prolonged

TAmax, and Tmax observed immediately post combined intervention compared to baseline. Five possible explanations were as follows: (1) type of verbal instruction, (2) a single combined session, (3) the number of trials for improving the different neural control of reaching only versus RTG performance, (4) level of task difficulty for training, and (5) the location of stimulation. The detail of each notion is described in the following paragraphs.

First, the unexpected results may be a result of the verbal instruction. In this study, the amplitude-focused instruction was given during RTG training that was not specific for improving movement speed.[21] Additionally, the verbal instruction might increase the working memory load that can lead to a deterioration of motor performance immediately post training.[22] Secondly, a single combined session might not be sufficient to improve performance. Based on a previous study, individuals with PD improved gait immediately following 12 combined sessions.[23] Thirdly, the number of trials in this study was not sufficient to enhance motor learning during a complex task such as RTG. The 120 trials used in this study is based on a study that successfully utilized rapid arm reaching only training.[24] The neural control of reaching and grasping an object is more complex and requires more coordination.[25,26] The RTG movement requires precise control in two components including transport component for moving forearm and hand to a specified object and grasp components for shaping the hand to grasp the object. Additionally, these components need to be coordinate temporally and spatially.[10] In previous evidence, individuals with PD usually had RTG deficits in term of motor planning, motor execution and transport-grasp coordination.[10]

Fourthly, the RTG training in this study may be less difficult than improving the motor planning and transport-grasp coordination. Insights into the pathophysiology perspective in individuals with PD, motor execution deficit may be a result of DA deficit in nigrostriatal pathway. As for the motor planning and transport-grasp coordination, it may be a result of DA loss in the ventral tegmentum area (VTA) of the mesocortical pathway. This impacted on the transmission of DA to the prefrontal cortex,[11] in particular dorsal lateral prefrontal cortex (DLPFC).[27,28] The prefrontal area is responsible for higher order planning, decision making, movement selection, and attentional processing.[29] In particular, in its role in executive function, DLPFC is associated with working memory[30] and cognitive flexibility.[31] Therefore, a DA deficit along the mesocortical pathway leads to inability to plan, initiate, and monitor goal-directed behavior with the flexibility to update goals when presented with new information.[32] Regarding the RTG training in this study, it was not specified to reduce the motor impairment in term of motor planning and RTG transport-grasp coordination. Individuals with PD need to improve their executive function through the prefrontal cortex function. In addition, the RTG training in this study may be less difficult than the RTG performance testing as measured in the barrier condition. Therefore, it may not support the prefrontal cortex function in term of the flexibility to update goals when presented with new information.[32]

Finally, in addition to the RTG training, the location for stimulation in the experimental group may not support TST in term of motor planning and RTG transport-grasp coordination as measuring by the temporal transport-grasp coordination. The HF-rTMS to M1 could improve only motor execution as shown in a recent study.[2] Therefore, M1 stimulation was not sufficient to improve the executive function as impaired by a DA loss in mesocortical pathway. Therefore, DLPFC stimu-lation may be suggested in the further study for improving the motor planning and RTG transport-grasp coordination. Additionally, the DA deficit in individuals with PD, this impacted on the interconnected brain regions that include reduced activity in the supplementary motor cortex and reduced efferent feedback in the basal ganglia-thalamocortical pathway. Accordingly, in addition to the DLPFC stimulation, additional stimulation over the supplementary motor cortex may be suggested in further study to improve motor planning and RTG transport-grasp coordination through the connection between the supplementary motor cortex and the basal ganglia function that plays a role in the kinematic scaling of movements.[15,33]

Additionally, the non-improvement of RTG performance in the experimental group has also been shown to be accompanied by the non-significant lengthening of CSP duration compared to the baseline. The authors expected the combination of HF-rTMS and TST would increase the cortical inhibition, but our resulted did not showed a significant difference. Even though, a single-session of HF-rTMS over left-M1 could induce a significant lengthening of CSP duration. A single combined session could not improve the inhi-bitory system. The possible explanation may be a result of a single-session of TST of RTG. Because of the TST, the previous study found that the inhibitory system can be enhanced following the 2-weeks TST of balance training on an unstable platform when compared to a control group performing a normal routine of physical activity.[34]

There were some limitations in our study. Firstly, regarding the unexpected results in the experimental group, the 120 trials used for training in this study was not sufficient to improve motor learning during RTG actions, due to their complexity and requirement for coordination.[26] Thus, the improvement of RTG actions may require more trials. Secondly, regarding the prolonged TAmax and temporal transport-grasp coordination, it may be the result of internal programming deficits. According to the DA deficit in the mesocortical pathway leading to inability to plan motor performance, the DLPFC stimulation may suggest for the future study to improve DA release in that pathway. Alternatively, the RTG training specifically induced executive function may be suggested for the future study. Thirdly, a single-session of HF-rTMS in conjunction with TST was not sufficient to

improve motor performance, so several sessions are suggested for future studies. Beneficial effects of the combined intervention is the long-term effects.[8] Previously, the paretic hand in individuals with stroke improved and their improvement persisted at least 2 weeks following a single-session rTMS with TST.[8] Therefore, a long-term effect is suggested to measure for a further study. Finally, according to a preliminary study, the sample size was small and participants were not homogeneous. Therefore, results to support the combined intervention or the HF-rTMS only could be definitively determined with a large sample size and more homogenous group.

In conclusion, the preliminary findings demonstrated that a single session of HF-rTMS on M1 combined with TST was not sufficient to improve the complex task of RTG performance in individuals with mild to moderate PD. It may be the result of the RTG training in this study because it may not sufficient to improve the aspect of RTG planning and transport-grasp coordination as they showed a prolonged TAmax and Tmax. Even though, the RTG execution could be improved following a single session of HF-rTMS to M1.

Disclosure

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

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Original Article

Quality of Life in Stroke Patients at Outpatient Rehabilitation Clinic, Siriraj Hospital

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ABSTRACT

Objectives: To study quality of life in stroke patients measured with Stroke Impact Scale (SIS) and related factors.

Study design: Descriptive study

Setting: Department of Rehabilitation Medicine, Siriraj Hospital

Subjects: Stroke patients at outpatient clinic, Department of Rehabilitation Medicine, Siriraj Hospital

Methods: Data collection and interview by questionnaire: demographic data, Thai version of SIS 3.0, modified version of Rankin scale (MRS), the Barthel index (BI) and the Patient Health Questionnaire-9 (PHQ9) Thai version.

Results: There were 175 stroke patients with an average age 63 years old (SD 11.4). The study revealed 59.4% males, 65.7% ischemic stroke, 82.9% first time stroke, 50.9% history of inpatient rehabilitation admission and 60% spasticity. Common comorbidities were 88.6% hypertension, 76.6% dyslipidemia, 32.6% diabetes mellitus and 18.9% heart disease. SIS score in descending order were communication 94.1 (12.0), memory and thinking 89.8 (16.2), emotion 72.7 (16.0), participation in social 64.8 (21.1), activities of daily living 62.6 (27.6), mobility 59.7 (31.5), the self-recovery rating 56.6 (22.2), the use of the weak hand 44.4 (36.9) and the strength of the body 40.8 (21.2) respectively. The mean of SIS composite physical domain was 51.9 (25.6). The factors that correlated with quality of life SIS composite physical domain were ability to perform activities of daily living by BI score (p <0.001), disability level by MRS (p < 0.001), spasticity (p < 0.05) and depression by PHQ9 score (p < 0.05).

Conclusion: Stroke affects quality of life in domains of body strength and the use of the weak hand more than other domains. The important factors were ability to perform activities of daily living by BI score and depression by PHQ9 score. Therefore, this study suggested that rehabilitation program to increase ability to perform activities of daily living and treatment of depression would improve quality of life.

Keywords: stroke, quality of life, depression, outpatients, rehabilitation

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Introduction

In Thailand, stroke is one of the common diseases in general practice. From the study in 2014, the prevalence of cerebrovascular disease was 1.30%[1] and is more common in males. The average age of stroke occurs at 65 years.[2] Stroke was also the leading cause of disease burden in Thailand.[3] Burden of disease is indicated by Disability-Adjusted Life Years (DALYs) which is associated with quality of life (QOL). Quality of life depends on multiple factors such as physical, psychological, social and environmental factors.

There were two kinds of QOL assessment form used in stroke patients, general QOL and stroke specific QOL assessment form. General QOL assessment form commonly used in Thailand are the Short Form 36 (SF-36)[4] or World Health Organization Quality of Life Instruments (WHOQOL-BREF).[5,6] There are many types of stroke-specific QOL assessment forms, such as Stroke Impact Scale (SIS), Stroke Specific Quality of Life measurement (SSQOL), and so on. The assessment of QOL for stroke patients should be performed in all aspects due to the variety of symptoms and severity. SIS is a questionnaire which has questions more than other measurements. It covers the effects of stroke in various areas. The third version of SIS (SIS 3.0) is a fifty-nine-item stroke-specific outcome. It consists of eight domains: strength, memory and thinking, emotion, communication, activity of daily living (ADL), mobility, hand function and social participation. Four of the subscales: strength, ADL, mobility and hand function, can be combined into a physical domain.[7] Scores for each domain range from 0 to 100 and higher scores indicate better QOL. According to a comparative study of the SIS and SF-36, SIS covers more specific problems with stroke patients especially in domains of ADL, mobility, hand function and social participation.[8]

In Thailand, SIS 3.0 was translated into Thai. The reliability and validity study of Thai version of SIS 3.0 found that it can be used to evaluate the QOL of Thai stroke patients.[9] However, there was no study using Thai version of SIS 3.0 to evaluate QOL in stroke patients in large scale. And as time

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passed, financial, social and environmental factors affecting QOL would change. Therefore, the objective of this research is to study the QOL of stroke patients by using the Thai version of SIS 3.0 and to find factors related to the QOL. The information will be useful for rehabilitation planning, helping patients and their families and developing stroke patient care guideline.

Methods

This descriptive study was conducted at the outpatient rehabilitation clinic of Siriraj Hospital – Thailand's largest university-based tertiary referral 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 636/2016 (EC2)).

Participants

Inclusion criteria

- Diagnosis of stroke with hemiplegia at least 1 month
- At least 18 years old

Exclusion criteria

- Dementia or cognitive impairment (defined as Thai Mental State Examination (TMSE) ≤ 23)
- Language impairment or could not speak Thai
- Unstable medical conditions

Instruments

1. Thai Mental State Examination (TMSE)[10]
2. Basic characteristic questionnaire
3. Barthel activities of daily living index (BI)[11-13]
4. Thai version of the Patient Health Questionaire-9 (PHQ9)[14,15]
5. Thai version of SIS 3.0[9]
6. Modified Rankin scale (MRS)[16-18]

Participants were interviewed by using basic characteristics questions, BI, PHQ-9 and Thai version of SIS 3.0. The participants did the Thai version of SIS 3.0 by themselves or the interviewer read the question and recorded the answers for them.

Statistical analysis

Data were analyzed by PASW (SPSS) Statistics for Windows version 18 (SPSS Inc. Chicago, IL, USA). Descriptive statistics were used to describe the basic data in this study. Categorical data were presented by the frequencies and percentage. Continuous data were presented by mean and standard deviation (SD). The continuous outcomes of Thai version of SIS 3.0 were analyzed by unpaired t-test for two independent groups and one-way analysis of variance (ANOVA) for more than two independent groups. A multi-factor ANOVA or general linear model (GLM) was used to determine factors related to QOL. Statistical significance was set at $p < 0.05$.

Results

There were 175 stroke patients with an average age of 63 years old (SD 11.4). The study revealed 59.4% males, 65.7% patients with ischemic stroke, 30.3% patients with hemorrhagic stroke, 82.9% had first time stroke. The number of patients with weakness of the left hemisphere and the right hemisphere were nearly equal. Basic characteristics, MRS disability level, BI and PHQ9 are shown in Tables 1 and 2.

SIS scores in various domains are shown in Table 3. The top three highest QOL scores were communication 94.1 (12.0), memory and thinking 89.8 (16.2) and emotion 72.7 (16.0) while the lowest score was the strength of the body domain at 40.8 (21.2).

Factors related to SIS scores were age, education, hypertension, occupation, income, spasticity, BI, MRS and depression. (Table 4)

In regard to SIS composite physical domain score, factors that were significantly correlated with better outcome were ability to perform activities of daily living by BI score ($p < 0.001$), low disability level by MRS ($p < 0.001$), no spasticity ($p < 0.05$), no depression by PHQ9 score ($p < 0.001$), history of rehabilitation ($p = 0.049$) and younger age ($p = 0.016$).

Table 1. Demographic data of 175 stroke patients

Information	
Age (years)[1]	63 (11.4)
Sex[2]	
Male	104 (59.4)
Female	71 (40.6)
Marital status[2]	
Single	26 (14.9)
Married	115 (65.7)
Divorced	12 (6.9)
Widowed	22 (12.6)
Caregiver[2]	
Family	163 (93.1)
Non-family	6 (3.4)
None	6 (3.4)
Residence[2]	
House	172 (98.3)
Nursing care	3 (1.7)
Education[2]	
Under bachelor degree	134 (77.0)
Bachelor degree and higher	40 (23.0)
Occupation[2]	
None	131 (74.9)
Employed	26 (14.9)
Own business	18 (10.3)
Income (baht)[2]	
< 30,000	154 (88.0)
≥ 30,000	21 (12.0)
Debt[2]	
Yes	44 (25.1)
No	131 (74.9)

[1]Mean (SD), [2]number (%)

Table 2. Clinical characteristics of stroke

Parameters	Number (%)
Type	
Ischemic	115 (65.7)
Hemorrhagic	53 (30.3)
Both	7 (4.0)
Side of weakness	
Right	78 (44.6)
Left	85 (48.6)
Both	12 (6.9)
Attack number	
1 time	145 (82.9)
> 1 time	29 (16.6)
Onset	
< 6mo	50 (28.6)
6mo-less than 1yr	32 (18.3)
1yr- less than 5yrs	49 (28.0)
5yr- less than 10yrs	25 (14.3)
> 10yr	19 (10.9)
Comorbidity	
Hypertension	155 (88.6)
Dyslipidemia	134 (76.6)
Diabetes mellitus	57 (32.6)
Heart disease	33 (18.9)
History of rehabilitation	
Never	48 (27.4)
Outpatient	38 (21.7)
Inpatient	89 (50.9)
Feeding	
Oral	167 (95.4)
NG tube	5 (2.9)
Both	3 (1.7)
Spasticity	
Present	105 (60.0)
Absent	70 (40.0)
Severity level of disability (MRS)	
0 No symptom	1 (0.6)
1 No significant disability	34 (19.4)
2 Slight disability	57 (32.6)
3 Moderate disability	54 (30.9)
4 Moderate severe disability	22 (12.6)
5 Severe disability	7 (4.0)
Activities of daily living, Barthel index (BI)	
BI 0-20	9 (5.1)
BI 25-45	25 (14.3)
BI 50-70	38 (21.7)
BI 75-90	39 (22.3)
BI 95-100	64 (36.6)
Depression, PHQ9	
Absent (0-8)	129 (73.7)
Present (9-27)	46 (26.3)

NG, nasogastric; MRS, modified Rankin Scale;
PHQ9, Patient Health Questionnaire-9

Table 3. Mean scores in each domain of SIS comparing to other studies

Dimensions	This study mean (SD)	Garnjanagoonchorn A. [9] mean (SD)	Carod-Artal FJ et al.[19] mean (SD)
SIS1 Strength	40.8 (21.2)	38.1 (21.7)	47.6 (27.9)
SIS2 Memory and thinking	89.8 (16.2)	86.5 (19.3)	70.8 (22.3)
SIS3 Emotion	72.7 (16.0)	72.0 (21.6)	52.2 (12.4)
SIS4 Communication	94.1 (12.0)	95.4 (9.3)	77.6 (22.1)
SIS5 ADL IADL	62.6 (27.6)	65.0 (26.1)	53.0 (25.5)
SIS6 Mobility	59.7 (31.5)	60.5 (30.3)	50.0 (28.5)
SIS7 Hand function	44.4 (36.9)	30.1 (33.6)	26.5 (34.2)
SIS8 Participation	64.8 (21.1)	65.0 (29.1)	50.6 (23.2)
The self-recovery rating	56.6 (22.2)	56.8 (20.5)	56.6 (25.1)
SIS Physical domain (1+5+6+7)	51.9 (25.6)	48.4 (20.3)	46.6 (24.8)

ADL, activities of daily living; IADL, instrumental activities of daily living

(Table 5) Regarding history of rehabilitation, there was significant difference between never and history of inpatient group at *p*-value 0.045.

A multi-factor ANOVA or general linear model (GLM) was conducted to determine factors that affect SIS physical domain score significantly. Factors that were significantly related to SIS physical domain score include the ability to perform ADL by BI score ($p < .001$), disability level by MRS ($p < 0.001$), spasticity ($p = 0.006$) and depression by PHQ9 score ($p = 0.034$). (Table 5)

Regarding rehabilitation program attendance and the severity of disability, 43.8% of those in the no rehabilitation program group (never rehabilitation) were patients with slight disability (MRS = 2), 37.1% of those with a history of inpatient rehabilitation were patients with moderate disability (MRS = 3) and 34.2% of those with a history of outpatient rehabilitation were patients with moderate to severe disability (MRS = 4-5).

Discussion

To our knowledge, this is the largest quality of life study in stroke patients using Thai version of SIS 3.0 in Thailand. Regarding stroke characteristics, ischemic stroke was the most common one. Hypertension, dyslipidemia and diabetes mellitus were the most common comorbidities which were modifiable stroke risk factors. Our study revealed that all domains of QOL of stroke patients measured by Thai version of SIS 3.0 is consistent with the previous research.[9,19] The study had the similar tendency of the SIS score as shown in

Table 4. Factors related to each domain of stroke impact scale (SIS)

Variable	*p*-value[a] SIS score									
	Physical 1+5+6+7	SIS1 Strength	SIS2 Memory and thinking	SIS3 Emotion	SIS4 Communication	SIS5 ADL	SIS6 Mobility	SIS7 Hand function	SIS8 Participation	Self-rating
Age	0.016*	0.906	0.691	0.923	0.960	0.006*	0.001*	0.036*	0.728	0.825
Sex	0.718	0.916	0.201	0.992	0.961	0.953	0.956	0.345	0.330	0.160
Marital status	0.693	0.535	0.869	0.318	0.875	0.727	0.845	0.165	0.276	0.169
Education	0.078	0.657	0.845	0.584	0.325	0.095	0.041*	0.100	0.703	0.813
Hypertension	0.603	0.601	0.902	0.503	0.002*	0.426	0.947	0.622	0.492	0.374
Dyslipidemia	0.794	0.815	0.402	0.919	0.420	0.749	0.874	0.629	0.059	0.264
Diabetes mellitus	0.566	0.741	0.294	0.785	0.122	0.488	0.620	0.645	0.521	0.120
Heart disease	0.173	0.894	0.149	0.084	0.280	0.113	0.094	0.273	0.201	0.479
Occupation	0.693	0.274	0.568	0.033*	0.989	0.160	0.046*	0.493	0.415	0.770
Income (Baht)	0.854	0.536	0.406	0.113	0.635	0.474	0.172	0.406	0.029*	0.364
Debt	0.463	0.326	0.521	0.983	0.476	0.875	0.741	0.282	0.272	0.066
Type	0.530	0.469	0.639	0.946	0.813	0.748	0.813	0.343	0.397	0.935
Side	0.678	0.205	0.303	0.583	0.752	0.743	0.917	0.391	0.855	0.520
Attack number	0.603	0.247	0.240	0.484	0.490	0.750	0.466	0.243	0.614	0.355
Onset	0.904	0.100	0.100	0.313	0.068	0.740	0.785	0.933	0.572	0.253
Spasticity	0.005*	0.002*	0.412	0.102	0.324	0.078	0.005*	0.017*	0.370	0.000
Barthel Index	< 0.001*	< 0.001*	0.001*	< 0.001*	< 0.001*	< 0.001*	< 0.001*	< 0.001*	0.001*	< 0.001*
MRS	< 0.001*	< 0.001*	0.022*	< 0.001*	< 0.001*	< 0.001*	< 0.001*	< 0.001*	0.016*	< 0.001*
Depression	< 0.001*	< 0.001*	<0.001*	< 0.001*	0.003*	< 0.001*	< 0.001*	< 0.001*	0.363	0.004*

[a] Comparison among groups by t-test or 1-way ANOVA; *$p < 0.05$ indicates statistical significance

MRS, modified Rankin scale

Talbe 5. The stroke impact scale (SIS) physical domain mean score and related factors

Variables	SIS physical domain		ANOVA (GLM)	
	Mean (SD)	*p*-value[a]	F	*p*-value[b]
Age (year)		0.016*	0.496	0.686
≤ 60	57.3 (23.7)			
61-70	52.6 (25.6)			
71-80	44.5 (27.4)			
≥ 81	36.4 (22.9)			
Barthel Index		< 0.001*	13.435	< 0.001*
BI 0-20	12.8 (9.0)			
BI 25-45	27.0 (19.7)			
BI 50-70	36.2 (13.1)			
BI 75-90	53.0 (17.1)			
BI 95-100	75.7 (13.8)			
MRS		< 0.001*	6.418	< 0.001*
No significant disability	78.2 (15.0)			
Slight disability	62.5 (17.4)			
Moderate disability	39.0 (17.5)			
Moderate severe disability	23.2 (18.7)			
Spasticity		0.005*	7.677	0.006*
Spasticity	47.4 (24.3)			
No spasticity	58.5 (26.3)			
Depression PHQ9 (≥ 9)		< 0.001*	4.587	0.034*
No depression	57.4 (24.8)			
Depression	36.2 (21.1)			
History of rehabilitation		0.049*	0.311	0.733
Never	57.3 (25.8)			
History of outpatient	43.7 (25.9)			
History of inpatient	52.5 (24.4)			

[a]Comparison among groups by t-test or 1-way ANOVA; [b]A multi-factor ANOVA of factors related to QOL of stroke patients in SIS physical domain;
*$p < 0.05$ indicates statistical significance
MRS, modified Rankin scale; PHQ9, patient health questionnaire-9

Table 3. The strength of the body and hand function domains had the lowest mean score while communication, emotion, memory and thinking had high mean score. High communication score may be due to the exclusion of patients with communication problems. Regarding emotion, memory and thinking score, the perceptions of stroke survivors about changes in their thinking and emotion may be less accurate than their perceptions about physical limitations resulting in a better SIS mean score in emotion domain.

The low score of body strength and hand function were part of physical impairment. Low body strength and hand function score were consistent with the report that motor deficits were probably the most commonly recognized impairment in persons with stroke.[20] Low hand function score may be due to poor recovery of upper limb function after stroke which was perceived as a major problem.[21] Spasticity, BI and MRS were factors related to SIS scores. All of these suggested the importance of physical aspect on QOL. This was also the reason for more analyzing in physical aspects.

In terms of SIS composite physical domain score, one of the factors significantly correlated with better outcome was history of rehabilitation. Never rehabilitation group had SIS physical domain score 57.3 (25.8) which was higher than history of inpatient rehabilitation group 52.5 (24.4) and outpatient rehabilitation group 43.7 (25.9). It could be explained from the different level of MRS disability. In our setting, patients who were admitted for intensive rehabilitation must have potential for training and functional improvement. Therefore, patients with low potential will not be admitted. This may be why outpatient group had low SIS physical domain score. Most of patients in never rehabilitation group were patients with slight disability so they did not need to attend hospital-based rehabilitation program. This finding also correlated with the previous report that a significant proportion of chronic stroke survivors attending the rehabilitation clinic continue to face limitations in their physical activities.[22]

Factors that were significantly related include the ability to perform ADL by BI score ($p < 0.001$), disability level by MRS ($p < 0.001$), spasticity ($p = 0.006$) and depression by PHQ9 score ($p = 0.034$). (Table 5) Disability level by MRS and ability to perform ADL by BI score were the predictors of QOL in most stroke survivors.[9,19,22-24] Mean scores of SIS in all domain were lower in group of more severely affected stroke survivors. Post-stroke depression also was the strong predictor of low QOL in our stroke survivors. The prevalence of post-stroke depression by PHQ9 in our study was about 26% which fell in the range of the previous report rates, 16%-92%.[25] This negative predictor of depression on QOL

is a finding that has been reported by previous study.[19,22,23] Spasticity was also negative influence on QOL especially on physical domain. The prevalence of spasticity was 60% in our study which fell in the range of the previous report rates, 30%-80%[26] but rather high when compared to 25% reported by Gillard PJ et al.[27] Low score of body strength and spasticity were important problems which corresponded with the reasons for seeking complementary and alternative medicine.[28]

There are several limitations in this study. This study is a cross sectional study so there is no monitoring of QOL that may change over time. Most subjects still lived with family, had family as caregiver and were able to access to medical care at hospital. The data may not reflect the group of stroke patients in the community which may have a lower QOL because we collect data from the stroke patient who could came to the hospital. Furthermore, the patients who have aphasia were excluded from the study due to the limitation in data collection. This study may not yet reflect the overall of the entire population of stroke patients.

In conclusion, the study found that stroke affects the QOL in many aspects including physical, mental, emotional and participation in society. The use of the weak hand and body strength are affected more than other domains. The important factors determining QOL were ability to perform ADL, disability level, spasticity and depression. In caring stroke survivors, all these important factors should be focused.

Disclosure

The authors declare that there is no conflict of interest.

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