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Content

Notes from the Editor-in-Chief

Over the past few months, our dedicated team of editors and reviewers have been working tirelessly to curate a collection of articles that offer valuable insights and advancements in their respective fields. We have strived to maintain the highest standards of quality and integrity in the selection process, ensuring that only the most rigorous and innovative research makes its way into our journal.

In today's rapidly evolving world, where new discoveries and breakthroughs occur at an unprecedented pace, it is crucial for us to stay at the forefront of knowledge and provide a platform for researchers and scholars to share their findings. Our commitment to fostering the dissemination of cutting-edge research remains unwavering, and we will continue to serve as a bridge between the scientific community and the wider public.

The first article of this issue is a randomized controlled trial conducted by Kittinanon N and Sukpongthai T. They studied the effect of vitamin D supplements in acute spinal cord injury patients and suggested that the patients with acute spinal cord injuries should receive vitamin D supplements to reduce existing vitamin D deficiency.

In the second article, Tikkapanyo N and her college studied about the factors associated with the good outcome after a single injection of platelet-rich plasma in patients with osteoarthritic knee and found that less than half of the participants had a clinically significant improvement in VAS after a single injection of IA PRP. The authors concluded that their study did not have sufficient statistical power to determine associated factors for good outcomes, possibly due to a small sample size.

Next, Mbada CE et al. compared the effects of singing during the Six-minute Treadmill Walk Test (6MTWT) and Six-Minute Treadmill Sing Walk Test (6MTSWT) on cardiovascular parameters in thirty-five healthy individuals. They concluded that slow-tempo singing decreases pulse rate and resting pulse rate significantly during 6MTWT among their participants.

Ammawat W and her college conducted the study to affirm the construct validity and internal consistency reliability of the Thai version of the Telephone-Based Cognitive Screening Tool (Thai-TeBCOG) in 225 healthy adult volunteers and found that this questionnaire has acceptable internal consistency and the construct validity of the tool was evaluated using EFA, and four extracted factors accounted for 54.48% of the total variance.

Pongratanakul R and her colleges developed and evaluated psychometric properties of a short-form of the Barthel Index in a university hospital in Thailand and recommended the use of the 3-item version as a screening tool for detecting functional changes in older adults undergoing abdominal surgery because of it is superior responsiveness to change, requires less assessment time and more practical for use in clinical practice.

Chootip C and her colleges reported their study about the feasibility and effect of gait training with assistance from a motorized wheelchair with a built-in bodyweight support frame on the balance and walking ability of elderly individuals with a risk of falling. They found that their innovative technology has the potential for use as an assistive device for training at home which would also reduce the burden on public healthcare.

Yanyong K studied the cost-effectiveness of intensive intermediate care rehabilitation using direct cost and effectiveness for inpatient and outpatient stroke patients in Nopparat Rajathanee Hospital and found that the treatment program statistically significantly improved BI scores. She suggested that further study about cost-effectiveness should be carried out.

The last articles of this issue is a case report conducted by Thanakorn T and his colleges. They demonstrated the efficacy of ortho-prosthesis and knee ankle foot orthosis on functional gait activities in pediatric congenital limb deficiency. They focused at the design of prosthesis and gait aid after surgical management and demonstrated the results in improving balance and functional gait activities.

I would also like to extend my deepest appreciation to the authors who have entrusted us with their work. Your dedication to advancing knowledge and pushing the boundaries of your respective fields is truly commendable. Your contributions are the lifeblood of this journal, and we are grateful for the opportunity to showcase your research to a global audience.

Assoc. Prof. Kingkaew Pajareya
Editor-In-Chief
The ASEAN Journal of Rehabilitation Medicine

Original Article

Effect of Vitamin D Supplements on Acute Spinal Cord Injury: A Double-Blinded, Randomized Control Trial

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ABSTRACT

Objectives: To study the effect of vitamin D supplements in acute spinal cord injury patients.

Study design: Double-blind randomized controlled trial.

Settings: Maharat Nakhon Ratchasima Hospital.

Subjects: Acute spinal cord injury patients (onset < 1 month) admitted to Maharat Nakhon Ratchasima Hospital between May 1, 2020 and September, 30, 2021.

Methods: Thirty patients with 25(OH)D vitamin D levels ≥ 20 ng/mL were randomly assigned to one of two groups: intervention or control. The intervention group received one tablet of 20,000 IU of vitamin D every two weeks for three months. The placebo was given to the control group. Vitamin D levels, the primary outcome, were measured at baseline and after three months. At the 3-month follow-up, sun exposure, a food frequency questionnaire, Spinal Cord Independence Measure III (SCIM III), and Leisure Time Physical Activity Questionnaire for People with Spinal Cord Injury (LTPAQ) were all assessed. The proportion test was used to compare the scores of the two groups for secondary outcomes.

Results: There were 13 patients in the intervention group and 17 in the control group. The majority in both groups had paraplegia and both groups had similar sun exposure and vitamin D food intake. Before receiving vitamin D supplementation, the intervention and control groups had mean vitamin D levels of 27.54 (5.23) and 29.11 (7.60) ng/mL, respectively. After the study period, the intervention group had a higher mean vitamin D level of 10.29 (8.59) ng/mL. The mean vitamin D level in the intervention group had increased by 10.29 (8.59) ng/mL, but the level in the control group was slightly decreased. There was also a statistically significant difference in the number of patients with vitamin D insufficiency/deficiency between the intervention group (2 (15.38%)) and the control group (9 (52.94%), but there was no statistically significant difference in SCIM III and LTPAQ between the two groups.

Conclusions: As a result, patients with acute spinal cord injuries should receive vitamin D supplements to reduce existing vitamin D deficiency.

Keywords: vitamin D supplement; acute spinal cord injury, vitamin D deficiency; Activities of daily living; 25(OH)D

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Introduction

Patients with spinal cord injuries have been shown to be at risk for vitamin D deficiency. Other factors contributing to vitamin D deficiency are insufficient exposure to sunlight, especially exposure to sunlight fewer than two times a week and less than half an hour each time, and inadequate intake of vitamin D from food.[1,2] There are other factors that can negatively affect vitamin D level in spinal cord injured persons as described in articles by Sheng-Dan Jiang et al.[3,4] Disuse osteoporosis, an imbalance in bone formation and resorption, and a change in the PTH-Vitamin D axis are three crucial factors that can lead to osteoporosis. Benlidayi et al.[5] conducted a comparative study between spinal cord injury patients and the general population which found that a greater proportion of patients with spinal cord injury suffered from vitamin D deficiency (25(OH)D < 20 ng/mL) than patients in the control group (83.3% vs 40%). Barbonetti et al.[6] conducted a study on 100 patients in Italy who had a chronic spinal cord injury for over one year and found that the prevalence of vitamin D deficiency was 78%. In Thailand, 61% of chronic spinal cord injury patients have been found to have low vitamin D levels. In this group, 32% was classified as deficiency and 29% was classified as insufficiency.[2]

There have also been reports of other risk factors related to vitamin D deficiency in patients with spinal cord injuries, e.g., African-American ethnicity, winter season, duration of spinal cord injury greater than one year,[7] high BMI, low self-sufficiency using the Spinal Cord Independence Measure (SCIM III) and low activity time using the Leisure Time Physical Activity Questionnaire for People with Spinal Cord Injury (LTPAQ-SCI) assessment.[6,8]

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A report on vitamin D supplementation given to patients with chronic spinal cord injury ranging from 8 weeks to 12 weeks at doses ranging from 2,000 to 6,000 IU per day found it to be effective in raising vitamin D levels in groups with vitamin D deficiency or insufficiency. However, when vitamin D levels were checked at 8-12 weeks,[9-11] the effect of vitamin D supplementation on physical performance or muscle strength was still controversial.

Vitamin D levels in post-spinal cord injury patients tend to decline as the deficiency progresses into the chronic phase. Low vitamin D levels in chronic spinal cord injury patients may be an independent predictor of worsening physical function outcomes over time. Thus, vitamin D supplementation in acute spinal cord injury patients would be expected to avoid vitamin D deficiency-related abnormalities and to improve physical function.

Vitamin D supplements have been formulated to maintain musculoskeletal health, support immune responses, and reduce the risk of vitamin D insufficiency, including its potential impact on conditions such as stroke and dementia.[12,13]

There is, however, only limited data on vitamin D deficiency in patients with acute spinal cord injury, and there has not yet been a study on vitamin D supplementation in that group of patients. The present study was designed to study vitamin D supplementation in a group of patients with acute spinal cord injury and to evaluate its effect on performance in activities of daily living and mobility.

Methods

Study populations

The study protocol was approved by the Research Ethics Committee of Maharat Nakhon Ratchasima Hospital, Committee No. 086/2020. The study group consisted of patients with spinal cord injuries who were admitted to a tertiary hospital in Thailand between May 1, 2020 and September 30, 2021 who met the study inclusion and exclusion criteria.

The inclusion criteria were that the patients must have been diagnosed with spinal cord injury for less than one month, be between 18 to 65 years old, and have a vitamin D (25(OH)D) level ≥ 20 ng/mL. The exclusion criteria were patients who had been treated with vitamin D or multivitamins (MTV) within the previous three months, had chronic kidney disease or liver dysfunction, or had been treated with anticonvulsants in the previous 3 months.

Outcome measurements

Prior to consenting to participate in the study, patients with a spinal cord injury who met the inclusion criteria were provided with information about the study, including purpose, methodology, and potential side effects. Participants were then interviewed and their baseline characteristics and other information were collected, including SCI data, the American Spinal Injury Association Impairment Scale (ASIA classification), and Spinal Cord Independence Measure III (SCIM III) Thai version. SCIM III is a reliable and valid disability scale[13] established to provide functional assessments of self-care capacity, breathing and sphincter control, and movement ability of people with spinal cord injury. The overall score ranges from 0 to 100, with 0 indicating complete dependency and 100 indicating complete independence. The overall score is composed of three subscales: self-care (0-20), breathing and sphincter management (0-40), and mobility (0-40).

Data from the Leisure Time Physical Activity Questionnaire for People with Spinal Cord Injury (LTPAQ), the Food Frequency Questionnaire, and the Sun Exposure Questionnaire was collected after three months of participation in the study. The Leisure Time Physical Activity Questionnaire for People with Spinal Cord Injury (LTPAQ) is a self-assessment questionnaire explicitly designed for SCI patients. The LTPAQ is the most extensively used questionnaire for measuring physical activity levels. It evaluates leisure-time physical activity in minutes and categorizes activity levels as low, moderate, and heavy.

The study of vitamin D supplements in acute SCI was double-blinded and randomized controlled to check the vitamin D level 3 months after beginning to take the supplement. The study used an electrochemiluminescence immunoassay (ECLIA), a fully automated technology approved by the US FDA for use as a detection tool, to quantify serum 25 (OH) D levels. Research assistants randomly selected 40 patients using mixed-blocked randomization. Patients in the intervention group received one 20,000 IU tablets of vitamin D the 1st and 15th of each month to be taken after breakfast for three months, and patients in the control group received one placebo tablet on the same schedule. Both groups were given dietary advice and recommendations regarding exposure to sunlight. They also received a follow-up call from the researcher on the 1st and 15th of each month to ensure compliance with the specified dosage. These rechecks during the study found patients were able to follow the regimen. At the 3-month mark, serum 25(OH)D levels were measured a second time (Fig. 1). Vitamin D (25(OH)D) level under 20 ng/mL was considered vitamin D deficiency, between 20-30 ng/mL was vitamin D insufficiency and vitamin D levels over 30 ng/mL were considered normal.[14]

Statistical analysis

In this study, the statistical significance level was set at 0.05, and the power of the test was 80%. When calculating the sample size, it was determined that 18 participants per group would be required for the study, with a reserve of 10% for incomplete participation. Therefore, this study set a goal of 20 people per group for a total of 40 people.

In this study, Stata 11 software was used for data analysis. The t-test was used to compare means of the two groups when the data were normally distributed. The Mann-Whitney test was used to compare to data that did not follow a normal distribution. Fisher's exact test was used to compare categorical data.

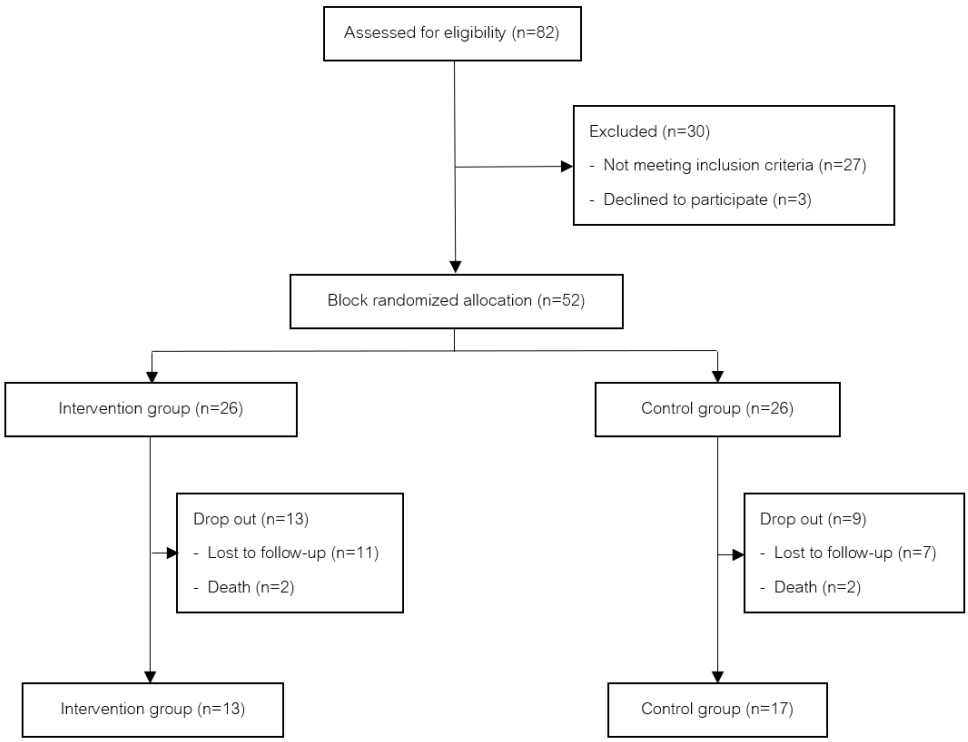

Figure 1. Flow diagram of the patients through the trial

Adverse events

Vitamin D toxicity is a condition that occurs when serum 25(OH)D levels are > 50 ng/mL which can occur if an individual receives vitamin D at doses > 10,000 IU per day. This condition leads to increased levels of calcium and phosphate in the blood. Patients can also experience nausea, bloating, constipation, anxiety, depression, and/or urinary tract stones. The dose used in this study did not reach a level that could cause vitamin D toxicity.

Results

Subject characteristic

A total of 52 patients with acute spinal cord injury (period of spinal cord injury under one month) who met the research inclusion criteria were enrolled in the trial and were randomly divided into two groups, blocked randomization, resulting in 26 participants each for the intervention and control group. During the study, 11 patients in the intervention group did not follow up after treatment, and two patients passed away. Seven patients in the control group did not follow up after treatment, and two died. These losses left 13 patients in the intervention group and 17 in the control group. The data of patients without follow-up were not included in the analysis comparing the results between the two groups after the treatment.

The participants in both groups were between 18-75 years old (mean age in the intervention and control groups were 48.7 and 47.0 years, respectively). There were nine males in the intervention group (69.2%) and 12 in the control group (70.5%). The average body mass index (BMI) did not exhibit a statistically significant difference between the two groups, with values of 23.75 in the intervention group and 23.65 in the control group, respectively.

Most of the spinal cord injuries in both groups were caused by accidents, spinal cord degeneration, and spinal cord infection. The numbers of patients with neurological injury levels of C, L, T, and S in the interven-tion group were 5, 4, 3, and 1, respectively. For the control group, the numbers were 6, 5, 6, and 0, respectively. Most patients in the intervention group were AIS D (6 cases), and in the control group the largest number were AIS C (9 cases).

Participants were assessed using the Spinal Cord Independence Measure III (SCIM III) Thai version. In the intervention group, the median values for the total self-care, respiratory and sphincter management, and mobility categories were 36, 14, 15, and 6 points, respectively; in the control group, the median values were 26, 8, 10, and 2 points, respectively.

Factors related to vitamin D level included sun exposure and eating behavior. It was found that most participants followed the recommendations regarding dietary intake of vitamin D and optimal exposure to sunlight[15,16] (Table 1).

There was no statistically significant difference in the mean baseline vitamin D levels (25(OH)D) (with a standard value of ≥ 20 ng/mL) between the two groups. The mean vitamin D level in the intervention group was 27.54, with a standard deviation of 5.23. In contrast, the control group had a mean vitamin D level of 29.11, with a standard deviation of 7.60.

Table 2 compares the mean difference in vitamin D levels between the intervention and control groups at baseline and at the three-month follow-up. The intervention group had a statistically significantly higher increase in vitamin D level

Table 1. Demographic data of patients at baseline

Factors	Intervention group (n = 13)	Control group (n = 17)	*p*-value
Age[2]	48.7 (16.49)	47 (14.23)	0.773
Sex, male[1]	9 (69)	12 (70)	1.000
BMI[2]	23.75 (4.88)	23.65 (3.47)	0.946
Cause of injury[1]			0.840
Trauma	9 (69)	10 (59)	
Infection	1 (8)	3 (18)	
Degenerative	3 (23)	2 (12)	
Cancer	0	1 (6)	
Infection	0	1 (6)	
Neurological level[1]			0.840
Cervical	5 (38)	6 (35)	
Thoracic	3 (23)	6 (35)	
Lumbar	4 (31)	5 (30)	
Sacral	1 (8)	0	
AIS[1]			0.072
A	3 (23)	4 (24)	
B	1 (8)	3 (18)	
C	3 (23)	9 (53)	
D	6 (46)	1 (5)	
SCIM[3]			
Self-care	14 (0-20)	8 (2-14)	0.458
Respiratory and sphincter management	15 (13-20)	10 (10-16)	0.138
Mobility	6 (2-15)	2 (0-4)	0.078
Total	36 (17-57)	26 (12-32)	0.143
Sun exposure duration[1]			1.000
≥ 30 min and frequency ≥ 2/week	8 (62)	11 (64)	
< 30 min and frequency ≥ 2/week	2 (15)	3 (18)	
< 30 min and frequency < 2/week	3 (23)	3 (18)	
Food[1]			1.000
Canned fish	11 (85)	10 (59)	
Cow milk	13 (100)	14 (82)	
Yogurt	8 (62)	8 (47)	
Butter/margarine	1 (8)	1 (6)	
Vitamin D level[2]	27.54 (5.23)	29.11 (7.60)	0.528

[1]Number (percent), [2]Mean (SD), [3]Median (IQR)
BMI, body mass index; AIS, Asia Impairment Scale, SCIM, spinal cord independence measure

Table 2. Comparison of the mean difference in vitamin D levels at baseline and 3-month follow-up between intervention and control groups

Mean (SD)	Intervention group (n = 13)	Control group (n = 17)	Mean difference (95% CI), intervention group – control group	*p*-value
Vit D level at baseline	27.54 (5.23)	29.11 (7.60)		
Vit D level at three months follow-up	37.83 (10.91)	28.72 (9.10)		
Vit D difference between three months and baseline	10.29 (8.59)	-0.39 (11.14)	10.68 (3.05, 18.33)	0.008

(10.29) than the control group, which while the control group had a modest reduction (-0.39). The intervention group had a larger proportion of participants with sufficient vitamin D levels (84.62%) than the control group (47.06%).

As for SCIM, after the trial the intervention group had a median total score and self-care, respiratory and sphincter management, and mobility category scores of 26, 1, 13, and 11 points, respectively. In the control group, the scores were 34, 4, 12, and 12 points, respectively. The analysis revealed no statistically significant difference in the SCIM scores between the two groups. (Table 3) In this study, the Leisure Time Physical Activity Questionnaire (LTPAQ) was used to compare physical activity between the intervention and control groups. The findings revealed no significant distinction between the two groups, suggesting that the utilization of LTPAQ had minimal impact on the observed outcome.

Table 3. Functional outcome at 3-month follow-up between intervention and control groups measure

SCIM difference median (min-max)	Intervention group (n = 13)	Control group (n = 17)	*p*-value
SCIM: Total	26 (16-54)	34 (20-45)	0.876
Self-care	1 (0-10)	4 (4-7)	0.961
Respiratory and sphincter management	13 (1-20)	12 (7-20)	0.713
Mobility	11 (5-24)	12 (7-21)	0.713

SCIM- Spinal Cord Independence Measure

Discussion and conclusions

Patients with acute spinal cord injury receiving vitamin D supplementation had increased vitamin D levels after three months. When compared with the intervention group, the increased vitamin D levels and the number of patients with deficiency or insufficiency were different at a statistically significant level. The results of this study are consistent with studies by Bauman et al.,[9] Flueck et al.,[10] and Amorim et al.[11]

In this study, after three months eight patients (47%) in the control group had reduced vitamin D levels compared to initial values, and nine had vitamin D deficiency or insufficiency. For three of those nine, the vitamin D baseline was at an average level, and six had vitamin D insufficiency. In the intervention group, there were two patients out of 13 with vitamin D deficiency (11.7%), and seven patients with vitamin D insufficiency (41%).

Previous studies have reported a 27.1-82.4% prevalence of vitamin D deficiency among patients with chronic spinal cord injury.[6, 11, 17] This study tested initial vitamin D levels and found 41% of the participants had vitamin D insufficiency and 11.7% had vitamin D deficiency. If these patients did not receive vitamin D supplementation, vitamin D deficiency might have increased. In this study, patients with vitamin D deficiency were excluded prior to the study. However, as there are as yet no guidelines for treating patients with vitamin D insufficiency in Thailand, patients with vitamin D insufficiency were not excluded and were included in the study.

This study shows that vitamin D supplementation at a dose of 20,000 IU every two weeks for three months in patients with acute spinal cord injury of less than one month duration can prevent vitamin deficiency or insufficiency.

In this study, vitamin D supplementation was not found to affect self-sufficiency levels as measured with SCIM III, and had no effect on activity level measured with LTPAQ, results consistent with the findings of Amorim et al.[11] that supplementation with vitamin D does not affect muscle strength.

In this study, 22 patients were missing at the three-month follow-up, of whom 13 were in the intervention group, and 9 were in the control group. There were four deaths, 13 cases with no follow-up due to the COVID-19 outbreak, and 5 who dropped out due to travel problems. Therefore, there were fewer patients in the intervention group than in the control group, which may have affected the analysis of the results.

This study was conducted among patients with acute spinal cord injury at the stage before vitamin D levels begin to decline following a spinal cord injury, unlike most studies which have been conducted with chronic spinal cord injury patients. A study by Dlugos et al.[18] found that vitamin D levels decline after two months of exposure to risk factors for vitamin D deficiency. This study aimed to examine the effects of changes in vitamin D levels due to spinal cord injuries and the effect of vitamin D supplementation on prevention of vitamin D deficiency. For that reason, the researchers chose to examine patients with a spinal cord injury which had occurred not more than one month previously and to follow-up with vitamin D supplementation in the intervention group for a period of three months.

The form of vitamin D used in this study was Vitamin D2 20,000 IU and dose was every two weeks for 12 weeks. This form is available in Thailand and the dosage is based on the dose used for supplementation in normal subjects.[19] This dose when used in patients with acute spinal cord injury, can help prevent insufficiency/deficiency of vitamin D. Past studies have varied in the doses and duration of supplementation, e.g., one study by Bauman et al.[9] used a 2,000 IU daily dose of vitamin D for 12 weeks while a study by Flueck et al.[8] used a daily dose of 6,000 IU of vitamin D for 12 weeks, and a study by Amorim et al.[11] used vitamin D at a dose of 25,000 IU every two weeks for eight weeks, a higher dose than that used in this study. The doses used in the previous studies cited were able to treat the vitamin D deficiency in all spinal cord injury patients.

Limitations

The number of study participants followed up was fewer than expected due to the COVID-19 pandemic, which negatively affected the power of statistical tests. In addition, the three-month follow-up period did not show a statistically significant difference in the effect of vitamin D supplementation in the intervention and control groups. Future studies building on this research should include longer follow-up periods.

Conclusions

Vitamin D should be given to patients with acute spinal cord injury to prevent vitamin D deficiency or insufficiency. Additionally, vitamin D supplementation at a dose of 20,000 IU every two weeks for three months can prevent vitamin D deficiency in patients with acute spinal cord injury. However, functional outcomes as determined by SCIM III and LTPAQ did not differ between the control and intervention groups.

Conflicts of Interest

The authors declare that there are no relevant conflicts of interest.

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Original Article

Factors Associated with the Good Outcome after a Single Injection of Platelet-Rich Plasma in Patients with Osteoarthritic Knee: A Prospective Cohort Study

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ABSTRACT

Objectives: To determine the associated factors with the good outcome of a single dose intraarticular platelet-rich plasma (IA PRP) injection on pain reduction in patients with knee osteoarthritis.

Study design: A prospective cohort study.

Setting: Outpatient Department of Rehabilitation Medicine at Phramongkutklao Hospital.

Subjects: Patients with mild to severe knee osteoarthritis

Methods: Patients with knee osteoarthritis who received a single IA PRP injection were eligible to participate in this study. The visual analog scale (VAS) score as a primary outcome and the dimension of physical function as measured by the SF-36 questionnaire were determined at baseline and at week four after the injection. A good outcome was defined as a ≥30% reduction from baseline VAS at week four. Logistic regression was performed to determine factors associated with good outcomes of a single injection of IA PRP.

Results: Fifty-eight patients with knee osteoarthritis participated in this study. The mean difference in VAS scores between baseline and week 4 was -1.58 (2.11) with a $p < 0.001$. However, only 41.34% of the participants had a good outcome. Multivariable analysis found no significant factors associated with good outcomes.

Conclusions: Less than half the participants had clinically significant improvement in VAS four weeks after a single injection of IA PRP. However, the present study did not have sufficient statistical power to determine associated factors for a good outcome, possibly due to the small sample size.

Keywords: knee osteoarthritis, platelet-rich plasma, intra-articular injection, cohort study

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Introduction

Knee osteoarthritis is the most common degenerative joint disease, occurring most frequently in older and female patients.[1] Patients may suffer from pain and inflammation in the knee which can limit their activities. In the advanced stage, knee deformities such as severe genu varus can be found that lead to disability and poor quality of life.[2, 3]

Non-pharmacological knee osteoarthritis treatments include education, weight reduction, exercises, physical modalities, knee braces, and walking aids. Pharmacological treatment usually aims to pain and inflammation in the early stage of knee osteoarthritis and on maintaining the quality of life of patients using oral paracetamol or non-steroidal anti-inflammatory drugs (NSAIDs).[4] Most analgesics have only short-term effects on control of symptoms; physicians must be aware of their efficacy and potential adverse reactions.[5]

Intra-articular (IA) injection is another effective treatment option for knee osteoarthritis. Platelet-rich plasma (PRP) injection is one form of intraarticular knee management which is prepared from the patient's own blood.[6] It is plasma with a high platelet concentration which can repair damaged tissue. PRP also provides some autologous growth factors and cytokines that act as anti-inflammatory agents and improve tissue regeneration.[7,8] IA PRP injection can reduce pain and improve quality of life among patients with knee osteoarthritis.[9]

Several previous studies comparing IA PRP and IA hyaluronic acid (HA) injections have reported that PRP is safe, easy to use, and acceptable to patients.[10] According to previous studies, clinical outcomes measured with instruments such as the visual analog scale and the Western Ontario and McMaster University (WOMAC) osteoarthritis index are better in the PRP group than in the HA group.[11,12] Furthermore, unlike HA, IA PRP is suitable for all stages of OA treatment. Adverse effects in the two groups were not significantly different.[13,14]

Several methods of PRP preparation and injection regimens have been described,[15,16] e.g., PRP can involve several injections or a single dose. A previous study reported that multiple injections of PRP had better results than a single dose.[17] However, clinical outcomes have been reported to improve considerably with only a single injection of PRP.[18,19]

Many factors are involved in the prediction of clinical outcomes of IA knee injection. Age, local knee tenderness, and

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radiographic score of the affected joint can predict response after three months of IA steroid injection therapy.[20] Furthermore, older age are associated with good outcomes with IA HA injection, while gender, body mass index (BMI), and race are not significantly associated.[21] However, a previous study showed that higher BMI and higher scores with the Kellgren and Lawrence (KL) system are significant predictive factors of failure of PRP injection.[22] In summary, it can be concluded that the ability to consistently predict the clinical outcome of IA knee injections for osteoarthritis is limited due to the varying influence of different factors.

Currently, there is little clinical evidence regarding predictors of good outcomes with a single IA PRP injection. The present study aimed to determine the factors associated with good outcomes from a single injection of IA PRP on pain reduction in patients with knee osteoarthritis.

Methods

Study design and participants

This prospective cohort study was a conducted in an outpatient clinic of the Department of Rehabilitation Medicine, Phramongkutklao Hospital, Bangkok, from August 2021 to December 2022. Adult patients aged 40 years or older with mild to severe osteoarthritis of the knee (KL grade 2 to 4) who experienced knee pain with a visual analog scale (VAS) score of at least 30 mm and who had received conservative treatment for at least three months were eligible to participate in the study. Patients with a history of knee surgery, secondary knee osteoarthritis, hematologic diseases, current users of anticoagulant/antiplatelet drugs, or those with a planned knee arthroplasty within eight weeks after the injection were excluded. All participants provided written informed consent before participating in the study. The Institutional Review Board, Royal Thai Army Medical Department gave ethical approval for this study (IRB number R085h/64).

Outcome measures

At enrolment, demographic and clinical characteristics of all participants were collected, including factors suspected of potentially being able to influence results after an injection. These factors included age, sex, BMI, duration of knee osteoarthritis, KL classification, and laxity of the collateral ligament.

The current study used the VAS score as the primary outcome of pain assessment. The participants were instructed to indicate their current pain intensity by placing a mark on a line extending from 0-100 mm. An interview was used to complete the short form-36 (SF-36) questionnaire in Thai.[23] There are eight dimensions in the SF-36 questionnaire; however, this study only focused on the items related to physical functioning (PF). There are ten questions about physical functioning, and the range of possible answers is 0 (worst) to 100 (best). Data were collected before and four weeks after IA PRP injection.

In this study, clinically significant difference (CID) in VAS was used to categorize the patient's results into two groups: good and poor outcomes. A good outcome was defined as a reduction in VAS from baseline of at least 30% at week four.

PRP preparation

The Arthrex Autologous Conditioned Plasma system (ACP®) was used to prepare the PRP. The process began with a trained technician collecting approximately 10 mL of venous blood from the median antecubital vein using a sterilized 20-gauge needle. The blood sample was then placed in a single centrifuge and spun at 1,500 rpm for 5 minutes. After cooling for approximately 3 minutes, the layer containing concentrated platelets was carefully extracted using a double syringe technique. The desired outcome was to obtain 5-7 mL of PRP.

Injection technique

The patient was supine with the knee flexed approximately 60-70 degrees. After an allergy check, the skin was prepared with povidine solution using a sterile technique. Subsequently, 5 mL of 1% Xylocaine without adrenaline was injected through the skin using a 22-gauge needle at the soft anterolateral spot adjacent to the patellar tendon. Finally, the physician injected a single syringe of the prepared PRP through the joint capsule at the same area as the Xylocaine injection. A cold pack was applied to the injection site for 10 minutes after the injection.

Patient safety

Patients were provided standard recommendations for post-injection care, including a period of rest for 1-2 days, avoidance of non-steroidal anti-inflammatory drugs for seven days, minimizing knee stretches until the pain subsides, and maintenance of normal range of motion in the knee joint. If necessary, paracetamol was administered for pain treatment. To ensure patient safety, all participants underwent a comprehensive screening for side effects immediately after the injection and during the 4-week follow-up period. Additionally, participants were informed that they could visit the clinic before the 4-week follow-up if they experienced any serious adverse effects such as fever or worsening arthritis. This process allowed identification and monitoring of potential adverse effects or complications that may have arisen due to the procedure.

Statistical analysis

The necessary sample size for this study was calculated using the logistic regression analysis events per variable (EPV) procedure.[24] Four to five variables, e.g., age, sex, obesity, the severity of knee OA, and the duration of symptoms, were intended to be analyzed using binary logistic regression. The number of EPV was set at 15, so the event (good outcome of PRP injection) was 75. A study by Tavassoli et al. found

Table 1. VAS and PF at baseline and at week 4 after a single injection of IA PRP

Outcome	Pre-injection Mean (SD)	Post injection Mean (SD)	Mean difference (Post - Pre)	*p*-value
VAS	5.93 (1.53)	4.36 (2.07)	-1.58 (2.11)	< 0.001
PF	35.78 (22.26)	44.74 (25.86)	8.97 (24.99)	0.008

VAS, visual analog scale; PF, physical function dimension of SF-36 questionnaire; SD, standard deviation, IA PRP, intra-articular platelet-rich plasma

that a single dose of PRP injection had a good result record in 86% of cases.[25] Based on that, the estimated sample size was determined to be approximately 88 patients (75/0.86).

In the descriptive analysis, frequency and percentage were used for categorical data, while mean and standard deviation were used for continuous data. A chi-square test or Fisher's exact test was used to assess the significant difference between proportions. Factors associated with a good outcome at week four after injection were identified using multiple logistic regression. The paired T-test was used to compare the results before and after IA PRP injection. The results were analyzed using STATA statistical software.

Results

A total of 58 outpatients with knee osteoarthritis were eligible to participate in this study. Most were over 65 years of age (62.07%), were women (86.21%), and had moderate to severe knee osteoarthritis (KL level 3 to 4) (84.48%). As shown in Table 1, VAS scores before and after injections had mean and standard deviation (SD) values of 5.93 (1.53) and 4.36 (2.07), respectively, with a mean difference (SD) of -1.58 (2.11) and $p < 0.001$. The PF scores were higher at week 4 after injection (mean=35.78, SD=22.26) than at pre-injection (mean=44.74, SD=25.86), t (57) = -2.73, p= 0.008. The percentage of patients with good outcomes was 41.34%. Pain at the injection site persisting for more than three days was the most common side effect (13.79%), as shown in Table 2. The univariable analysis found no associated factors for good VAS responders (Table 3). Additionally, no associated

Table 2. Side effects reported or observed at week 4 after a single injection of IA PRP

Side effects	Frequency	Percentage
Pain at injected site > 3 days	8	13.79
Knee swelling > 3 days	3	5.17
Subcutaneous hemorrhage	1	1.72
Knee joint Effusion	0	0.00
Arthritis	0	0.00

IA PRP, intra-articular platelet-rich plasma

Table 3. Univariable analysis of factors associated with a good response to a single injection of IA PRP

Variables	Overall	VAS Response		Odds ratio	*p*-value
		Good	Poor		
Age					
≤ 65	22 (37.93)	12 (54.55)	10 (45.45)	2.4	0.111[a]
> 65	36 (62.07)	12 (33.33)	24 (66.67)		
Sex					
Female	50 (86.21)	22 (44)	28 (56)	2.35	0.449[b]
Male	8 (13.79)	2 (25)	6 (75)		
BMI (kg/m^2)					
≤ 25	25 (43.10)	11 (44)	14 (56)	1.21	0.724[a]
> 25	33 (56.90)	13 (39.39)	20 (60.61)		
Duration					
< 5 years	35 (60.34)	17 (48.57)	18 (51.43)	2.16	0.17[a]
≥ 5 years	23 (39.66)	7 (30.43)	16 (69.57)		
KL level					
2	9 (15.52)	4 (44.44)	5 (55.56)	1.16	1[b]
3-4	49 (84.48)	20 (40.82)	29 (59.62)		
MCL laxity					
No	36 (63.16)	14 (38.89)	22 (61.11)	0.85	0.768[a]
Yes	21 (36.84)	9 (42.86)	12 (57.14)		
LCL laxity					
No	48 (84.21)	20 (41.67)	28 (58.33)	1.43	0.726[b]
Yes	9 (15.79)	3 (33.33)	6 (66.67)		

Values are reported as number (percentage); [a]Chi-square test, [b]Fisher exact test

BMI, Body Mass Index; KL, Kellgren-Lawrence classification; MCL, Medial collateral ligament; LCL, Lateral collateral ligament; IA PRP, intra-articular platelet-rich plasma

Table 4. Logistic regression analysis to determine associated factors for good response of a single injection of IA PRP

Variables	Adjusted odds ratio	95% CI		*p*-value
		Lower	Upper	
Age: ≤ 65	2.63	0.81	8.33	0.111
Sex: female	3.69	0.57	23.66	0.168
BMI: ≤ 25 kg/m^2	1.22	0.34	4.55	0.769
Duration: < 5 years	2.56	0.72	9.09	0.145
KL level: 2	1.26	0.21	7.53	0.8
Constant	0.21	0.13	3.15	0.257

BMI, body mass index; KL, Kellgren Lawrence classification;
CI, confidence interval; IA PRP, intra-articular platelet-rich plasma

factors for good outcomes were found in a multivariable analysis (Table 4).

Discussion

Knee osteoarthritis is a destructive degenerative disease which causes joint cartilage and the underlying bone to gradually degenerate over time. Higher levels of cartilage-degrading enzymes are expressed in knee osteoarthritis,[26] an indication that attempts to treat knee osteoarthritis have been unsuccessful.

This study aimed to determine the factors associated with a good outcome, i.e., pain reduction, after a single injection of IA PRP in patients with knee osteoarthritis. The main findings revealed that VAS at week 4 was lower than at baseline (mean difference = -1.58 (2.11) with $p < 0.001$). However, only 24 of 58 participants (41.4%) experienced a reduction of at least 30% in pain intensity, the indication of a good outcome. No demographic or clinical factors were found to have a statistically significant association with a good outcome. However, there is a possibility that participants who were female (adjusted odds ratio [OR] = 3.69, $p = 0.168$), aged ≤ 65 years (adjusted OR = 2.63, $p = 0.111$), and had a duration of knee osteoarthritis < 5 years (adjusted OR = 2.56, $p = 0.145$) had a greater chance of experiencing a good outcome. These three associations had low p-values that could potentially reach statistical significance ($p < 0.05$) with a larger number of participants.

In that regard, a study by Mazzola M and colleagues found that people over 60 had an autologous PRP injection failure rate similar to this study.[22] In this study, there was no statistically significant correlation between age and good response ($p = 0.111$), possibly due to the small sample size. More research is needed to evaluate the relationship of age and good outcomes.

More female patients had significant clinical improvement than males in this study. However, previous studies have reported finding no significant impact of gender on the clinical results of either autologous PRP injection or IA Hyaluronic injection.[21, 22] That 86% of the individuals in our study were women may have been a factor in the overall greater positive reaction to PRP injection in this study, i.e., there may have been a reduction in generalizability due to the small number of male participants. The upshot is that it is not possible to definitively state that sex has an impact on the outcome of IA PRP injection based on these results.

The chronic osteoarthritic knee symptoms of patients may be associated with central sensitization which plays an essential role in pain signaling in the central nervous system, resulting in increased pain sensitivity, duration of pain, and areas affected.[27,28] A study by Fatimah et al. reported that no association between response and duration of symptoms could be identified based on regression and correlation statistics of intraarticular steroid injection.[20] However, it is difficult to establish whether the duration of a symptom is a contributing factor due to the numerous factors that impact knee osteoarthritis over time.[2] In practice, patients with persistent symptoms are usually encouraged to combine many treatment modalities to manage their pain. In this study, a single injection of IA PRP generally had a poor response among participants with longer periods of symptoms of knee osteoarthritis.

BMI > 25 kg/m^2 and KL grade > 2 were found to be primary independent risk factors for autologous PRP injection failure in a study by Alessio-Mazzola et al.[22] However, in the present study, BMI ≤ 25 kg/m^2 and KL grade 2 were not associated with good responses to IA PRP injection. Again, this result might be due to the limited population size in this study.

Previous research has demonstrated that PRP injections significantly improve physical function compared to HA injections.[7,10] In the present study, four weeks after the IA PRP injection, there was an improvement in the physical function of the patients. That positive response of physical function to a single injection and short duration of IA PRP treatment support those previous reports.

This study has several limitations. First, the sample size did not reach the target due to the impact of the COVID-19 situation. Consequently, the statistical power of regression analysis to determine associated factors was compromised. Second, approximately 90% of the participants were female, so it was not possible to generalize the study results to the general population. Finally, this study had a relatively follow-up short period. Nevertheless, focusing on factors related to positive outcomes and on the short-term effects of a single dosage of PRP are issues important enough to warrant further investigation.[29]

Conclusions

A single injection of IA PRP can result in significant improvements in pain and physical function in patients with knee osteoarthritis after at four weeks. Age over 65 years, female gender, and duration of symptoms less than five years are factors that tend to be related to a good pain reduction response to treatment. However, the associations of these three factors were not demonstrated to be statistically significant. A larger number of participants will be required for further studies.

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Original Article

Can Singing Evoke a Significant Cardiovascular Response on a Six-Minute Treadmill Walk Test?: A Crossover Study

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ABSTRACT

Objectives: This study compared the effects of the Six-minute Treadmill Walk Test (6MTWT) and Six-Minute Treadmill Sing Walk Test (6MTSWT) on cardiovascular parameters.

Study design: Crossover study.

Setting: Undergraduates of Obafemi Awolowo University, Ile-Ife, Nigeria.

Subjects: Thirty-five healthy individuals.

Methods: The participants performed both the 6MTWT and the 6MTSWT in random order with a 10-minute rest interval between. The 6MTSWT was the same as the 6MTWT with the exception that the participants were required while walking to sing along to a popular local song rendered at 80 beats per minute through a headset and synchronized to the treadmill speed. Pre-and-post-walk systolic blood pressure (SBP), diastolic blood pressure (DBP), pulse rate (PR), rate of perceived exertion (RPE), and rate pressure product (RPP) were recorded.

Results: Each test resulted in a significant difference in SBP, RPP, and RPE ($p < 0.05$). There were also significant differences between the groups in mean change of PR with 6MTWT and 6MTSWT (2.37±3.90 vs. 0.54±3.24; t= 2.133; $p = 0.037$, respectively) and RPP (776.80±602.24 vs. 483.86±399.28; t = 2.398; $p = 0.019$, respectively).

Conclusions: Slow-tempo singing decreases PR and RPP significantly during 6MTWT among healthy young individuals.

Keywords: six-minute treadmill walk test, cardiovascular parameters, singing, walk tests

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Introduction

The American Thoracic Society (ATS) guidelines[1] stipulate the standard length of the hallway in a six-minute Walk Test (6MWT) to be 30 meters long, and the standard width to be 3 meters. However, finding the required space may be problematical in some centers. Preliminary data have shown that the six-minute treadmill walk test (6MTWT) protocol is a feasible and reliable alternative for predicting maximal oxygen consumption and assessing heart rate in apparently healthy adults.[2] It has also been reported that 6MTWT is a cost-effective measure for determining parameters of an exercise prescription, especially exercise intensity in a clinical environment.[3]

Although undertaking 6MTWT can resolve problems of limited space, consumes less time, and allow constant monitoring during the exercise,[4] few studies have utilized a treadmill instead of a corridor walk for 6MWT.[5,6] More importantly, data on the effect of singing during a 6MTWT is limited, although there is evidence of the effects of singing on cardiovascular parameters.[7-9] Specifically, some researchers have reported varying effects of different kinds of music on some cardiovascular parameters, including blood pressure and pulse rate.[10,11] Additionally, singing has been associated with a 10% reduction in the rate of perceived exertion during the exercise of a low-to-moderate intensity.[7,12-14]

Singing has been widely used to accompany athletic activity as a way to enhance the psychological state, establish an effective mindset, sustain motivation, resist mental and emotional fatigue, as well as to facilitate physical and athletic performance.[12,15,16] However, the effects of singing seem to have been less explored among patient populations undertaking the 6MTWT even though cardiorespiratory dysfunctions are among the main indications for them to undergo the test. It is possible that the cardiovascular parameters of patients who undergo 6MTWT can be positively improved if singing is incorporated into the procedure. Moreover, due to its peculiar characteristics, singing is increasingly employed in the rehabilitation of patients with medical, physical, and psychosocial problems.[16]

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To our knowledge, no studies have been conducted to ascertain if singing can enhance cardiovascular parameters during 6MTT. This study aimed to compare the effects of 6MTWT and the six-minute treadmill sing walk test (6MTSWT) on cardiovascular parameters in apparently healthy individuals.

Methods

Participants

After obtaining ethical approval for the study, male and female undergraduates of Obafemi Awolowo University, Ile-Ife, Nigeria, were recruited purposively after obtaining their written consent. Inclusion criteria included: (1) undergraduates age between 18 and 28 years, (2) stable blood pressure and pulse rate, (3) native Yoruba speakers, and (4) having the ability to walk. Participants were excluded if: (1) they had a history of chest discomfort, angina pectoris, or cardiovascular disease, (2) they had any orthopedic condition affecting their ability to walk, and (3) if they had a history of severe cardiorespiratory disease. Based on the sample size formula for two groups comparison with effect size = 1, power = 0.8, and alpha value = 0.05, the necessary sample size was calculated to be 30.[17] In all, a total number of 35 participants were recruited for the study.

Procedure

Ethical approval for this study was obtained from the Institute of Public Health, Obafemi Awolowo University, Ile-Ife, Nigeria. Written informed consent of participants was obtained, eligibility screening of the participants was conducted,and the height and weight of each participant was measured. Participants were told that they were not obligated to complete the study and that if they experienced symptoms such as shortness of breath, fatigue, or discomfort during the exercise the test would be terminated. Participants watched a demonstration on the treadmill for familiarization prior to the actual test. The order of the test was determined by random drawing. Participants performed 6MTWT first if "A" was drawn or 6MTSWT if it was "B." Before testing, each participant rested in a chair near the treadmill for 10 minutes. During this period, the blood pressure (BP), heart rate (HR), and oxygen saturation level ($Sp0_2$) of each participant was measured by a digital automatic blood monitor (Omron, M2 Compact(HEM-7102-E(V), Hoofddorp, The Netherlands) and a pulse oximeter (EC-500A, M/s. Swayam Thermometer Industries, New Delhi, India) was fixed at the index finger. Each participant rested for 10 minutes prior to the test and again between the two tests. The music used for the 6MTSWT was the Nigerian nativesong 'Eye Adaba,' a Yoruba genre popular among the study population which was familiar to the participants (www.youtube.com/watch?v=_M6xe8jD93w). The song was rendered at 80 beats/min through a headset (BAT music, Model: 5800, Shenzhen, Guangdong, China). The 80bpm was derived from a step conversion chart which convertedthe two-mph speed to 80 steps/min. Participants in this study had no previous singing training.

Six-minute treadmill walk test

Each participant began walking on the treadmill at 2.0 mph for the 6MTWT. The treadmill incline was initially 0% and was increased by 2% every 2 minutes to a maximum exertion of 6%. The test was terminated at the patient's request if there was evidence of dyspnea, chest pain, diaphoresis, or at the end of the full 6 minutes. The BP, HR, and Sp02 were taken again immediately after the test with the participants sitting.

Six-minute treadmill sing walk test

The 6MTSWT was similarly performed on a powered treadmill at a speed of 2.0 mph. Initial readings of BP, HR, and Sp02 were taken at the start and at the end of the 6MTWT. During the test the treadmill incline was increased by 2% every 2 minutes to a maximum exertion of 6%. Each participant was given a headset and was asked to sing along as the song played. As with the 6MTWT, the test was terminated at the patient's request if there was evidence of dyspnea, chest pain, diaphoresis, or at the end of the full 6 minutes. Readings were again taken immediately afterward with the participants in a sitting position.

Outcome measurements

The Borg Rating of Perceived Exertion scale, which has a range of 6 to 20 points, was used to assess the Perceived Exertion Rate (RPE) in both tests. In addition, BP, PR, and SpO_2 were measured pre- and post-test while Rate Pressure Product (RPP) and Metabolic Equivalents (METs) were calculated for each participant from the cardiovascular measures. Rate Pressure Product = Systolic Blood Pressure (mmHg) X Heart Rate (bpm).[18,19]

Data analysis

Data were analyzed using descriptive (mean and standard deviation) and inferential statistics. The paired t-test was used to assess the differences between the pre-and post-walk test cardiovascular parameters within each group, while the independent t-test was used to compare the differences in cardiovascular parameters of the participants between the six-minute treadmill walk test and the six-minute treadmill sing walk test. Pearson's moment correlation coefficients were used to investigate the relationship between the cardiovascular parameters of the two tests. The alpha level was set at $p < 0.05$. Statistical Package for Social Sciences(SPSS) version 23 (Chicago, Illinois, USA) was used for data analysis.

Results

The physical characteristics of the participants are presented in Table 1. The majority (62.86 %) of the participants were male. The mean age and body mass indexes were 22.29±1.36 years and 21.12±2.66kg/m^2. The paired t-test comparison of cardiovascular parameters at baseline and after 6MTWT showed significant differences in SBP, PR, RPP, and PRE ($p < 0.05$). However, there was no significant

Table 1. Physical characteristics of the participants (N=35)

Valiables	(n/%) / $\overline{x}$ (SD)
Gender (male)	22 (62.86)
Age (years)	22.29 (1.36)
Height (m)	1.70 (0.09)
Weight (kg)	61.20 (10.2)
BMI (kg/m^2)	21.12 (2.66)

BMI, body mass index; $\overline{x}$ (SD), mean ± standard deviation; n frequency; % percentage

difference in DBP (p > 0.05) (Table 2).

Similarly, the paired t-test comparison of cardiopulmonary parameters at baseline and after 6MTSWT showed significant differences in SBP, RPP, and RPE (p < 0.05).With this test, there was no significant difference in DBP or in PR (p > 0.05) (Table 2). Table 3 shows an independent t-test comparison of cardiopulmonary responses (mean change) between 6MTWT and 6MTSWT. There was a significant difference in the PR (2.37±3.90 vs. 0.54±3.24: p = 0.037) and RPP (776.80± 602.24 vs. 483.86±399.28, p = 0.019), but there was no significant difference in systolic blood pressure (SBP), diastolic blood pressure (DBP), or RPE values (p > 0.05). Table 4 shows the relationship between 6MTWT and 6MTSWT for the cardiovascular parameters using Pearson's Product Moment Correlation Coefficients. The results show a significant correlation between RPP response and distance covered in 6MTSWT only (r = 0.402, p = 0.017).

Table 2. Paired t-test comparison of cardiovascular parameters at baseline and after a six-minute treadmill walk test and after six-minute treadmill sing-walk test (N=35)

Valiables	6MTWT				6MTSWT			
	Pre-test $\overline{x}$ (SD)	Post-test $\overline{x}$ (SD)	T	*p-value*	Pre-test $\overline{x}$ (SD)	Post-test $\overline{x}$ (SD)	T	*p-value*
SBP	116.63 (13.3)	123.06 (14.4)	-8.975	0.001*	113.51 (13.3)	119.03 (13.7	-7.334	0.001*
DBP	72.91 (9.40)	71.11 (8.91)	1.482	0.148	74.17 (12.7)	70.89 (12.4	2.827	0.08
PR	74.09 (11.5)	76.46 (12.4)	-3.594	0.001*	76.60 (11.8)	77.14 (12.6	-0.992	0.328
RPP	8641.14 (1655.52)	9417.94 (1932.93)	-7.631	0.001*	8729.34 (1800.72)	9213.20 (1939.64)	-7.169	0.001*
RPE	6.00 (0.00)	9.80 (1.83)	-12.30	0.001*	6.00 (0.00)	9.74 (2.06)	-10.734	0.001*
SpO2	97.80 (1.13)	97.34 (1.16)	----------	--------	97.71 (1.07)	97.63 (1.35)	-----	------
METs	3.89 (0.15)	4.16 (0.15)	---------	-------	3.89 (0.15)	4.16 (0.15)	-------	-------

*indicates a significant difference; SBP, systolic blood pressure (mmHg); DBP, diastolic blood pressure (mmHg); SpO_2, oxygen saturation pressure; PR, pulse rate (bpm); RPP, rate pressure product (mmHg; RPE, rate of perceived exertion; METs, metabolic equivalents of tasks; 6MTWT, six-minute treadmill walk test; 6MTSWT, six-minute treadmill sing-walk test

Table 3. Independent t-test comparison of cardiovascular responses (mean change) between the six-minute treadmill walk test and six-minute treadmill sing-walk test (N=35)

Variable	6MTWT $\overline{X}$ (SD)	6MTSWT $\overline{X}$±SD	t	*p*-value
SBP	6.43 (4.24)	5.51 (4.45)	0.880	0.382
DBP	1.80 (7.19)	3.29 (6.87)	0.884	0.380*
PR	2.37 (3.90)	0.54 (3.24)	2.133	0.037*
RPP	776.80 (602.24)	483.86 (399.28)	2.398	0.019*
RPE	3.80 (1.83)	3.74 (2.06)	0.123	0.903

*Indicates a significant difference

SBP, systolic blood pressure (mmHg); DBP, diastolic blood pressure (mmHg); PR, pulse rate (bpm); RPP, rate pressure product (mmHg); RPE, rate of perceived exertion

Table 4. Relationship of the Pearson's Product Moment Correlation Coefficient of cardiovascular parameters between the six-minute treadmill walk test and the six-minute treadmill sing walk test

Variable	6MTWT (distance)		6MTSWT (distance)	
	Pearson moment correlation (r)	p-value	Pearson moment correlation (r)	*p*-value
SBP	0.240	0.164	-0.027	0.878
DBP	0.111	0.526	-0.183	0.294
SPO_2	-0.185	0.288	-0.56	0.748
PR	-0.236	0.173	-0.314	0.067
RPP	-0.015	0.932	-0.402	0.017*
RPE	0.103	0.556	0.290	0.091

*Significant correlation

SBP, systolic blood pressure (mmHg); DBP, diastolic blood pressure (mmHg); SPO_2, oxygen saturation pressure; PR, pulse rate (bpm); RPP, rate pressure product (mmHg); RPE, rate of perceived exertion

Discussion

This study compared the effects of 6MTWT and 6MTSWT on cardiovascular parameters in apparently healthy individuals. The study's findings show that slow-tempo singing during 6MTWT significantly decreased the PR and RPP of healthy young individuals. The participants were young, age between 20-25 years, thus eliminating the possible moderating effect of high variability in age on cardiovascular response. Age has been reported to influence cardiovascular response to exercise,[20] including the six-minute walk test.[21]

In this study, both 6MTWT and 6MTSWT led to a significant increase in SBP, RPP, and RPE. The significant increase in SBP in 6MTWT is in accord with previous studies.[22,23] Both tests reduced DBP response; however, the difference between the groups was not statistically significant. Sembulingan and Sembulingan[24] and Stebbins et al.[25] reported that DBP reduces endurance level due to the accumulation of metabolic end products in tissues. Changes in DBP during exercise suggest an unstable form of hypertension related to coronary heart diseases and other heart-related problems, which is affected by

body position during exercise and by the type of exercise.[26] The 6MTWT and 6MTSWT tests are both submaximal exercises and therefore are not expected to elicit any significant changes in the participants' DBP, especially as they were young and free from any cardiovascular dysfunction prior to and at the time of recruitment.

The findings of this study show that 6MTWT leads to a significantly higher cardiovascular response in PR and RPP when compared with 6MTSWT. The higher increase in PR during 6MTWT may be explained by the fact that 6MTWT evokes a higher increase in venous return, myocardial contractility, and stimulation of the sympathetic nervous system leading to an increase in blood pressure and more blood going to the exercising muscles, thereby increasing cardiac output and vasodilatation.[23] Participants' lower PR response to 6MTSWT may be attributable to reduced sympathetic outflow during singing.[12] Olsson et al.[27] reported that singing slow songs resulted in slower PR compared to faster songs. The song's tempo used in the study was slow (80 bpm).

The nature of music songs, such as the tempo and phrasing, emerges as a critical element in mediating the effects of singing,[7] and responses to singing provide a mild form of sympathetic stimulation[7] as observed in this study. Because singing can reduce pulse rate, it might also provide the added benefit of reducing patients' susceptibility to ischemia. Studies have reported that any activity or factor that can shorten the diastolic phase of the cardiac cycle, such as increasing PR, will impair the supply of blood to the subendocardium, rendering that region more susceptible to ischaemia.[28,29]

Change in RPP was found to be significantly lower in 6MTSWT than in 6MTWT. RPP is a valuable marker of the oxygen requirement for the heart to function. The heart, being a muscular organ, needs a steady supply of oxygen and nutrients for effective functioning.[30] A deficient supply of these elements increases the likelihood of heart problems.[31] The significant reduction of RPP among the participants during 6MTSWT in this study suggests that it may aid the successful rehabilitation of patients with cardio-respiratory problems and may also help reduce the incidence of those problems in patients with risk factors for developing cardio-respiratory dysfunctions.

The findings of this study show that slow-tempo singing might alter cardiovascular parameters positively and may clinically help patients with cardiovascular diseases, e.g., hypertension. This finding appears to be relevant for cardiovascular patients as the test protocol (6MTSWT), a sub-maximal test, is generally tolerated by this group of patients. However, despite the potential clinical implications, this study has some potential limitations. One limitation is that the study was carried out among young, apparently healthy individuals, so the generalizability of the findings to older adult populations may be limited. Furthermore, cardiovascular response to the walk and sing-walk tests lasting for either shorter or longer periods may give different results than those observed in this study. Lastly, we did not analyze the period, carryover, and sequence effects which may potentially have affected the study findings. Further studies of the efficacy of 6MTSWT in individuals with varied demographics and different patients populations, especially those with cardiovascular diseases, are warranted.

Conclusion

Slow-tempo singing decreases PR and RPP significantly during 6MTWT in healthy young individuals.

Disclosure

There are no conflicts of interest to disclose

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Original Article

Construct Validity and Internal Consistency Reliability of the Thai Version of the Telephone-Based Cognitive Screening Tool

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ABSTRACT

Objectives: To affirm the construct validity and internal consistency reliability of the Thai version of the Telephone-Based Cognitive Screening Tool (Thai-TeBCOG).

Study design: A cross-sectional study.

Setting: Health-promoting hospitals, elderly schools in Bangkok, Chiang Mai, Khon Kaen, Chon Buri, and Nakhon Si Thammarat, Thailand.

Subjects: Participants of the study were 225 healthy adult volunteers between the ages of 23 and 80 and were from Thailand's city of Bangkok and provinces of Chiang Mai, Khon Kaen, Chon Buri, and Nakhon Si Thammarat. The volunteers were evaluated and assessed to be free of dementia, cognitive impairment, and depression.

Methods: Participants' demographics and information were gathered using a number of instruments and two main procedures. Firstly, items on the screening instruments were addressed through face-to-face interviews lasting on average approximately 15 minutes. Secondly, the Thai-TeBCOG was administered remotely over the phone for about 20 minutes. Cronbach's alpha was used to measure internal consistency, and exploratory factor analysis (EFA) was applied in assessing the questionnaire's construct validity.

Results: There were 13 items on the Thai version of the Telephone-Based Cognitive Screening Tool. The internal consistency and the construct validity of the screening tool were examined by using Cronbach's alpha coefficient and exploratory factor analysis, respectively. The results showed that the Thai-TeBCOG's internal consistency was acceptable with a Cronbach's alpha of 0.75. The construct validity of the tool was evaluated using EFA, and four extracted factors accounted for 54.48% of the total variance.

Conclusions: Four domains of individual differences were investigated. This study contributes to a growing body of knowledge aimed at increasing the effectiveness of cognitive screening tools for adults in different contexts.

Keywords*:* cognitive screening, telephone survey, interviews, exploratory factor analysis

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Introduction

The Coronavirus pandemic (COVID-19) and recent economic crises have had significant impacts on the lifestyles of adults, as well as leading to stress and memory loss among adult populations. While the majority of people who contract COVID-19 are likely to recover, they may be affected in the long term with memory or attention problems.[1,2] To be specific, a decline in cognitive processes, attention, memory, executive function, and organizing & planning abilities has been shown to occur in otherwise recovered patients.[3] Additionally, upon the spread of COVID-19, many countries, Thailand among them, implemented social distancing policies and stay-at-home orders, restricting their population's movements. As a result, individuals may have lost connection to health-tracking systems, health promotion initiatives, and information about how to prevent cognitive decline. While a number of cognitive performance screening tools, such as the Thai version of the Montreal Cognitive Assessment (MoCA),[4] the Abbreviated Mental Test (AMT),[5] and the Rowland Universal Dementia Assessment Scale-Thai version,[6] are presently available, a limitation of these tests is that face-to-face interactions are required. During times of pandemic and for those who live in remote areas, face-to-face interactions are not always suitable. These limitations could be transcended with the development of a telephone interview for cognitive performance screening.[7] However, few cognitive evaluation methods have been shown to be adequate for Thai contexts. In order to address this research gap, the present study undertook a literature review, which informed the creation of a novel questionnaire designated as the Telephone-Based Cognitive Screening Tool (Thai-TeBCOG). Providing health services remotely and through online social networks in Thailand reduces repetitive tasks, saves time and travel expenses, and facilitates effective health services. The objective of this study was to conduct a preliminary investigation into the cognitive components of the Thai-TeBCOG by utilizing Exploratory Factor Analysis

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(EFA). It is possible that an effective screening tool could be implemented as an initial step before administering a more intensive intervention program. Such a tool would increase the usefulness of clinical evaluations in a variety of health-care settings.

Literature review

Domains of cognitive functions in adults

Clinical assessments examine the various domains of cognitive functions to assess a person's cognitive state. Cognitive domains or functional systems in the brain include attention, memory, language, perception, and executive function.[8] Depending on the research objective, studies have handled domain classification differently. Liaison studies have discussed domains of cognitive functions in terms of regional brain functions, referring to the functioning of the frontal lobe, the temporal lobe, or other brain regions. The complexity of the operation, based on hierarchical cognitive domains, has also been used to classify cognitive domains, leading to 'top-down' versus 'bottom-up' designations. Bottom-level domains refer to simpler operations, such as sensing stimuli through sensory modalities and perceptions. In contrast, top-level domains are the most complex, such as reasoning and problem solving. In bottom-up strategies, the cognitive domains are primarily sensation, perception, motor skills & construction, attention & concentration, memory, executive functioning, processing speed, and language/verbal skills.[9]

Research has attributed age-related cognitive decline to various domains of cognitive function. Brain shrinkage has been shown to take place over time, particularly in the prefrontal regions.[10] The prefrontal cortex appears to be involved in the cognitive control of the following components: sustained attention, selective attention & inhibitory control, working memory, and multi-tasking & task switching.[11] Some of these cognitive control components appear in the Unity and Diversity Model of Executive Functions, proposed by Miyake et al. (2000),[12] which encompasses a wide range of higher-order cognitive processes, such as updating, inhibiting, and set-shifting. Lacreuse et al. (2020) agree that age-related decline in executive functions is caused by changes in the prefrontal areas.[13] Harvey (2019) argues that although simple working memory tasks activate the frontal lobe, they do not entail problem solving or cognitive resource management and suggests that the term "executive functioning" should be broadly used to refer to reasoning and problem solving.[9] In line with this definition, inductive reasoning could be classified as executive functioning. Meanwhile, age-related brain shrinkage has also been observed in medial temporal regions, where the hippocampus is embedded,[10] potentially hampering collaboration between working memory and long-term memory. Similarly, a person with atrophy in the medial temporal regions may exhibit language deficits due to the inaccessibility of long-term memories, particularly, semantic memories where linguistic information is stored. Another indicator of overall cognitive performance is processing speed. Individuals with both cortical and frontostriatal degeneration, or those with severe mental illness, may have slower processing speeds.[9]

Widely used cognitive assessment tools, such as the Mini-Mental State Examination (MMSE) and the Montreal Cognitive Assessment (MoCA), assess orientation and calculation, among other cognitive components. In cases of mild cognitive impairment or dementia, time, place, and person orientation play an important role in predicting overall decline. Disorientation to time in elderly hospital patients is a useful indicator of the presence and severity of dementia, and a patient's inability to correctly identify the month or year is a strong enough indicator of dementia to warrant a more thorough cognitive assessment.[14] Calculation, meanwhile, is used to assess concentration, attention, and working memory. In addition, the MoCA includes an abstraction aimed at evaluating multi-faceted executive functions.[15]

Based on the literature, cognitive screening tools engage numerous cognitive domains to assess a patient's cognitive state. The researchers focused the current study on attention & concentration, memory, executive functioning, processing speed, language/verbal skills, and orientation. These cognitive components could be assessed through a number of cognitive tasks that were included on the Thai-TeBCOG. The Thai-TeBCOG was tested on the Thai population and its validity was investigated with EFA.

Methods

Participants

The participants in the present study were community-dwelling adults ranging in age from 23 to 80 years (mean = 48.96, standard deviation = 15.71) residing in Bangkok, Chiang Mai, Khon Kaen, Chon Buri, and Nakhon Si Thammarat, Thailand. The study made extensive use of participant characteristics and employed cognitive interview techniques along with multi-stage sampling. The locations representing Bangkok and the four regions of Thailand were randomly chosen. Based on convenience sampling method, 48, 39, 48, 45, and 45 volunteer participants were selected from Bangkok, Chiang Mai, Khon Kaen, Chon Buri, and Nakhon Si Thammarat, respectively. To circumvent potential impediments to the participants' participation, researchers identified cognitive impairments using a RUDAS cutoff value of 23-24 and symptoms of depression using a Patient Health Questionnaire-9 (PHQ-9) cutoff value of 7. Only healthy volunteers, without any diagnosis of dementia, cognitive impairment, or depression, were selected to participate in this study. In total, 225 participants (67.60% female and 32.40% male) participated in this study. The majority of them (63.20%) had graduated with a bachelor's degree or higher. Thailand's average monthly income per household is approximately 26,018.42 THB, and in the present study, the percentage of households with incomes ranging from 15,001 to 30,000 THB; 30,001 to 50,000 THB; higher than 50,000 THB; and lower than 15,000 THB was 32.60%, 19.20%, 13.4%, and 34.80%, respectively.

Procedures

Study protocols were approved by the Mahidol University Institutional Review Board Committee (MU-CIRB 2020/337.1610). Participants received an information sheet, which they reviewed independently, and were given an informed consent form to sign. The various instruments in this study were employed in gathering data in two stages. Firstly, items on the screening instruments were addressed through face-to-face interviews lasting an average of approximately 15 minutes. Secondly, the Telephone-Based Cognitive Screening Tool was administered over the phone. These interviews took about 20 minutes. The participants were recruited for this study between September 2021 and March 2022.

Measurements

Screening Instruments

The Rowland Universal Dementia Rating Scale (RUDAS)

The RUDAS is a short cognitive assessment tool that was developed and validated by Rowland et al. This screening tool tests six domains and consists of tasks relating to body orientation, cube drawing, problem solving, praxis (coordination between both hands), memory (remembering a shopping list), and semantic verbal fluency (naming animals).[16,17] The total RUDAS score is 30 points, and the initial validation study proposed a cut-off value of 23 to screen for cognitive impairment. A RUDAS-Thai cut-off value of 24 out of 30 identifies people with dementia in cases where respondents have completed at least 6 years of primary education, and otherwise, the cut-off value decreases to 23.[18] The RUDAS-Thai is easy to use, takes less than 15 minutes to complete, and has previously been evaluated for content validity and test-retest reliability. With a Pearson's value of 0.80, the instrument was shown to have 78.7% sensitivity and 61.8% specificity.[18,19] The RUDAS-Thai was administered to each participant in this study.

The Patient Health Questionnaire-9 (PHQ-9)

Depressive symptoms were initially screened using the 2 Questions for Depression Screening (2Q) tool, consisting of two questions: 'Do you feel depressed?' and 'Have you lost interest or pleasure in doing things, or felt bored?' If a participant answered 'yes' to one or both of the two questions, the PHQ-9 was administered. The PHQ-9 inquires whether any of 9 symptoms were present for more than half of the days over the 2 weeks prior to answering the questionnaire. Severity of depression according to PHQ-9 is classified as follows: scores ranging from 7-12 signify 'mild' depression; 13-17 signify 'moderate' depression; and 18 or above signify 'severe' depression. The PHQ-9 has a high degree of sensitivity and specificity,[20] and it is recommended that participants with scores of greater than 7 see a healthcare provider.

Socio-demographic variables

An abridged questionnaire was created to gather data on socio-demographic factors, such as age, gender, educational status, and family income.

The Thai version of the Telephone-Based Cognitive Screening Tool (Thai-TeBCOG)

The 13-item Thai-TeBCOG, a cognitive evaluation test with a full score of 40 points, requires an estimated 15 to 20 minutes to administer. The items in the Thai-TeBCOG and their point allocations are described as follows: 1) Orientation to time is utilized to assess mental capacity relevant to date awareness and involves the examiner asking for the current date, including the day of the month, the month, and the year (3 points, 1 for each item); 2) Orientation to phone number is assessed by requesting that the examinee recall his/her 10-digit telephone number (1 point); 3) Ability to calculate is assessed by asking the examinee to subtract 6 from 70 and to continue to subtract 6 from their previous answer until they have completed five consecutive subtractions (5 points, 1 for each item); 4) Attention is quantified by performing a reverse spelling test, such as asking the examinee to spell ต ะ ข า บ (/takhap/ 'centipede') backwards (5 points, 1 for each item); 5) Memory-recall is assessed by employing a five-item word list recall test, wherein the examinee is given a list of five words and is asked to recall those words at a later point in the assessment (5 points, 1 for each item); 6) Working memory is assessed with the backward digit span test (5 points, 1 for each item); 7) Verbal fluency is measured using a one-minute fruit name generation test in which the examinee is given one minute to produce as many fruit names as possible (4 points); 8) Repeating a sentence is an ability examined by asking the examinee to repeat กระรอกปีนขึ้นต้นไม้ตอนกลางคืน (/krarok pin khuen tonmai ton klangkhuen/ 'A squirrel climbs up a tree at night'.) (1 point); 9) Object naming refers to the examinee's ability to produce the names of objects, and the examinee is required to respond to two questions: อะไรที่คนมักเอาไว้ใช้ตัดกระดาษ (/arai thi khon mak ao wai chai tat kradat/ 'What do people generally use to cut paper?') and ผักที่มีรสเผ็ด สีเขียวและสีแดง (/phak thi mi rot phet si khiaw lae si daeng/ 'What is a naturally spicy green or red vegetable?' (2 points, 1 for each item); 10) Processing Speed is assessed by the examinee's performance reciting the months of the year in reverse order from ธันวาคม (/thanwakhom/ 'December') through มกราคม (/makarakhom/ 'January') (4 points); 11) Inductive reasoning is the process of identifying a rule or a pattern based on cases belonging to that rule, and to test this, the examinee is assigned the task of predicting the next number in a list (2 points); 12) Abstraction involves the examinee being asked to identify commonalities between certain terms and to specify their category while avoiding concrete responses to the best of their ability (2 points); and 13) Executive functions are assessed by measuring the examinee's ability to plan and to describe sequences by answering clarifying questions, and this assessment is carried out by requesting the examinee answer irrelevant questions. (2 points).

The content validity of the Thai-TeBCOG was calculated using the Content Validity Index (CVI). A panel of five experts,

selected from senior professionals and considered to have extensive knowledge and experience in the fields of Cognitive Psychology and Neuroscience, evaluated each item on the screening tool. The credentials of the five professional experts were as follows: one expert with a PhD in Cognitive Science and an MSc in Clinical Psychology; one expert with an MD/ PhD in Neuroscience and Occupational Science and in Community Mental Health; one expert with a PhD in Community Medicine; one expert with a PhD in Occupational Science; and finally, one expert with an MSc in Mental Health. Each panelist was asked to rate each item on a scale ranging from 1-4 based on its relevance and clarity, where a score of 1 indicated 'not relevant;' 2 indicated 'relevant, but needs revision;' 3 indicated 'relevant, requiring minor revisions;' and 4 indicated 'relevant'. The I-CVI was calculated by dividing the number of experts who had given scores of 3-4 ('relevant') by the total number of experts. The resulting item-level content validity index for the tool ranged from 0.8 to 1, where a value of at least 0.78 was regarded as acceptable.[21,22] The average I-CVI score of the tool was 0.98, meaning that on average each item on the tool was assessed as having an outstanding content validity with a high level of agreement among panel members.[21] To ensure that the measurement tool would accurately measure the concept it was intended to measure, items with poor agreement among panel members would need to be removed from the tool. An I-CVI score of 0.70 is considered to be the threshold, with lower scores suggesting the item should be removed from the measurement tool.[21,23]

Statistical methods

The data were analyzed using IBM's Statistical Package for the Social Sciences (SPSS) (version PASW 18). Construct validity of the tool was examined using EFA, along with the extraction method of principal component analysis (PCA) and Oblimin rotation. Kaiser-Meyer-Olkin (KMO) and Bartlett's test were used to determine the sufficiency of sample size and its suitability for factor analysis (KMO ≥ 0.6 being an acceptable value for conducting EFA). The factors were retained if they had an eigenvalue of greater than 1. Variables with a factor loading greater than 0.40 were considered to be relevant to factor interpretation.[24] CVI and impact scores were calculated using Excel.

Results

Internal consistency

Descriptive statistics are presented in Table 1, including minimum, maximum, mean, standard deviation, skewness, and kurtosis of participants' scores for each of the 13 items, as well as their overall scores. The reliability analysis of the Thai-TeBCOG showed a Cronbach's standard coefficient of 0.754. The coefficient being greater than 0.7 demonstrated a satisfactory level of internal consistency dependability.

As seen in Table 2, almost all of the items assessing cognitive abilities from the same scale demonstrated significant correlation with each other. Inductive reasoning and abstraction abilities were discovered to be linked to a variety of other items. The majority of the associations were statistically significant and positive, and the majority of the values in the correlation matrix were moderate, eliminating the likelihood that the correlation matrix was an identity matrix.

The construct validity of the Thai version of the Telephone-Based Cognitive Screening Tool

To ensure that having a small sample size had not affected the research results, tests for skewness and kurtosis were estimated for each dependent variable (Table 1). In line with the guidelines for skewness |3.00| and kurtosis |10.00| by Kline (2005), a skewness of greater than 3.00 and a kurtosis of greater than 10.0 were considered 'non-normal' in this study.[25] The variables of 'Orientation to time,' 'Orientation to phone number,' and 'Object naming' were shown to have skewness

Table 1. Descriptive statistics of cognitive measures at initial testing (n=225)

Item	Min	Max	M	SD	Skewness	Kurtosis
1. Orientation to time (OT)	1	3	2.92	0.31	-3.88	15.80[a]
2. Orientation to phone number (PHONE No.)	0	1	0.96	0.19	-5.05	23.71[a]
3. Ability to calculate (CALC)	0	5	3.94	1.44	-1.25	0.43
4. Attention (ATTN)	0	5	4.42	1.45	-2.49	4.70
5. Memory-recall (M-ReCALL)	0	5	3.90	1.34	-1.16	0.53
6. Working Memory (WM)	0	5	2.88	1.34	-0.01	-0.97
7. Verbal Fluency (VF)	0	5	2.69	0.61	-1.58	4.05
8. Repeating a sentence (RPT-S)	0	2	0.79	0.42	-1.23	0.06
9. Object Naming (OBJ-N)	0	2	1.92	0.28	-3.83	15.05[a]
10. Processing Speed (PS)	0	4	2.93	1.30	-0.94	-0.37
11. Inductive Reasoning (IR)	0	4	1.30	0.77	0.09	0.26
12. Abstraction (ABS)	0	2	1.73	0.53	-1.90	2.73
13. Executive Functions (EFs)	0	2	1.72	0.48	-1.32	0.58
Total Score	13	40	32.09	6.09	-1.074	0.435

[a]Skewness or kurtosis outside the acceptable range; Min, minimum; Max, maximum; M, mean; SD, standard deviation

Table 2. Inter-correlation between the items (n=225)

Items	1	2	3	4	5	6	7	8	9	10	11	12
1	1											
2	.103	1										
3	.149*	.292**	1									
4	.139*	.287**	.430**	1								
5	.066	.184**	.203**	.200**	1							
6	.084	.145*	.309**	.264**	.330**	1						
7	.167*	.295**	.226**	.352**	.180**	.163**	1					
8	.135*	.131*	.147*	.292**	.074	.241**	.243**	1				
9	.234**	.034	.132*	.165*	.111	.095	.226**	.127	1			
10	.174**	.267**	.435**	.397**	.204**	.295**	.348**	.259**	.242**	1		
11	.203**	.139*	.329**	.355**	.194**	.278**	.192**	.339**	.210**	.436**	1	
12	.241**	.219**	.320**	.328**	.331**	.275**	.291**	.182**	.251**	.423**	.187**	1
13	.012	.036	.200**	.196**	.185**	.233**	.107	.140*	.071	.212**	.101	.259**

Notes: 1, orientation to time; 2, orientation to phone number; 3, calculation; 4, attention; 5, memory-recall; 6, working memory; 7, verbal fluency; 8, repeating a sentence; 9, object naming; 10, processing speed; 11, inductive reasoning; 12, abstraction; and 13, executive functions

**Correlation was significant at the 0.01 level (2-tailed)

*Correlation was significant at the 0.05 level (2-tailed)

Table 3. KMO and Bartlett's Test

Kaiser-Meyer-Olkin Measure of Sampling Adequacy		0.839
Bartlett's Test of Sphericity	Approx. Chi-Square	522.882
	df	78
	Sig	0.000*

*Represents significance with a significance value of less than 0.001

and kurtosis scores outside of the acceptable range, demonstrating that these cognitive measures did not result in normally distributed responses.[26] Table 3 shows the results of KMO and Bartlett's Test, where the KMO value of cognitive ability was greater than 0.8 (at 0.839) and Bartlett's test Chi-Square was approximated at 522.882 (p < 0.001). The data were subsequently analyzed using Exploratory Factor Analysis (EFA).

As displayed in Table 4, factor analysis using the Oblimin rotation method identified four factorial components with eigenvalues of greater than 1, accounting for 54.48% of the total variance. All 13 items on the instrument remained in the extraction table. The pattern matrices were carefully examined. The tests, producing factor loadings for a four-factor structure, ranged from .51 to .83 for factor one (orientation to phone number, verbal fluency, attention, and ability to calculate); from .54 to .69 for factor two (executive functions, memory-recall, working memory, and abstraction); from .44 to .74 for factor three (repeating a sentence, inductive reasoning, and processing speed); and from .70 to .76 for factor four (object naming and orientation to time). The scree plot shows the number of extracted factors (Figure 1).

Table 4. Factor Analysis after Oblimin with Kaiser Normalization Rotation for the Thai-TeBCOG (n = 225)

Item	Component			
	1	2	3	4
2. Orientation to phone number (PHONE No.)	.83			
7. Verbal Fluency (VF)	.58			
4. Attention (ATTN)	.52		.46	
3. Ability to calculate (CALC)	.51			
13. Executive Functions (EFs)		.69		
5. Memory-recall (M-ReCALL)		.67		
6. Working Memory (WM)		.60		
12. Abstraction (ABS)		.54		.43
8. Repeating a sentence (RPT-S)			.74	
11. Inductive Reasoning (IR)			.73	
10. Processing Speed (PS)	.43		.44	
9. Object Naming (OBJ-N)				.76
1. Orientation to time (OT)				.70
Eigenvalue	1.96	1.82	1.82	1.48
Variance explained (%)	15.09	14.03	13.98	11.38
Cumulative %	15.09	29.12	43.10	54.48

[a]Extraction methods: principal component analysis; rotation method: Oblimin with kaiser normalization; factor loadings < 0.4 removed

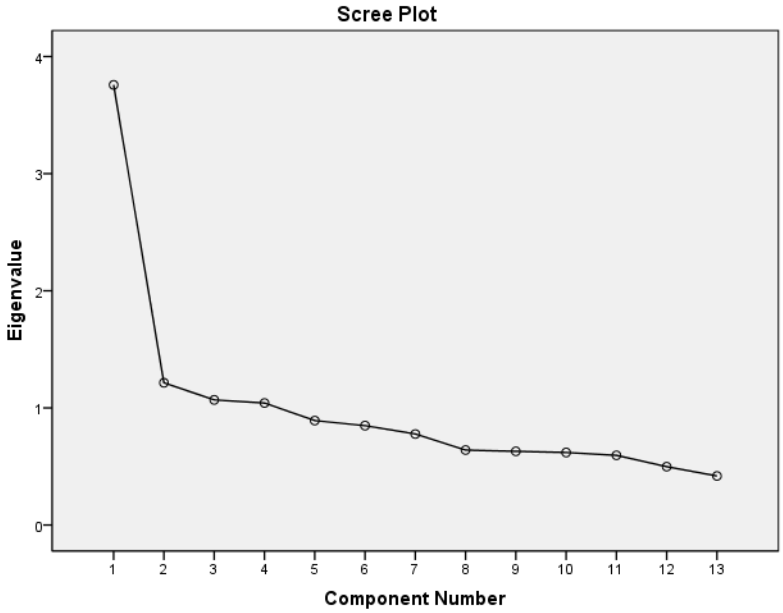

Figure 1. The scree plot, showing eigenvalues of all component numbers reflecting the EFA results for the Thai version of the Telephone-Based Cognitive Screening Tool

Discussion

The internal consistency analysis of the Thai-TeBCOG found a Cronbach's alpha value of 0.754, indicating reasonably good reliability, according to previous literature.[21,23] Previous studies on various versions of telephone-based cognitive tools have reported alpha values averaging around 0.7. For example, the Persian version of the Telephone Interview for Cognitive Status-modified (TICS-m) questionnaire had what was considered an excellent internal consistency (Cronbach's alpha = 0.712) when tested among community dwelling adults.[27] Similarly, when the telephone cognitive screen (T-CogS) was translated into a Turkish version (T-CogS-TR), the overall Cronbach's alpha coefficient was 0.763, indicating a satisfactory level of internal consistency.[28]

The results of the present study also showed that a multidimensional structure (higher order model) provided a better description of the existing relationships among the cognitive components within the Thai-TeBCOG. The results of the EFA confirmed that the four components had the following composite indicators: 1) ATTENTION (orientation to phone number, verbal fluency, attention, and ability to calculate), 2) EXECUTIVE FUNCTIONS AND MEMORY (executive functions, memory-recall, working memory, and abstractions), 3) LANGUAGE (repeating a sentence, inductive reasoning, and processing speed), and 4) NAMING AND ORIENTATION (object naming and orientation to time). This is consistent with earlier research in which factor analysis was used to identify latent dimensions in the Telephone Interview for Cognitive Status (Modified) and variables were divided into four factors: 'verbal memory', 'orientation/mental tracking', 'language/reasoning', and 'attention/working memory'.[29]

The results of the current investigation suggested that the effectiveness of the Thai-TeBCOG is in line with two widely recognized telephone screenings for cognitive impairment, the Montreal Cognitive Assessment (MoCA) and the Telephone Interview for Cognitive Status (TICS). Modeling of the Portuguese version of the Montreal Cognitive Assessment (MoCA) indicated that the tool could be split into a two factor model factorial structure, defined as MEMORY, including memory, language, and orientation sub-tests, and ATTENTION/EXECUTIVE FUNCTIONS, comprised of attention, executive functions, and visuospatial abilities tasks.[30] The Persian version of the TICS-m has been shown to have six factors consistent with the original TICS-m questionnaire: 'orientation,' 'registration/free recall,' 'attention/calculation,' 'comprehension, semantics, and recent memory,' 'language/repetition,' and 'delayed recall'.[27,31] Importantly, by using this scale, researchers have been able to assess cognitive performance in adulthood. During times of pandemic, the Thai-TeBCOG evaluation would be useful, as it would allow those who have been affected by COVID-19 for an extended period to track how their symptoms and cognitive abilities are changing over time. This study's finding of an excellent internal consistency for the Thai-TeBCOG when used in Thai contexts is a result of the tool being tailored to Thai people living in the four different regions of Thailand, as well as Bangkok (the capital city), according to their different regional dialects and local cultures. The age range of participants in this study spanned from 23 to 80 years, indicating that the Thai-TeBCOG has the potential to be utilized for assessing individuals across a wide range of ages. While this study has several important research implications, financial constraints limited the study to a preliminary and incomplete evaluation of psychometric aspects. In addition, the findings cannot be extrapolated beyond the sample used in this EFA. Therefore, future research should duplicate the findings from this investigation to explore the robustness of the Thai-TeBCOG. Norming studies with

larger and more heterogeneous samples are desperately needed. In addition, a CFA should be carried out to establish numerous psychometric features, such as cutoff point, sensitivity, and specificity.

Conclusion

Exploratory factor analysis showed a four-factor model based on prior literature and theoretical considerations to be a good fit. The thirteen items on the Thai-TeBCOG require about 20 minutes to administer via telephone. The Thai-TeBCOG is proposed as a brief, economical, valid, and reliable cognitive screening tool, beneficial for its ability to assess a broad set of cognitive domains, coupled with the advantage that it can be administered by non-professionals. Due to the increased incidence of long-term health effects attributable to Long COVID, health care practitioners may require novel approaches to evaluate cognitive impairment, especially in patients who lack convenient access to clinical settings. The results of this study show that the Thai-TeBCOG is a valid and practical tool for assessing adults in a variety of age groups, including older adults, when cognitive evaluation via in-person interviews is impractical.

Disclosure

The authors have no conflicts of interest related to this study to disclose.

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Original Article

Development and Psychometric Evaluation of a Short-Form Barthel Index for Older Patients Undergoing Abdominal Surgery

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ABSTRACT

Objectives: To develop and evaluate psychometric properties of a short-form of the Barthel Index.

Study design: Retrospective study.

Setting: A university hospital in Thailand.

Subjects: Patients aged 60 or over who had abdominal surgery and were enrolled in the Siriraj Integrated Perioperative Geriatric Excellent Research Center studies between January 2017 and August 2021.

Methods: Electronic medical records of patients were retrospectively reviewed and 96 patients were recruited. Items from the Barthel index were chosen for the short-form based on importance as determined from the index of overall superiority which was obtained from each item's total correlation score and the effect size of the item. The psychometric properties of the short-form were analyzed.

Results: The mean Barthel index score dropped from 92.8 at the time of surgery to 87.6 four weeks post-surgery. The five items with the highest ranking in the index of overall superiority were toilet use, stair climbing, bathing, mobility, and dressing. The psychometric properties of the 3-item and the 5-item versions included internal consistency (Cronbach's alpha coefficients 0.72 and 0.84), intraclass correlation coefficient (0.72 (95%CI 0.60-0.80) and 0.74 (95%CI 0.61-0.83), and responsiveness to change (effect size 0.69 and 0.52), respectively. The 5-item version showed higher internal consistency, while the 3-item version had superior responsiveness to change.

Conclusions: We recommend the use of the 3-item version as a screening tool for detecting functional changes in older adults undergoing abdominal surgery because of its superior responsiveness to change. Additionally, it requires less assessment time and is more practical for use in clinical practice.

Keywords: geriatrics, Barthel index, abdominal surgery, short-form Barthel Index

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Introduction

As Thailand transitions toward an aging society, the proportion of patients undergoing surgery consists increasingly of older adults. Older patients are more vulnerable to functional decline and are slower to recover after surgery. Following abdominal surgery, some older patients lose their independence, can no longer engage in self-care activities[1] and require rehabilitation training or post-acute care to regain their previous level of function.[2,3]

Various tools are used to assess patients' abilities in performing self-care tasks. The Barthel index, which assesses ten areas of performance in activities of daily living (ADL), is one of the best known and most widely used tools, including used by older patients.[4-6] In theory, different illnesses can negatively affect patients differently. For example, a study of intensive care unit patients found that the abilities that underwent the most significant decline after an operation were stair climbing, walking, and toilet use.[7] The most degraded abilities in patients following surgery for bone and muscle tumors included stair climbing, walking, and bathing.[8] Numerous studies have investigated the functional decline of older adults undergoing surgery[1,9-16] but most have reported functional decline as a total score without specifying which aspects of ADL were most affected.[9,11-13,15,16] The present study investigated in which of the ten areas in the Barthel index older patients saw a decline or loss after abdominal surgery.

After identifying the most affected items, the short-form versions of the Barthel index were developed. The short-form versions are more practical for use in clinical practice, are less time-consuming, and enhance patient cooperation in answering questions. Previous short-form versions of the Barthel index developed for use with patients with neurological diseases have reported good consistency[17] and responsiveness to change,[18] results similar to the original 10-item Barthel index.

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The present study aimed to identify the items of the Barthel index that showed a decline or loss after undergoing abdominal surgery, to develop short-form versions of the Barthel index and to examine the psychometric properties of those versions.

Materials and methods

Study design

This study was a retrospective chart review. The protocol for this study was approved by the Siriraj Institutional Review Board (SIRB) (COA no. SI 654/2021) and conforms to the ethical principles in the Helsinki Declaration of 1964 and subsequent amendments.

Participants

All patient data were obtained from electronic medical records in the database of the Siriraj Integrated Perioperative Geriatric Excellent Research Center (SiPG), a multidisciplinary research group at Siriraj Hospital, Mahidol University. Records of older patients (age ≥ 60) enrolled in SiPG studies from January 2017 through August 2021 were reviewed. To be eligible for inclusion in this study, participants had to be aged 60 or over (male or female), have undergone elective abdominal surgery (except gastrostomy or jejunostomy), and had to have Barthel index assessments both prior to and at four weeks after surgery. Patients with severe dementia (Thai mental state examination (TMSE) ≤ 10[19]); severe depression (Thai version PHQ-9 assessment[20] ≥ 19[21]); a pre-operative Barthel index score of less than 10, incomplete data in the Barthel index pre- or post-surgery; orthopedic or neurologic conditions interfering with activities of daily living (such as paralysis or amputation); and those not having recovered from a coma and/or who were unable to communicate were excluded due to possible negative impact on ADL performance.

Measures used in the study

1. The Thai version of the Barthel index (score range: 0-100)

The Barthel index is an assessment tool used to evaluate patients' ability to help themselves in everyday activities. It is divided into ten basic tasks, each rated according to the level of help required.[22] The Barthel index assessment is widely used with older adults,[4-6,23] and has demonstrated acceptable reliability and good responsiveness.[23] A study of the Thai version of the Barthel index among older patients with hip fractures was found to have good accuracy and reliability.[24] In the present study, Barthel index scores were obtained via a face-to-face interviews pre-operatively and by phone interviews conducted by research coordinators four weeks post-surgery. The telephone interviews had excellent agreement with the face-to-face interviews (report weighted k = 0.9).[25]

2. The Thai mental state examination (TMSE)[26]

The TMSE is the Thai version of the Mini-Mental Status Examination (MMSE). The TMSE has been used extensively in the Thai population to screen for cognitive impairment and dementia. However, as dementia can negatively affect an older person's ability to help themselves and because the Barthel index may not accurately represent the abilities of patients with severe dementia,[28,29] the present study excluded older adults with severe dementia (TMSE ≤ 10).[27]

3. The Thai version of the Patient Health Questionnaire (PHQ-9)[20]

The PHQ-9 is used to screen for and classify the severity of depression. When used with older adults, the PHQ-9 can detect depression with results that are close to the 15-item Geriatric depression scale.[30] PHQ-9 scores range from 0 to 27. According to criteria set by the Department of Mental Health, Thailand, classifies depression as severe when the PHQ-9 score is ≥ 19.[21] The influence of depression on ADL ability in older adults has been found to be harmful when the depression was severe,[31] while the impact was less apparent when the degree of depression was unclassified.[32] Accordingly, older adults with a severe degree of depression were excluded from the study.

4. The Thai version of the EuroQOL-5D-5L Questionnaire

The EuroQOL-5D-5L Questionnaire, used to assess quality of life, is divided into two parts. The first part, the EQ-5D descriptive system, assesses perceived problems in five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The score of this section is reported as the EQ-5D-5L utility score (EQ-US). Scoring of this section was derived from an evaluation study of a set of the Thai population.[33] The second part, the EQ visual analog scale (EQ VAS), assesses a patient's overall health, and has a score range of 0-100.

Barthel index scores were recorded for 10 items pre-surgery and again four-weeks post-surgery. PHQ-9, TMSE and EuroQOL scores were recorded only before surgery. Other information collected included general baseline characteristics, type of surgery, and length of hospital stay.

Development of short-form versions of the Barthel index

The method used to develop the short-form version followed the procedure for developing an index for stroke patients used in a study by Hobart and Thompson.[17] The process of identifying items to be included in the short-form was as follows:

1. Find corrected item-total correlations

Corrected item-total correlations are the correlations between the item of interest and other items in the scale. For example, the corrected item-total correlation of "feeding" is the correlation between a "feeding" score and the sum of scores of nine other items. The items of interest, e.g., feeding, were excluded to ensure the correlations were unbiased. The cor-

relations were computed using inter-item correlation reliability analysis. A high correlation indicates that the item correlates well with the construct measured by the Barthel index.

2. *Find the effect sizes of each item*

An effect size is a standardized change score which can be calculated from a mean change score per standard deviation (SD) of scores before and after surgery. A paired t-test was used to calculate the mean change score. A large effect size indicates good sensitivity to the responsiveness to change.

$$\text{Effect size} = \frac{\text{mean change score}}{\text{SD of a score before surgery}}$$

3. *Find the index of overall item superiority*

To develop an index of overall item superiority, values of corrected item-total correlations and effect sizes were arranged in descending order, with items with the highest value ranked first (a high corrected item-total correlation indicates a good correlation, and a high effect size represents good responsiveness). Then, cross-products of rank numbers of corrected item-total correlations and effect sizes of each item were calculated to create an index of overall item superiority. The cross-product with lower numbers indicates better items, so the lowest items were selected to be included in the short-form Barthel index.

Statistical methods

Data analysis was performed using the PASW Statistics version 18 for Windows (SPSS, Inc., Chicago, IL, USA).[34] Demographic and clinical data are presented as descriptive statistics. Categorical data are shown as numbers and percentages. Continuous data that were normally distributed are given as mean ± standard deviation, and those that were non-normally distributed are given as median and range. A paired t-test was used to calculate mean differences between pre-and post-surgery; results are presented with 95%CI. Categorical data were analyzed with a chi-square test. As changes in the Barthel index score can differ among the three types of surgery, the number of patients with negative score changes in each of the three surgery types was compared using the Fisher's Exact Test.

Because the total score of the original versions and the developed short-form versions differed, each form's total score needed to be equalized to enable direct comparisons among the tests. For that reason, the scores from all versions were re-calculated to have a maximum score of 20 using the formula;

$$\text{Transformed score} = \frac{\text{actual score X 20}}{\text{maximum possible score}}$$

To evaluate the psychometric properties of the newly developed short-form, internal consistency, representing reliability, was analyzed using Cronbach's alpha coefficients. An analysis of agreement between the short-form and the original version was conducted using the intraclass correlation coefficient (ICC). EQ-5D utility and VAS scores were chosen as a reference to find convergent validities. Pearson's correlation coefficient or Spearman's correlation coefficient were used to finding convergent validities, depending on the normality of data distribution. The ability of each form to respond to changes over time was determined by calculating mean differences between pre-and post-surgery using a paired t-test. Effect sizes and standardized response means were also calculated. Effect size is the mean difference divided by the standard deviation of Barthel index scores pre-surgery.[35] The standardized response mean is mean differences divided by the standard deviation of change scores. Results were considered statistically significant if the $p < 0.05$.

Results

The database of Siriraj Integrated Perioperative Geriatric Excellent Research Center (SiPG) registry during the study period included 1,523 older patients. Of those patients, 563 were scheduled for elective abdominal surgery, and 96 of those met the criteria and were included in the study.

The mean age of the participants was 70, and nearly two-thirds were male. Hypertension, musculoskeletal pain, dyslipidemia, and diabetes were the most prevalent co-morbidities. Most participants who screened positive for depres-

Table 1. Demographic and health characteristics of participants (N=96)

Characteristics	
Age (years), mean±SD	70.2±6.7
Female gender, n (%)	34 (35)
Co-morbidities*, n (%)	
Hypertension	63 (66)
Musculoskeletal pain (either at the hip or knee)	36 (38)
Dyslipidemia	34 (35)
Diabetes	29 (30)
Cardiac diseases	13 (14)
Previous stroke	7 (7)
CKD stage 4 or 5	3 (3)
Deep vein thrombosis	1 (1)
Other underlying diseases	39 (41)
No underlying diseases	2 (2)
ASA classification, n (%)	
2	60 (62)
3	36 (38)
Type of operation, n (%)	
Upper abdominal surgery	33 (34)
Lower abdominal surgery	28 (29)
Urological surgery	35 (37)
Length of stay (days), median (IQR**)	7 (5-11)
Pre-admission PHQ9 score, mean±SD	3.59±3.56
Score < 7, n (%)	81 (84)
Score 7-12, n (%)	12 (13)
Score 13-18, n (%)	3 (3)
EQ-5Dutility, mean±SD	0.87±0.15
EQ-5DVAS, mean±SD	71.27±16.17

CKD, Chronic kidney disease; ASA, The American Society of Anesthesiologists (ASA) physical status classification; SD, standard deviation
*No patients had pre-existing illnesses of dementia, asthma, or COPD
**IQR, interquartile range

sion were in the mild severity category. The health characteristics of participants are presented in Table 1.

Elective abdominal operations were classified into three main categories: upper abdominal surgery, lower abdominal surgery, and urological surgery; 34%, 29%, and 37% of patients, respectively, underwent each type of surgery which was not statistically significantly different. Of the upper abdominal surgeries, 82% (27/33) were hepatobiliary surgery. Other upper abdominal surgeries included pancreatic (3%, 3/33), small intestine (2%, 2/33), and gastric surgery (1%, 1/33). All patients who underwent lower abdominal surgery had colorectal surgery. Urological surgery operations included bladder (40%, 14/35), prostate (31%, 11/35), renal (26%, 9/35), and adrenal surgery (3%, 1/35).

The mean Barthel index score before surgery was 92.8, but it declined to 87.6 by four weeks post-surgery. The mean negative score change was -5.2 (95% CI -7.4 to -3.0, $p < 0.001$). Categorizing scores according to the degree of dependency[36] found the percentage of independent older patients (BI = 100) fell from 54.2% to 33.2%. Of the ten dependency items, those with statistically significant negative mean changes, in descending order, were stair climbing, bladder, toilet use, mobility, and bathing (Table 2).

As the type of surgery can influence changes in Barthel index scores, a comparison of the three types of surgeries was performed. When considering the total Barthel index score, the number of patients with negative score changes was predominant in urological operations (statistical significance $p = 0.006$). Each of the ten items was analyzed separately. The number of patients with negative score changes was similar or minimally different, but not statistically significant ($p > 0.05$) for all items except the bladder which statistically significantly worsened following urological operations ($p = 0.001$). Details of the urological surgeries were then explored. Among the 15 cases with bladder problems, six had undergone ileal conduit surgery, seven had received prostatectomy, and one had received a radical cystoprostatectomy with ileoneobladder, all of which can disrupt bladder function. After removing bladder operations from total Barthel index scores, there was little difference among the three categories of surgery ($p = 0.89$). Thus, the impact of surgery on the functional decline of each item could be considered equivalent.

The next step was to identify items to be included in the short-form. Corrected item-total correlations and effect sizes of each item were calculated and ranked as described in the method section. Then the cross-products were used to develop an index of overall item superiority (Table 3). Items with the lowest values in the index of overall item superiority were incorporated into the 3-item and the 5-item versions of the Barthel index. Both the 3-item and 5-item versions included toilet use, stair climbing, and bathing, while the 5-item version included two additional items: mobility and dressing. The scores of the fourth and fifth items were nearly identical, so the 4-item version was not studied.

Table 2. Barthel index scores at pre-surgery and four weeks post-surgery

Items in the BI (score range)	Pre-surgery mean±SD	Four weeks post-surgery mean±SD	Mean difference (95%CI)	*p*-value
Total BI score (0-100)	92.8±11.1	87.6±16.4	-5.2 (-7.4, -3.0)	< 0.001*
Toilet use (0-10)	9.8±0.9	9.2±2.4	-0.6 (-1.0, -0.2)	0.002*
Stair climbing (0-10)	9.3±2.5	7.6±4.2	-1.7 (-2.5, -0.9)	< 0.001*
Bathing (0-5)	4.7±1.1	4.3±1.7	-0.4 (-0.7, -0.1)	0.01*
Mobility (0-15)	14.3±2.4	13.8±3.5	-0.5 (-1.0, 0.0)	0.049*
Dressing (0-10)	9.8±1.0	9.6±1.3	-0.2 (-0.3, 0.0)	0.08
Bladder (0-10)	7.3±4.0	6.3±4.6	-1.1 (-2.0, -0.2)	0.02*
Feeding (0-10)	9.9±0.7	9.7±1.3	-0.2 (-0.4, 0.1)	0.26
Transfer (0-15)	14.6±1.9	14.5±2.1	-0.1 (-0.4, 0.2)	0.48
Grooming (0-5)	5.0±0.5	4.9±0.7	-0.1 (-0.2, 0.1)	0.32
Bowels (0-10)	8.0±3.7	7.6±4.0	-0.4 (-1.0, 0.2)	0.24

[a]Paired t-test, *$p < 0.05$

BI, Barthel index

Table 3. Analysis of the Barthel index score in the development of the short-form

BI items	Item-total correlations[a]		Effect size[b]		Overall item superiority	
	Value	Ranking	Value	Ranking	Value	Ranking
Toilet use	0.62	2	0.71	1	2	1.5
Stair climbing	0.63	1	0.66	2	2	1.5
Bathing	0.49	5	0.37	3	15	3
Mobility	0.51	4	0.22	5	20	4
Dressing	0.58	3	0.16	7	21	5
Bladder	0.24	10	0.27	4	40	6
Feeding	0.34	7	0.22	6	42	7
Transfer	0.43	6	0.06	10	60	8
Grooming	0.26	8	0.10	8	64	9
Bowels	0.25	9	0.10	9	81	10

The pattern of this table is from "The five-item Barthel index" in a study of Hobart and Thompson[9]
[a]Inter-item correlation reliability analysis, [b]mean difference divided by a standard deviation of Barthel index scores pre-surgery
BI, Barthel index

Table 4. Psychometric properties of the short-forms and the original Barthel index

	Pre-BI	Post-BI	Mean difference[a] (95%CI)	*p*-value	α[b]	ICC[c] (95%CI)	Convergent validity[d] EQ-5D$_{utility,}$ ρ	Convergent validity[d] EQ-5D$_{VAS,}$ ρ	Effect sizes[e]	SRM[f]
10-item BI (0-20)	18.6±2.2	17.5±3.3	-1.0 (-1.5, -0.6)	<0.001	0.67	-	0.25 (P=.01)	0.24 (P=.02)	-0.45	-0.48
5-item BI (0-20)	19.2±2.7	17.8±4.5	-1.4 (-2.0, -0.7)	<0.001	0.84	0.74 (0.61, 0.83)	0.26 (P=.01)	0.26 (P=.01)	-0.52	-0.41
3-item BI (0-20)	19.1±3.2	16.9±5.8	-2.2 (-3.1, -1.2)	<0.001	0.72	0.72 (0.60, 0.80)	0.19 (P=.06)	0.22 (P=.03)	-0.69	-0.46

[a]Paired t-test, [b]Cronbach's Alpha coefficients, [c]Intraclass correlation coefficient, [d]Spearman's rank correlation, [e]mean difference divided by a standard deviation of Barthel index scores pre-surgery, [f]mean differences divided by the standard deviation of change scores
BI, Barthel index; SRM, standardized response means

Psychometric properties of the short-form versions of the Barthel index

1. Internal consistency

The 10-item, 5-item, and 3-item Barthel indexes had Cronbach's alpha coefficients of 0.67, 0.84, and 0.72, respectively. Internal consistency of both short forms was superior to the original version, and both exceeded 0.70, which is considered acceptable.[37] This finding indicates that items in the short form version appear to be interrelated and hence, can measure the same constructs.

2. Intraclass correlation coefficient (ICC)

Agreement between the short-form and the original 10-item Barthel index version was analyzed using intraclass correlation coefficients. The ICCs of the 5-item version and the 3-item version are 0.74 (95%CI 0.61-0.83) and 0.72 (95%CI 0.60-0.80), respectively, which is a moderate degree of agreement (0.5-0.75).[38]

3. Convergent validity

Convergent validities of the Barthel index were determined by calculating correlations between EQ-5D-5L utility scores and VAS scores using Spearman's correlation coefficient as the data was distributed non-normally. The degree of correlation was interpreted as: < 0.3 = weak, 0.3-0.5 = fair, 0.6-0.8 = moderately strong, and ≥ 0.8 = strong.[39] All obtained correlation scores were within the range of 0.2-0.3, which is considered to indicate weak or negligible correlation.[40,41]

4. Responsiveness to change[35]

The degree of responsiveness to change was determined by calculating mean differences between pre-and post-surgery, effect sizes, and standardized response means (SRM). Effect sizes are mean differences divided by standard deviations of baseline scores, while SRMs are mean differences divided by standard deviations of change scores. Larger values reflect superior responsiveness. Both effect sizes and SRM were interpreted following Cohen: ≤ 0.2 = small, 0.5 = moderate, and ≥ 0.8 = large.[35,42] Effect sizes of both the short-forms were in the moderate range (effect size > 0.50).[35] The 3-item version had the largest effect size among the three versions (Table 4).

Discussion

We found that older adults showed a statistically significant decline in ADL four weeks after surgery compared to baseline. The most substantial drops were in stair climbing, bladder control, toilet use, mobility, and bathing. After statistically analysing the data, items with the best ranking in an index of overall superiority were identified and included in

the short-form, including toilet use, stair climbing, bathing, mobility, and dressing. In terms of psychometric properties, both short-form versions demonstrated acceptable internal consistency, moderate agreement with the original version, and moderate responsiveness to change. However, both versions had weak convergent validities towards the quality-of-life score, similar to the original version.

Older people are at greater risk of physical deterioration and loss of functional independence after major surgery. The results of this study are in line with a study by Lawrence et al. which reported the largest drop in ADL summary scores occurring in the first week and continuing to decline approximately six weeks after surgery.[1] Older patients undergoing different surgeries/with different illnesses may lose the ability to perform different ADLs. The items with significant drops identified in this study were also commonly found in other conditions as well. Of the five items included in the short form, patients admitted to the intensive care unit were found to lose all five abilities.[7] In patients with acute medical illnesses, with the exception of stair climbing which was not included in the ADL assessment, the other four items were negatively affected.[43] In addition, after musculoskeletal tumor surgery patients showed a loss of ability to help themselves in mobility, bathing, and stair climbing.[8]

Internal consistency of both the short-forms exceeded the acceptable value and were superior to the original version. Items included in the short-form, particularly the first three items (toilet use, stair climbing, and bathing), require physical movement, may be proscribed after major abdominal surgery or profound deconditioning. This could help explain the higher degree of internal consistency of the short-form versions.

Agreement between the short-forms (5-item and 3-item) and the original version as measured by ICCs was moderate. The lower degree of agreement in this study could be due to the mean scores of the 10-item Barthel index being significantly lower than the 5-item and 3-item Barthel index ($p < 0.001$ and $p < 0.001$). In addition, the bowel and bladder function scores were relatively low, neither of which were included in the short-form versions, resulting in a significant mean difference between the original and the short-form and a lower ICC.

Convergent validities between the Barthel index and EQ-5D-5L scores were low or negligible (ρ 0.25, $p = 0.01$ for 10-item BI; ρ 0.26, $p = 0.01$ for 5-item BI; ρ 0.19, $p = 0.06$ for 3-item BI). Correlations between the Barthel index scores and EQ-VAS scores in older patients with hip fractures (r-value 0.28, $p < 0.001$)[44] and stroke patients (ρ 0.24, $p < 0.001$)[45] were also weak. The low correlation could result from the fact that the two tests do not measure the same aspects. While the Barthel index evaluates only physical functions, the EQ-5D-5L measures multiple domains, including physical functions (mobility, self-care, usual activities), anxiety/depression, and pain/discomfort. Anxiety/depression and pain/discomfort in the EQ-5D-5L were found to have a lower correlation to the Barthel index than domains related to physical function in reports of studies of stroke and older adult patients.[46,47] Eighty-six percent (83/98) of the study's participants were pre-operatively diagnosed with malignancy which may have affected patients' anxiety/depression and pain/discomfort scores, items not assessed in the Barthel index, resulting in lower convergent validities.

Responsiveness to change is defined as the ability of a test to detect changes over time. Effect sizes and standardized response means are both commonly used to statistically report the level of responsiveness to change. The responsiveness of the Barthel index has been investigated in various disease populations such as multiple sclerosis (effect size = 0.37),[48] stroke (effect size = 0.95),[48] and older patients with hip fractures (effect size = 2.13).[44] The responsiveness of that instrument might vary depending on the diseases being investigated. Effect sizes of the Barthel index were found to be more prominent in stroke patients than in multiple sclerosis patients.[48] However, the present study is the first to report the effect sizes of the Barthel index in older adults after abdominal surgery. Of the three versions, the 3-item version has the largest effect size, which is considered moderate (effect size = 0.69), and has an SRM value comparable to the original version, indicating that the 3-item version is the most responsive.

Assessing the ability to perform ADLs of older patients before and after surgery allows healthcare personnel to detect lost functions, provide treatment, and restore patients to a self-supporting state. In assessing patients, a concise assessment tool should be used in practice.

Assessing older patients' ability to perform ADLs before and after surgery assists healthcare personnel to detect lost functions, to provide appropriate treatment, and help restore patients to a self-supporting state. This study found that both the 5-item and the 3-item version can help in that regard. This study found that the 5-item version has higher internal consistency, while the 3-item version has superior responsiveness to change. Both versions have a comparable agreement with the original version.

In the effort to develop a shorter and more practicable assessment tool that could be used in older patients undergoing elective abdominal surgery, the new short form has some limitations. First, the short-form might only be applicable to older adults with near or total independence in self-care activities pre-operation as our mean Barthel index score was high. Second, the convergent validity of the Barthel index should be investigated using other measurements in addition to the EQ-5D-5L as it assesses multiple domains rather than just physical functions. Additionally, a prospective study investigating the practicability of the 3-item Barthel index and evaluating its psychometric properties in actual practice is needed.

Conclusion

We recommend the use of the 3-item Barthel index as a screening tool for detecting functional changes in older adults undergoing abdominal surgery because of its superior responsiveness to change. In addition, the short version requires less assessment time and is less of a burden on patients, making it more suitable for clinical use.

Disclosure

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Original Article

Feasibility and Effect of Gait Training with Assistance from a Motorized Wheelchair with Built-In Bodyweight Support Frame on the Balance and Walking Ability of Elderly Individuals with a Risk of Falling

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ABSTRACT

Objectives: To study the feasibility and effect of gait training with assistance from a motorized wheelchair with a built-in body-weight support frame (MW-BWSF) on the balance and walking ability of elderly individuals with a risk of falling.
Study design: Experimental study.
Setting: Rehabilitation clinic, Department of Rehabilitation, Songkhla Hospital, Thailand.
Subjects: Elderly individuals aged 60 years or older at rehabilitation clinic, Songkhla hospital between March 2022 and February 2023.
Methods: This experimental trial involved elderly individuals aged 60 years or older with minimal leg muscle weakness or who were at risk of falling. The participants were trained with assistance from the MW-BWSF for eight sessions over four weeks. Gait speed, step length, Time Up and Go Test (TUGT), and Berg Balance Scale (BBS) were assessed three times: before the start of the program, at the end of the fourth training session, and the end of the eighth training session.
Results: A total of 22 elderly individuals participated in the study. The gait training with the MW-BWSF showed a statistically significant improvement in gait speed, step length, TUGT, and BBS score after the eight sessions. The total distance walked during training also increased significantly. The participants reported high satisfaction with the device and with the training method.
Conclusions: The study demonstrated the feasibility and effectiveness of gait training with assistance from the MW-BWSF in improving the balance and walking ability of elderly individuals with a risk of falling. This innovative technology has the potential for use as an assistive device for training at home which would also reduce the burden on public healthcare.

Keywords: elderly, risk of falling, leg weakness, motorized wheelchairs

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Introduction

In 2005, Thailand became an aging society and progressed to a complete-aged society in 2022, with an expected transition to a super-aged society by 2033. Elderly individuals often face gait impairment and balance deficit due to age-related changes and illnesses such as stroke and osteoarthritis.[1,2] These impairments increase the risk of falls and fall-related injuries,[3] and are expected to become an increasingly significant burden on public healthcare in the next decade.

Various techniques have been developed to improve balance and reduce falls, with gait and balance training being one of the proven methods.[4-12] Meta analysis has found that the average effectiveness of fall prevention is approximately 30%. Body weight-supported treadmill training (BWSTT) is one of the more effective methods,[13,14] and has been reported to reduce fall rates between 70-90%, likely due to the continuous stepping practice at different speeds and directions during training.

However, BWSTT requires a supervising person to adjust the treadmill speed and amount of bodyweight support, making it difficult for elderly individuals to train independently at home. In response to this need, a novel motorized wheelchair with a built-in bodyweight support frame (MW-BWSF) was invented by Mr. Somkid Somnugpong from the Welding Department of Kamphaengphet Technical College.

The MW-BWSF has two motorized back wheels and allows users to select the direction and speed of the device by manipulating a joystick located at the distal end of the right armrest. Push buttons are provided for adjusting the height of the built-in body weight supporting frame. The mechanical design allows the device to safely support patients with a body weight of up to 100 kilograms. The seat of the wheelchair automatically retracts as the bodyweight supporting frame rises, allowing patients to practice stepping without hitting their legs on the wheelchair seat. When the supporting frame is lowered, the wheelchair seat returns to its normal position, allowing the user to sit safely.

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Movement of the wheelchair along the ground when the steering joystick is not being manipulated. Similarly, adjustment of the weight support height stops automatically when the height adjustment buttons are not being pressed. This innovation was granted a petty patent in 2020. A pilot test conducted with ten healthy adult volunteers weighing 50-100 kg showed good usability with no unexpected risks.

This research was conducted to study the feasibility and effect of gait training with assistance from a MW-BWSF on the balance and walking ability of elderly persons with a risk of falling.

Method

Study design

This experimental trial was approved by the Human Research Ethics Committee of Songkhla Hospital (approval number SKH IRB 2020-MD-IN3-05008).

Participants

The study included elderly individuals aged 60 years or older with minimal weakness of leg muscles (manual muscle testing grade 4-5) with a risk of falling. The research was conducted at the rehabilitation clinic, Department of Rehabilitation, Songkhla Hospital, Thailand. The sample size was calculated based on data from a previous study that examined the effect of partial body weight support treadmill training on the improvement of walking and balance in elderly individuals living in elderly community-dwellers.[13] The mean score on the Berg balance scale Alpha was 0.05 and Beta was 0.20. All values were entered into the formula, giving in a calculated sample size of 22 people.

Inclusion criteria

1. Persons 60 years or older with no history of recent injury or sickness requiring in-patient admission within a month before the study.
2. Minimal weakness of leg muscles (manual muscle testing grade 4-5), or subjectively reported unsteadiness when standing or walking, having worries about falling, or having a history of falling in the last year.
3. Able to walk at least 10 meters (with or without walking aids).
4. Adequate cognitive function and hand dexterity to operate the MW-BWSF correctly.

Exclusion criteria

1. Severe joint contracture of the lower extremities prohibiting an upright standing body position.
2. Heart failure, myocardial infarction, arrhythmia, or any unstable medical condition that makes active low-intensity exercise not possible.

The intervention

A physiotherapist and a physiatrist at Songkhla Hospital carried out the training. All participants were trained under their supervision for eight sessions over four weeks.

The bodyweight supporting harness was put on the participants and secured to the bodyweight support frame. The supervisor then instructed the subjects to adjust the height of the body weight support frame to determine the appropriate position. Getting the machine ready to use required an average of 5 minutes. Subjects were then asked to practice walking straight 10-meter laps, with a U-turn at the end of each lap. The speed and direction of walking was determined by the subject using the joystick. The aim was for the subject to walk continuously for approximately 10 minutes, followed by a 3-minute rest, and then to repeat the process until 30 minutes of walking time had elapsed. Additional rest breaks were allowed as frequently as needed.

Outcome measurements

Gait speed, step length, Time Up and Go Test (TUGT), and Berg Balance Scale (BBS) were assessed three times: before the start of the training program, at the end of the fourth training session, and at the end of the eighth training session. The total distance walked was measured at each training session. Global satisfaction with the device and training method was evaluated using the Treatment Satisfaction

Figure 1. The device in sitting position.

Figure 2. The device in the standing position

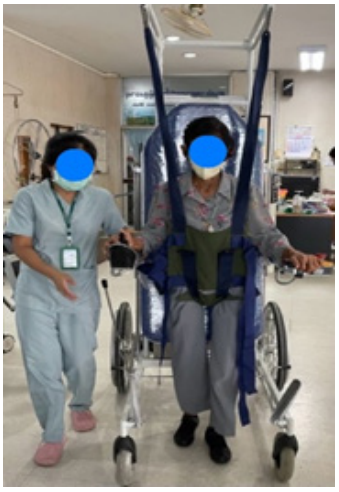

Figure 3. The device during training.

Questionnaire for Medication and a 1 to 5 Likert scale at the end of the final training session. The amount of bodyweight support during training was recorded. Participants were also invited to provide open comments about their training experience and any changes they experienced due to the training.

When the body weight support strap appeared slack and participants did not feel the vertical supporting force, the amount of body weight support was recorded as "no support." When the bodyweight support strap was not slack and participants felt a vertical supporting force, the amount of body weight support was recorded as "partial support."

Data were analyzed using IBM SPSS Statistics 21 and Epi-Info 7.2 software. Demographic information, gait speed, step length, BBS, TUGT, and walking distance during each session were recorded and analyzed. In addition, changes in gait speed, step length, BBS, TUGT, and walking distance before training and at the end of the fourth and eighth sessions was analyzed using the Wilcoxon Signed Ranks Test.

Results

Between March 1, 2022 and February 28, 2023, the training program was conducted with 22 participants, 18 females and 4 males. One participant withdrew from the study after a short test run, stating that wearing the harness was "uncomfortable and restraining," and that the participant expected they might not be able to tolerate continuous use of the device for 30 minutes. The participant denied any pain or injurious sensation.

The mean age of the participants was 76.22±7.17 years, the mean weight was 60.95±10.10 kg, and the mean height was 155.22±8.89 cm. Prior to the training, all participants reported feeling unsteady when standing or walking and had concerns about falling. Five participants had a history of one or more falls in the past year. Three participants had motor power grade 4, and all were ambulatory with the support of a walker frame.

Statistically significant improvements were observed in gait speed, step length, TUGT, and BBS at the end of the fourth and eighth training sessions compared to before the program ($p < 0.001$). The study also showed statistically significant increases in total walking distance after the fourth and eighth sessions compared to the first session ($p < 0.001$). Before the study, three participants ambulated with a walker, and three used a one-point cane. At the end of the study, three people ambulated with a walker, and one used a one-point cane.

Table 1. Baseline characteristics of the population

	Population (N = 22)
Sex[1]	
Male	4 (18.18)
Female	18 (81.82)
Age (yrs)[1] (Mean 76.22)	
60-69	3 (13.64)
70-79	12 (54.53)
> 80	7 (31.83)
Body weight (ks)[1] (Mean 60.95)	
40-49	4 (18.18)
50-59	4 (18.18)
60-69	10 (45.46)
> 70	4 (18.18)
Height (cms)[1] (Mean 155.22)	
140-149	5 (22.73)
150-159	12 (54.53)
160-169	3 (13.64)
> 170	2 (9.10)

[1]Number (%)

Regarding partial weight support during walking training, 14 individuals needed bodyweight support, while the rest walked with "no bodyweight support" after the completion of the first training session. At the eighth session, only 11 subjects needed to be assisted with some partial bodyweight support while walking.

The participants in the study gave the training an average satisfaction score of 4.36±0.58 points on a scale of 1-5. In addition, all participants reported increased walking confidence and felt they could walk faster and longer distances than before the training.

Discussion

The assessment tools used in this study, including TUGT, BBS, and temporal-spatial gait parameter assessment, have been validated and demonstrated to be reliable, supporting the validity and reliability of the findings.[16]

The subjects in this study included individuals of different ages and body weights, comparable to the typical elderly population commonly found in geriatric clinics and community health centers.

Table 2. Gait speed, step length, TUGT, BBS, and walking distance before training and after 4 and 8 training sessions

	Before train-ing	After training 4 sessions mean±SD	*p*-value	After training 8 sessions mean±SD	*p*-value
Gait speed[1] (km/hr)	2.06 (0.95)	2.36 (0.95)	< 0.001[a]	2.56 (0.94)	< 0.001[a]
Step length[1] (centimeters)	40.24 (10.94)	43.31 (11.25)	0.010[a]	46.56 (14.44)	< 0.001[a]
TUGT[1] (seconds)	25.50 (31.90)	19.86 (19.79)	< 0.00[1a]	15.72 (13.38)	< 0.001[a]
BBS[1]	40.09 (12.07)	42.86 (12.08)	< 0.001[a]	45.31 (11.46)	< 0.001[a]
Walking distance in each session[1] (meters)	232.36 (103.79)	343.54 (125.25)	< 0.001[a]	418.90 (91.76)	< 0.001[a]

[1]Mean (SD); Wilcoxon Signed Ranks Test, TGUT, Time Up and Go Test, BBS, Berg Balance Scale, [a]Statistically significant

The findings of this study are consistent with previous research by Dr. Wongphaet, which showed that partial body weight support gait training can improve walking ability and balance. While previous studies reported results after training periods of 4 weeks or longer, this study found significant improvement after only 2 weeks, suggesting more rapid improvement in gait and balance is possible than has been reported in previous studies. None of the subjects who completed the training complained of any discomfort or side effects of training using the device. The two subjects who had used a single cane prior to the training used were able to walk confidently without any gait aid and reported feeling "stronger" and "having more confidence" in walking. The three subjects who had used a walker prior to the training used were not able to walk without a walker.

Even though the inclusion criteria and training protocol in this study differ in some respects from the study by Dr. Wongphaet, they share several important features, such as the use of subjective fear of falling and history of falls as inclusion criteria and high repetition gait training with "as little as possible" bodyweight support and "as fast as possible" walking training speed. The inclusion criteria for lower extremity muscle weakness selected for this study were chosen because of the Thai Ministry of Health (MOPH) announcement that leg weakness should be used as one of the criteria for identifying elderly persons at risk of falling.[17] In spite of that difference, a comparison of the results between these two studies is appropriate.

All subjects reported high satisfaction with using this device. However, the opinions of the health care personnel involved in the study have not yet been assessed, something which is essential before a new invention is accepted for clinical use.

As this was a small experimental study without a control group, further randomized controlled trials are necessary. Future research could assess changes in gait ability and balance rehabilitation with the MW-BWSF in other populations, e.g., stroke or Parkinson's disease patients.[18] Additionally it is essential that further research be conducted to determine the feasibility and effectiveness of using this type of device at home, as use during in-hospital training may differ from home use.

Conclusions

Gait training with the help of a motorized wheelchair with a built-in bodyweight support frame (MW-BWSF) can significantly improve gait abilities and balance in elderly individuals with minimal leg muscle weakness or who are at risk of falling. Statistically significant improvement can be achieved after as few as four training sessions.

Disclosure

The authors declare no conflicts of interest related to the device used in this study.

Acknowledgments

The device used in this research is an innovation of Mr. Somkid Somnugpong of the Welding Department of Kamphaengphet Technical College. It was registered as a petty patent with the Department of Intellectual Property on January 7, 2020.

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Original Article

Cost-Effectiveness of Intensive Intermediate Care Rehabilitation for Stroke Patients in Nopparat Rajathanee Hospital: A Retrospective Observational Study

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ABSTRACT

Objectives: To study the cost-effectiveness of intensive intermediate care rehabilitation using direct cost and effectiveness for inpatient and outpatient stroke patients in Nopparat Rajathanee Hospital.

Study design: Retrospective observational study.

Setting: The rehabilitation and stroke units, Nopparat Rajathanee Hospital, Bangkok, Thailand.

Subjects: Intensive intermediate care rehabilitation stroke patients during October 2021 - September 2022.

Methods: Demographic data, Barthel index at admission (BIA), and Barthel index at discharge (BID) were obtained from medical records. BI gain (BID-BIA) and percentage of rehabilitation effectiveness ((BID-BIA)/(BI max-BIA) x 100) were calculated. In addition, capital cost, labor cost, and materials cost of health care providers were determined.

Results: Thirty-four stroke patients were recruited into this study: 52.9% were males, 90.9% had an ischemic stroke, and the mean age was 56 years (SD 13.71). At discharge, the average BI had increased significantly over the value at admission ($p < 0.05$), with a mean BI gain of 5.09 (SD 2.30) in inpatient rehabilitation and 4.77 (SD 2.26) in outpatient rehabilitation. The mean rehabilitation effectiveness percentage was 47.4 in inpatient rehabilitation and 53.0 in outpatient rehabilitation. The average direct cost of inpatient rehabilitation was 21,000 THB (600 USD)/person/admission or 1,500 THB (43 USD)/day. The average direct cost of outpatient rehabilitation was 399 THB (11 USD)/person/day. The average direct cost per 1 point improvement in the Barthel index was 4,127 THB (118 USD) in inpatient and 1,171 THB (33 USD) in outpatient rehabilitation

Conclusions: Intensive intermediate care rehabilitation for stroke patients in Nopparat Rajathanee Hospital statistically significantly improved BI scores. Rehabilitation effectiveness in this study was close to the results in a previous study. The direct cost of inpatient and outpatient stroke rehabilitation in Nopparat Rajathanee Hospital should continue to be used to determine cost-effectiveness.

Keywords: Barthel index, cost-effectiveness, rehabilitation, stroke

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Introduction

Stroke is a major public health problem in Thailand. The National Health Security Office reported a new case incidence of 328 per 100,000 population in 2020, with the trend increasing yearly.[1] According to a 2017 study by the Burden of Disease Research Program Thailand (BOD Thailand), stroke was the leading cause of Disability-Adjusted Life Year (DALY) loss in females and the second leading cause in males.[2] Stroke patients also have a variety of impairments, including weakness, difficulty swallowing, as well as cognitive and communication problems, all of which are major causes of disability, including family, society, and community problems, as well as economic costs to the country.

The intermediate care (IMC) service system provides rehabilitation care for up to six months following the diagnosis of a disease. This service system is composed of multidisciplinary teams that collaborate and link healthcare facilities at all levels. Depending on their needs and readiness, patients and families will be offered various rehabilitation services, including inpatient, outpatient, community-based, and home visit services.[3] The IMC service plan is a new field of service developed by the Ministry of Public Health and is based on providing a “seamless service network” to fill the gap left by the lack of sufficient transitional care for acute care patients. Under the plan, the patients will be evaluated for admission and treated by the intermediate care services of the multidisciplinary teams. If the patient’s abilities remain inadequate for discharge after six months, he or she will be moved to long-term care. Rehabilitation aims to maximize patients’ functional ability to maintain the highest possible level of independence, improve their quality of life, and reduce the family burden.

Nopparat Rajathanee Hospital has been providing stroke IMC outpatient services since 2021. In fiscal year 2022, the hospital began intensive intermediate care in the OPD service and provided two IMC beds for stroke patients in the stroke unit intensive rehabilitation program for a period of two weeks after achieving stable medical and neurological signs without

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the need for readmission for rehabilitation. This system allows patients and their families to save energy as well as transportation costs. According to a study by Kuptniratsaikul et al., inpatient rehabilitation services have better outcomes than outpatient services, and intensive rehabilitation is the most efficient type of admission for stroke patients.[4] Salter et al. reported that patients admitted to stroke rehabilitation within 30 days of their first unilateral stroke experienced more significant functional gain and shorter lengths of stay than those admitted after 30 days.[5]

A study of intensive rehabilitation in stroke patients at Bangklam Hospital in Songkhla, Thailand, the first hospital to develop an intermediate care rehabilitation service following the Ministry of Public Health's plan, discovered that patients who were recruited into the IMC ward immediately after vital signs and neurological signs had stabilized showed a high BI gain of 0.4 points per day, with a total score of 20 points.[6] Additionally, according to Stefano Paolucci et al., starting treatment within the first 20 days is associated with a significantly higher likelihood of excellent therapeutic response. That study found a strong association between onset-admission interval (OAI) and functional outcome.[7] In this study, rehabilitation was started as early as possible.

Many studies of the economic impact of stroke have focused on short-term in-hospital care. For example, a 2017 study of the cost of acute care for ischemic stroke in Thailand reported that the average expense for acute ischemic stroke treatment per patient was 42,400 THB (1,211 USD). The hospital room and routine services accounted for most of the cost (57%), followed by imaging (23%). The average stay was 5.7 days. Rehabilitation costs were only 1.23% of the total expenses in that study.[8] However, the study was based on acute care rehabilitation costs rather than long-term care costs.

According to a 2009 multi-center study of inpatient rehabilitation services for stroke patients in Thailand, the average total cost for all treatment during rehabilitation was 28,399 THB (approximately 789 USD). The cost ratio of non-rehabilitation-related costs to rehabilitation costs was approximately 2:1. The average length of stay was 29.4 days (SD 17.9). The average number of stroke rehabilitation treatment units (1 unit of treatment = 20 minutes) was 319.5, with 205 units of nursing, 40 units of physical therapy, and 34 units of occupational therapy.[9] The total time required for rehabilitation was 24.66 hours. Thus, if the rehab is 3 hours per day, it takes only 8.2 days to complete intensive stroke rehabilitation.

This study aimed to identify cost components and to better estimate the total long-term costs of stroke rehabilitation treatment inpatient and outpatient service in Nopparat Rajathanee Hospital. The cost per unit of service is the most important information for the administrator when budgeting and managing.

Methods

Study design

The Ethics Committee of Nopparat Rajathanee Hospital approved this retrospective observational study (approval number 19/2566).

Participants

Stroke patients who were admitted to the stroke unit who met the inclusion criteria in the screening form and who were admitted to intensive intermediate care rehabilitation from October 2021 - November 2022 were recruited into the study. Inclusion criteria were onset < 6 months, stable medical and neurological conditions, BI < 15 or > 15 with more than one disability, able to follow a 2-step command, and no severe complications. All patients or immediate family members were asked for informed consent.

Data collection

Demographic and clinical data, e.g., sex, age, underlying diseases, type of stroke, Barthel index score from onset to entry into rehabilitation, and health care coverage were collected. The type of intensive rehabilitation, either inpatient or outpatient service, was determined by physiatrists, the patient's context, and the availability of beds in the stroke unit. The intensive rehabilitation program consisted of therapists' conventional physical and occupational therapies. The frequency of inpatient and outpatient rehabilitation services in the clinical practice guidelines for stroke rehabilitation published by Prasat Neurological Institute of Thailand, Ministry of Public Health, was 15 hours per week and 2-3 hours per day.[10] The standard inpatient length of stay for intensive rehabilitation in the stroke unit was two weeks, with a total rehabilitation time of 30 hours, the same as the outpatient intensive rehabilitation program.

The direct costs of rehabilitation services included capital costs, labor costs, and materials costs. The capital cost of the buildings was calculated using the straight-line method at a discount rate of 5% per year, and the capital cost of the equipment at a rate of 7%. Each factor's total cost was divided by the number of patients served by each center.

Outcome measurements

Rehabilitation effectiveness was assessed using the Barthel index gain, i.e., the difference between the Barthel index score at discharge (BID) and Barthel index score at admission (BIA) and the percentage of rehabilitation effectiveness. Percentage of rehabilitation effectiveness was calculated as (BID-BIA) / (BI max-BIA) x 100. The Barthel index is a reliable disability scale commonly used to assess disability and to track the functional recovery of stroke patients.

A retrospective review of direct cost records from service-provider centers such as the administrative section, stroke unit, rehabilitation service, human resources, finance department,

and computer center was performed. The conventional system of cost calculation was used. Under that system, direct costs are directly ascribed to a cost object and typically include three parts: capital cost, labor cost, and materials cost. Analysis of direct costs was conducted using a standard cost accounting approach. The capital cost was calculated using straight-line depreciation.[11]

Annual depreciation cost = total instrument costs/useful life of instruments in years

Depreciation cost per test = annual depreciation cost/ number of reportable patient tests performed per year

Labor costs included salaries and accommodation costs. Materials costs included all types of expendable material used during the study period, such as stationery, medical material, etc.

Statistical analysis

SPSS version 21 was used for data analysis. The demographic data were analyzed using descriptive statistics, i.e., frequency, mean and standard deviation (SD). The rehabilitation effectiveness as measured by BI gain was calculated and BI gain within groups was evaluated using the paired t-test. The difference in effectiveness among the different types of rehabilitation services was analyzed using the analysis of variance (ANOVA) test. Statistical significance was set at a $p < 0.05$.

Results

Thirty-five stroke patients were recruited into intensive intermediate care rehabilitation from October 2021 to September 2022. One patient was excluded due to relocating to another province, leaving 34 patients for analysis (Figure 1). Inpatient rehabilitation accounted for 11 patients, while outpatient rehabilitation accounted for 23.

Table 1 shows patient demographic data. Most patients were male (52.9%), 90.9% had had an ischemic stroke, and the average age was 56 years (SD 13.71). More than half the patients had more than one risk factor for stroke. The average time from onset of stroke to rehabilitation was 6.05 days (SD 0.77). Most of the patients (73.5%) were covered by the National Health Security Scheme (NHSS). The demographic data in the two groups were not statistically significantly different. There were no major complications; however, two inpatients experienced vertigo, and one experienced knee pain.

Table 2 shows a comparison between BI scores at admission (BIA) and BI scores at discharge (BID). Barthel Index at discharge increased significantly ($p < 0.05$) with a mean BI gain of 5.09 points (SD 2.30) in inpatient rehabilitation, 4.77 points (2.26) in outpatient rehabilitation, and an average of 4.88 points (3.16) in both groups combined.

Table 3 shows a comparison of inpatient and outpatient services. The mean BIA, BID, BI gain, and mean percentage of rehabilitation effectiveness in both groups were not statistically significantly different between the inpatient and outpatient services.

As shown in Table 4, the average direct cost of inpatient rehabilitation was 1,500 THB (43 USD) per day or 21,000 THB (600 USD) per person/admission. Outpatient rehabilitation had an average direct cost of 399 THB (11 USD) per person per day. Labor, capital, and materials costs, in descending order, were the most expensive. The average direct cost per 1 point of Barthel index improvement in inpatient rehabilitation

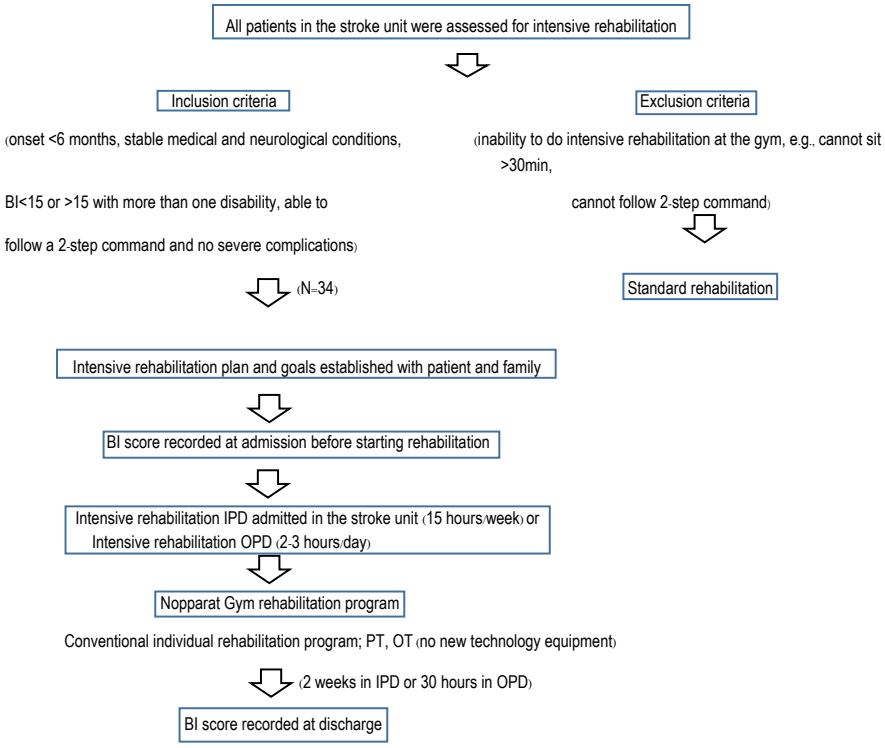

Figure1. Flow of the intensive rehabilitation study

Table 1. Demographic and clinical data

Characteristics	All participants	IPD (n=11)	OPD (n=23)	*p*-value
Age (years)[1]	56 (13.71)	61	54	0.233
Sex (male: female)[2]	18:16 (52.9: 47.1)	5:6	13:10	0.406
Etiology of stroke (ischemic, hemorrhagic)[2]	31:3 (90.9: 9.1)	9:2	22:1	0.239
Stroke risk factors[2]				
Hypertension	5 (14.7)	1	4	
Dyslipidemia	6 (17.6)	3	3	
Diabetes mellitus	2 (5.9)	1	1	
Smoking	3 (8.8)	2	1	
Alcohol	1 (2.9)	0	1	
> 1 risk factor	17 (50)	4	13	0.206
Interval to onset of rehabilitation (days)[1]	6.05 (0.77)	4.12	6.33	0.101
Health care coverage[2]				
Civil servant medical welfare	4 (11.8)	1	3	
National health security scheme (NHSS)	25 (73.5)	9	15	
Social security scheme (SSS)	5 (14.7)	1	5	0.266

[1]Mean (standard deviation, SD), [2]number (%); IPD, inpatient department; OPD, outpatient department

Table 2. Comparison of Barthel index scores at admission (BIA) and Barthel index scores at discharge (BID)

	BIA	BID	BI gains	*p*-value
IPD intensive rehabilitation (n=11)	9.27 (3.19)	14.36 (2.15)	5.09 (2.30)	< 0.001
OPD intensive rehabilitation (n=23)	11.00 (3.58)	15.77 (3.19)	4.77 (2.26)	< 0.001
Both groups of intensive rehabilitation (n=34)	10.44 (3.45)	15.32 (2.88)	4.88 (3.16)	< 0.001

Mean (standard deviation, SD); IPD, inpatient department; OPD, outpatient department

Table 3. Comparison of Barthel index scores between inpatient and outpatient service

	IPD (n=11)	OPD (n=23)	*p*-value
Barthel index at admission	9.27 (3.19)	11.00 (3.58)	0.519
Barthel index at discharge	14.36 (2.15)	15.77 (3.19)	0.721
Barthel index gain	5.09 (2.30)	4.77 (2.26)	0.708
Mean percentage of rehabilitation effectiveness	47.43 (31.11)	53.00 (34.21)	0.407

Mean (standard deviation, SD); IPD, inpatient department; OPD, outpatient department

Table 4. Service costs per patient per day (THB)

Service costs	IPD (n=11)	OPD (n=23)	*p*-value
Direct costs	1,500.39	399.20	
Capital costs	313.92 (20.92)	81.74 (20.47)	
Labor costs	1,138.52 (75.88)	296.21 (74.20)	
Materials costs	47.95 (3.20)	21.25 (5.33)	
Cost per 1 point of Barthel index gain	4,126.71	171.06	< 0.001

Mean (percentage); IPD, inpatient department; OPD, outpatient department

was 4,127 THB (118 USD) and was 1,171 THB (33 USD) in outpatient rehabilitation. The difference between groups was statistically significant. (1 USD = 35.04 THB on average in 2022)

Discussion

This study investigated the cost-effectiveness of intensive intermediate-care rehabilitation for stroke patients in Nopparat Rajathanee Hospital, a tertiary-level government hospital in Thailand. The study found the average inpatient BI gain was 5.09 points (SD 2.3), which was higher than outpatient service, which was 4.77 (SD 2.26), confirming the findings of previous studies.[4,12,13] However, there was no statistically significant difference between IPD and OPD in this study. This finding could be due to the system of case selection for intensive rehabilitation: the outpatient group had higher rehabilitation potential and anticipated level of compliance with rehabilitation compared to the IPD group. The higher level of compliance with outpatient intensive rehabilitation programs may have been due to early rehabilitation and prognostic evaluation. Both groups received the same rehabilitation program.

The Barthel Index at discharge increased significantly ($p < 0.05$) with a mean BI gain in inpatient rehabilitation of 5.09 (SD 2.30), which is lower than the 6.56 (SD 4.48) reported at Luangphorpern Hospital.[14] and the 5.79 (SD 3.89) in a 9-multicenter study4; but higher than the 4.4 (3.6) in a 14-multicenter study.[15] The average length of stay of those studies were 14,

35.65, 29.4, and 23.9 days, respectively. In this study, the mean percentage of inpatient rehabilitation effectiveness was 47.74. This duration was lower than a study at Luangphorpern Hospital, which reported an inpatient rehabilitation effectiveness of 56.62%. The reason for the differences could be the shorter length of stay (LOS) at Nopparat Rajathanee Hospital.

The average BI gain in inpatient rehabilitation was 0.36 points per day, with a 6.05-day onset to rehabilitation interval. This result was comparable to the BI gain of 0.4 points per day in a study at Bangklam Hospital, where patients were admitted to rehabilitation immediately after being discharged from the acute stroke ward. The LOS in the two studies was 14 days at Nopparat Rajathanee Hospital and 20 days at Bangklam Hospital. Although the National Health Security Office (NHSO) stated that the standard LOS for neuromuscular inpatient rehabilitation is 23.5 days, a shorter LOS can result in a positive outcome if patients receive early rehabilitation.

A study by Kuptniratsaikul et al. showed that intensive rehabilitation of stroke patients resulted in high BI gains of 0.23+0.32 points per day. Factors affecting the effectiveness of rehabilitation services, besides stroke and intensive types of admission, were shorter OAI (Onset-Admission Interval) < 3 months, lower BIA (< 10) and longer LOS (> 30 days).[14] Advantages of this study include early recruitment into intensive rehabilitation (average 6.05 days) and the mean BIA scores in both groups (10.44), but the LOS was only 14 days due to bed limitations.

Another tertiary hospital study of accessibility to medical rehabilitation services for acute stroke in Maharat Nakhon Ratchasima Hospital found that the LOS in the acute phase was four days, and the LOS in the rehabilitation phase was eight days. The short-term goal was to educate patients and their families and to prepare them for further rehabilitation.[16] Over 14 days, patients and families in this study learned together about intensive rehabilitation and a home program. The IMC bed service will be extended to the IMC ward.

According to Stefano Paolucci et al., early intervention, i.e., starting treatment within 20 days, is associated with a significantly higher probability of excellent therapeutic response and a fivefold lower dropout risk than with patients who start treatment later.[7] In this study, rehabilitation began as soon as the patients' and families' medical and neurological conditions were stable, the programs were on time provided in a timely manner, and the level of patient and family compliance was high. The only dropout was a patient who moved to a different area.

In the present study, the average direct cost of inpatient rehabilitation was 21,000 THB per person per admission or 1,500 THB per day, which is comparable to the 22,140 THB per person per admission or 1,089 THB per day reported in a cost analysis of rehabilitation service at the Sirindhon National Medical Rehabilitation Center17z and is lower than the unit cost of inpatient stroke rehabilitation in Siriraj Hospital of 3,251.53 THB per day.[18] The average inpatient direct cost per 1 point of BI improvement was 4,127 THB, less than Siriraj Hospital's cost of 7,761.73 THB.

The cost of investments in equipment and facilities represents primarily capital costs, so advanced-level hospitals could be expected to incur higher costs. The direct cost of stroke treatment is determined primarily by the length of hospital stay (LOHS). The duration of inpatient rehabilitation must achieve a balance between hospital resource constraints and patient benefits during hospitalization.

The average direct cost of outpatient rehabilitation in this study was 399 THB per person per day, less than that of outpatient rehabilitation at Sirindhon National Medical Rehabilitation Center of 562 THB per person per day. The higher cost at the Sirindhon Center may be due to having more modern equipment in specialized rehabilitation centers. Because rehabilitation necessitates a multidisciplinary team, labor costs account for the majority of costs in many studies, including those conducted by Sirindhon National Medical Rehabilitation Center, Siriraj Hospital, and the present study.

The present study found that both inpatient and outpatient intermediate intensive rehabilitation were effective, but that they had different capital and labor costs. Patient characteristics did not contribute to differences in costs, so promotion of community-based rehabilitation can be beneficial and, at the same time, can also help reduce healthcare costs.

The following are among the study's limitations: (1) the study only calculated the BI score; no other disabilities, such as communication, swallowing, or cognitive impairments, that can affect overall rehabilitation effectiveness were taken into account. (2) This study included only stroke patients with a high potential for rehabilitation due to bed limitations and early rehabilitation in a limited time frame. As a result, spontaneous functional recovery after a stroke may have overlapped with rehabilitation recovery. (3) The study only looked at direct costs; indirect costs were excluded because the hospital did not operate a supporting cost center that could provide the necessary information.

This study determined direct costs from the viewpoint of the health care provider only. Aspects of patient and family costs should be considered as well in further research.

Additional research is needed to develop a more complete picture of stroke intermediate care rehabilitation, including other functions that can influence rehabilitation effectiveness, e.g., swallowing impairment, cognitive function, psychosocial problems, and other aspects of care provision such as multidisciplinary discharge planning, long-term care planning, and total unit cost analysis, which would be helpful for materials and health economics management.

Conclusions

In both inpatient and outpatient services, intensive intermediate care rehabilitation for stroke patients in Nopparat

Rajathanee Hospital was associated with statistically significantly improved BI scores. The effectiveness of rehabilitation in this study was comparable to [*the previous study that found in previous studies at other institutions. The direct costs of inpatient and outpatient stroke rehabilitation in Nopparat Rajathanee Hospital can serve as a basis for determining cost-effectiveness in the future.

Disclosure

The author declares no conflicts of interest.

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The Efficacy of Ortho-Prosthesis and Knee Ankle Foot Orthosis on Functional Gait Activities in Pediatric Congenital Limb Deficiency: A Case Report

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ABSTRACT

Objectives: This study aimed to demonstrate the efficacy of ortho-prosthesis and knee-ankle foot orthosis (KAFO) in improving functional gait activities in children with congenital limb deficiencies.

Study design: A case report.

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

Subjects: The study presents the case of a 10-year-old child with a left congenital femoral deficiency with fibular hemimelia and right tibial hemimelia.

Methods: A pediatric orthopedist provided surgical treatment, and a prosthetist and orthotist prescribed the design, choosing the appropriate KAFO for the right side and ortho-prosthesis for the left side. Outcome measurements were recorded using the Four Square Step Test (FSST), Time Up and Go (TUG) Test, and the 10-Meter Walk Test after using the devices for two and five months.

Results: The results of FSST and TUG showed improvement after five months of training, with 19.69% and 34.25% less time required, respectively. The parameters of the 10-Meter Walk Test also improved after five months of training.

Conclusions: Appropriate fitting of different devices and training using those devices can help improve balance and functional gait activities in children with congenital limb deficiencies.

Keywords: tibia hemimelia, knee ankle foot orthosis, ortho-prosthesis, congenital femoral deficiency

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Introduction

Congenital limb deficiency is a partial or complete absence of a limb due to limb formation failure during pregnancy. The etiology of congenital limb deficiencies is unknown; lower limb deficiencies are generally less common than upper limb deficiencies.[1] Surgical amputation is necessary in only 19% of cases of congenital limb deficiency.[2] Children with limb deficiencies may require a multidisciplinary team to help them manage their condition and to achieve their maximal functional capacity. The goals of surgery in cases of congenital limb deficiency are to remove the bony overgrowth or to adjust the residual limb to facilitate proper prosthesis fitting.[3] Prostheses and orthoses can help these children achieve independence in activities of daily living. The prosthesis and orthosis prescription and fitting process considers several factors, including the child's cognitive maturity and physical ability.

The fitting typically begins for children with lower limb deficiencies between nine to sixteen months of age. Children with congenital limb deficiencies often experience unstable gait patterns due to heavy and locked joints of the knee and ankle. Providing appropriate training during the initial phase of prosthesis fitting can help reduce gait deviations and improve gait stability.[4] However, previous studies have rarely addressed congenital limb deficiencies and the effectiveness of ortho-prosthesis and knee-ankle foot orthosis in improving functional gait activities in those cases. There is also a need to investigate the impact of these devices on outcome measures and to determine the necessity for periodic replacement of prostheses and orthoses as the child develops. This study aimed to demonstrate the efficacy of ortho-prosthesis and knee-ankle foot orthosis (KAFO) in improving functional gait in cases of congenital limb deficiencies.

Case presentation

The subject was a 10-year-old male subject (weight: 37.4 kg, height: 124 cm) with a left congenital femoral deficiency and fibular hemimelia (Paley 3c) and right tibial hemimelia (Jones type I, Paley 5b).[5] Congenital femoral deficiency presented as congenital short femur with fibular hemimelia (Paley 3C).[6] The neck of the femur had retroversion, genu varum, and hypoplasia of the lateral condyle, causing knee instability in the anteroposterior plane and muscle and vascular pathoanatomy. Physical characteristics included leg length

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discrepancy, hip flexion contracture, hip rotation instability, knee instability, and fixed equinovarus. He received limb lengthening to extend the femur and shortening osteotomy to realign the distal tibia (Figure 1).

Tibial hemimelia with Jones type I presented as a total absence of the tibia and hypoplastic distal femoral epiphysis. Paley 5b presented as the absolute absence of the tibia and patella. Physical characteristics presented included genu valgum, complete toe development, and fixed equinovarus. He initially received orthopedic treatment with Brown's procedure (fibular centralization) for tibial hemimelia. The first correction of knee flexion contracture used a k-wire to stop partial bone growth after the fibula had been moved to the central part of the knee and the knee joint began to straighten, followed by a second operation for fixation of the fibular head with the femur, creation of ligament and muscle by separating the peroneal nerve from the fibular bone and bisecting the biceps tendon to create a lateral collateral ligament and, in place of the quadriceps, connecting the semitendinosus tendon, iliotibial band, tensor fascia latae, and adductor magnus to the muscle of the femur so all the transfer muscle would bring the fibular bone to the center and using k-wire at the fibula and distal femur for the prevention of fibular slip. The next operation was knee extension using a circular frame and k-wire. The k-wire was removed after six months, but KAFO and the physical therapy approach were continued.

The patient was referred to the prosthetics and orthotics clinic after a surgical assessment procedure and prescription of the appropriate ortho-prosthesis (left) and KAFO (right). The assessment of the patient found that the left hip showed external rotation and flexion contracture, along with a knee flexion contracture of approximately 10 degrees and equinovarus of the foot. On the right side, there was also hip external rotation and flexion contracture, along with knee flexion and foot plantarflexion (Fig. 2). Range of motion was limited, and manual muscle testing yielded a grade of 3 with a positive Thomas Test. The subject always used an ortho-prosthesis and KAFO to perform activities by himself at school and outside the home, but he performed daily activities at home without any device. He had used several ortho-prostheses and KAFOs after the surgical procedures to support growth development.

Ortho-prosthesis and KAFO design and techniques

The child's lower limb devices comprised an ortho-prosthesis for the left and KAFO for the right. Both devices allowed full weight bearing and were designed to provide stability and support while walking. A prosthetist and an orthotist took a cast of the right side at the hip level to fabricate a KAFO to reduce the chances of ankle and knee contracture. The casting process for the KAFO involved a two-step approach, beginning with a partial weight casting of the patient's right leg while seated with the hip and knee flexed at 90 degrees and the ankle corrected for any deformities. Plaster of Paris was applied using a slab technique from the calf to the plantar surface, followed by circumferential wrapping from the shank to the foot to capture the shape of the leg. The plaster was then allowed to harden, after which a full weight-bearing casting was made with the patient standing to ensure stability and proper alignment. The heel compensation was set in the fabrication process by drawing a reference line perpendicular to the floor in both the coronal and sagittal planes.

Special attention was paid to sensitive and prominent areas, with modifications made to the plaster to build up areas as needed for comfort and fit. Flaring techniques were used at

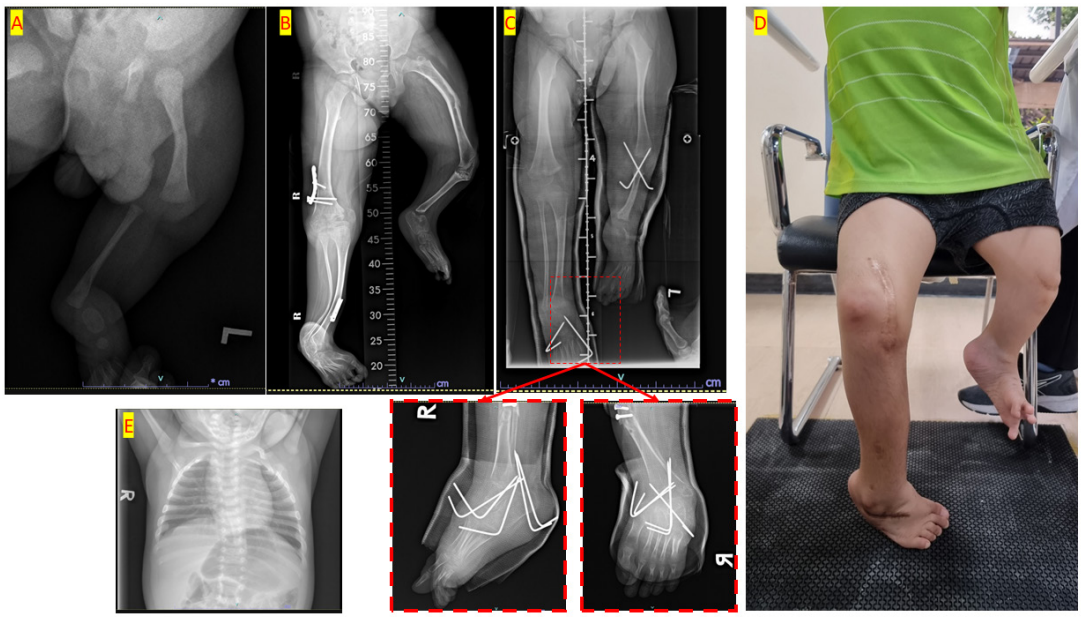

Figure 1. Radiography of left congenital femoral deficiency with fibular hemimelia and right tibial hemimelia. A: malaligned fibula and femur bones resulting from maldevelopment of the lower limb; B: internal fixation of the right femur de-rotation with extension osteotomy plate, right tibial de-rotation with a tubular 1/3 plate; C: internal fixation to correct the foot in both the sagittal and coronal plane; D: standing without supportive device; E: effect of anomalies on the spine.

Figure 2. A: Sagittal plane view of the right leg with full extension; B: Top view in the supine position

Figure 3. Fitting with: A: right side knee-ankle foot orthosis and B: left side ortho-prosthesis

the device's opening to facilitate donning and doffing and to prevent the edge of the device from pressing against the patient's skin. The fabrication used a 5 mm thick sheet of polypropylene plastic with a foam liner to minimize skin friction and a stainless-steel upright. First, a positive cast was created, then thermoformed using a plastic material along the anterior seamline. The upright was then bent along the plastic shell in both the upper and lower parts.

The next step involved cutting and fabricating the heel compensation part according to the patient's alignment. Biomechanical techniques were employed in the fitting and delivery process using a 3-point pressure system. The trim line was established by positioning the proximal thigh section beneath the gluteal area and 2.5 cm below the perineum area and aligning the greater trochanter neck with a posterior thigh shell to provide a counterforce. The distal thigh section was placed above the medial and lateral condyles. The proximal leg section encompassed the anterior knee area, employing a plastic shell instead of a kneecap to deliver the necessary corrective force. The distal leg section was fitted with a posterior shell that offered additional counterforce. The full-length foot section covered the distal first metatarsal head and proximal fifth metatarsal head to manage varus deformity. Straps were attached at the thigh part 45 degrees from the ankle and around the metatarsal head. An anti-slipper was affixed to the footplate's underside to facilitate walking without shoes. This feature is particularly useful for patients with heel compensation or uneven leg length, as they may require an outsole to achieve a plantigrade foot alignment with the floor. Additionally, it addresses the challenge of finding suitable footwear for these patients. The ortho-prosthesis consisted of a quadrilateral socket, drop lock orthotic knee joint attached using an exoskeletal prosthesis fabricated from acrylic resin and a metal upright bar (Figure 3).

Pediatric orthotic training and outcome measures

The child's training began with introducing him to the ortho-prosthesis and KAFO, followed by an Introduction and Familiarization phase. After he became comfortable with the prosthesis, the static balance training phase began,

teaching the child to balance while standing in parallel bars. Following that, Dynamic Balance Training helped the child maintain balance while walking with gradually decreasing support. Gait Training then taught the child to walk with the ortho-prosthesis and KAFO, starting with short steps and progressively increasing stride length. Additionally, the child underwent endurance and strength training to improve walking abilities. Advanced training was then begun to achieve the goal of independent walking and playing with friends, including running, jumping, and sports-specific movements. After giving him the devices, we followed up with the patient at two and five months to recheck the quality of the device and the patient's performance. Each outcome measurement was repeated three times, and the average value was recorded.

The assessment included using a BTS-G Walk sensor to evaluate the patient's functional gait performance with the orthosis and ortho-prosthesis during a 10-Meter Walk Test and the Timed Up and Go Test on a level surface. The Four Square Step Test was also performed without any assistive devices.

Four Square Step Test (FSST)

The Four Square Step Test (FSST) is used to check a subject's dynamic stability and ability to step forward, sideways, and backward over small obstacles. The FSST results after five months showed a 19.69% improvement over the results after two months.

Timed Up and Go (TUG) Test

The time to complete the TUG Test showed the difference between the device's short- and long-term use. The TUG Test showed a reduction of 34.25% after using the devices for five months compared to two months.

10-Meter Walk Test

The 10-Meter Walk Test revealed improvements in several variables after using ortho-prosthesis and KAFO for five months compared to two months. Both the symmetry index and the walking quality index also showed improvement after using the ortho-prosthesis for five months. However, the improvement from using KAFO as measured by the Gait Quality Index for five months compared to two months was found to be minimal.

Results of the Four Square Step Test, Time up and go, and 10-meter walk test with ortho-prosthesis and KAFO after using the devices for two months and five months are shown in Table 1.

Discussion

This case study aims to evaluate the efficacy of ortho-prostheses and KAFO in improving gait stability, reducing gait deviations, and enhancing the overall quality of gait in children with congenital limb deficiencies. The findings suggest that appropriate ortho-prosthesis and KAFO interventions can effectively improve gait stability in children with congenital limb deficiencies, potentially leading to improved mobility and reduced risk of falls. The choice of prosthesis and orthosis design is crucial to enhancing the ability to carry out various activities. The ischial containment socket ortho-prosthesis design effectively redistributes and offloads weight to a two-point load-bearing area at the ischium and the foot heel, reducing excessive pressures on the leg during ambulation. Additionally, the KAFO design, with an anterior shell providing improved leg control by pushing the knee backward during ambulation, reduces the likelihood of developing further contractures. The locked knee joint with KAFO enhances stability by preventing knee collapse while walking.

The incidence of successful adaptation to ortho-prosthesis in children with congenital limb deficiency is greater than in adults with traumatic limb amputation.[7] Individuals with limb loss resulting from accidents or amputations exhibit a higher tendency to experience falls while performing stability tasks that take longer than 24 seconds.[8] Differences in successful adaptation and fall risk may be attributable to variations in the individual's age at onset, the nature of the limb loss, and differences in cognitive abilities between children and adults. The Four Square Step Test (FSST) is a standardized assessment tool that is used to measure dynamic stability and the ability to step over obstacles in different directions. It is often used to assess an individual's risk of falling, balance, and mobility. The current study showed improved FSST performance after five months of using prosthetic devices.

The secondary objective is to describe and propose a systematic, objective assessment process for ortho-prosthesis fitting in children with congenital limb deficiencies. The Time

Table 1. Outcome of the Four Square Step Test, Timed Up and Go Test and 10-Meter Walk Test

Variable mean (SD)	2 months	5 months	Difference
Four Square Step Test (s)	16.51 (0.4)	13.65 (2.39)	2.86
Time Up and Go Test (s)	11.68 (1.71)	9.14 (0.78)	2.54
10-Meter Walk Test			
Walking duration (s)	10.82 (1.32)	11.5 (0.84)	0.68
Walking speed (m/s)	1.21 (0.16)	1.23 (0.12)	0.02
Symmetry index	72.83 (12.48)	82.06 (6.54)	9.23
Walking quality index left	94.91 (4.73)	98.08 (2.46)	3.17
Walking quality index right	92.84 (2.57)	93.96 (4.12)	1.12

s, seconds; m/s, meters/second

Up and Go (TUG) Test is a commonly used assessment tool to assess the risk of falling in people who use prostheses or orthoses. Some researchers have used two different models (Gaussian bell-shaped curve and linear regression line) to classify participants as fallers or non-fallers based on their TUG Test data. Both models have been able to distinguish between fallers and non-fallers significantly. These findings suggest that the TUG Test could help assess the risk of falls in older adults and may be more efficient and precise than other methods currently used.[9] The TUG Test is a good diagnostic tool for differentiating between groups of patients. It can help assess the mobility of children and adolescents, monitoring the effects of physical therapy and surgical procedures.[10] Promising improvement was observed in the current study using the proposed assessment process.

The current study found improvement during the 10-Meter Walk Test. The result exhibited greater improvement with the ortho-prosthesis than with the KAFO. The 10-Meter Walk Test is a commonly used assessment tool in the medical field to evaluate gait patterns and identify specific gait parameters that may be affected by neurological or orthopedic conditions. It is a quick and easy way to measure walking speed, cadence, step length, stride length, and other parameters such as walking symmetry and propulsion. Gait parameters, e.g., stance, swing, and double support times, can vary significantly during fast walking in children aged 5-8. This information serves as a valuable reference point for clinicians and researchers to compare gait patterns of children with abnormalities and evaluate the effectiveness of interventions to improve gait.[11] However, recent research has shown that gait patterns during the 10-Meter Walking Test, which is commonly used in clinical practice, differ from observations of walking at home among individuals with hemiparesis. The main difference is in stride length, with exercises focusing on improving stride length recommended for enhancing walking ability at home. Clinicians should consider the specific gait parameters being measured when assessing and treating gait abnormalities in their patients.[12]

Ortho-prosthesis and KAFO interventions can improve gait outcomes in children with congenital limb deficiencies. From a clinical perspective, the findings of this study have important implications for the selection of treatment for children with congenital limb deficiencies. Specifically, clinicians may consider using a prosthesis or orthosis in conjunction with outcome measures to improve gait and reduce the risk of falls in this population. Additionally, using outcome measures may help clinicians monitor the effectiveness of interventions over time and adjust treatment plans accordingly.

The methods for improving gait outcomes used in this study could lead to increased mobility and reduced risk of falls for children with congenital limb deficiencies. In this case study, the longer walking duration at five months compared to two months highlights some important factors that might influence individual progress and adaptation to ortho-prostheses and KAFO. Initially, i.e., during the first few months, the child may still adjust to the new devices, resulting in slightly slower walking times. Their walking duration should improve as they continue to practice and gain more experience. The improvement in walking duration also reflects the strengthening of muscles employed during walking resulting from consistent use of ortho-prostheses and KAFO. Moreover, the child may gain confidence and experience increased comfort, which can positively impact walking performance as reflected in a smoother and more efficient gait and contribute to longer walking duration.

Conclusions

The present case study provides evidence that ortho-prosthesis and KAFO effectively improve functional gait outcomes in children with congenital limb deficiencies. The interventions using those devices demonstrated positive effects on increasing gait stability, reducing gait deviation, and improving overall gait quality. These outcomes were evident in the improvements in the Four Square Step Test, Time Up and Go Test, and the 10-Meter Walk Test. Using an ortho-prosthesis and KAFO resulted in enhanced functional mobility and gait performance in the children, highlighting the importance of appropriate fitting of the devices and subsequent training using these devices. These findings contribute to a better understanding of the potential benefits of these interventions in improving the quality of life for children with congenital limb deficiencies.

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