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Content

Editorial

Original Articles

Notes from the Editor-in-Chief

Over the past few months, our dedicated team of editors and reviewers has been working tirelessly to curate a collection of articles that provide valuable insights and advancements in various fields. We have maintained the highest standards of quality and integrity in the selection process, ensuring that only the most rigorous and innovative research is included in our journal.

Our commitment to facilitating the dissemination of cutting-edge research is unwavering, and we continue to serve as a bridge between the scientific community and the wider public.

In this issue, the first article, conducted by Charussuriyong P., presents the findings of a randomized controlled trial that assessed the effectiveness of anodal transcranial direct current stimulation in improving language ability in patients with post-stroke aphasia. The study revealed no statistically significant difference between the two groups, both immediately after treatment and at the one-month follow-up.

The second article, conducted by Panompornpanich A. and her team, reports on a randomized controlled trial that evaluated the efficacy of rhythmic auditory stimulation on balance in children with cerebral palsy from Sri-Sangwan School in Bangkok, Thailand. The study concludes that the addition of rhythmic auditory stimulation to physical therapy may not improve the efficacy of training beyond the effects of physical therapy alone.

The third article featured in this issue is a prospective cohort study conducted by Salinpramote B and her colleague. The study aimed to evaluate the effectiveness of home-based rehabilitation programs on the functional outcomes of patients with traumatic spinal cord injuries during the post-acute phase. Additionally, the researchers analyzed factors associated with improved functional outcomes.

Moving on, we have a prospective cohort study by Chadchavalpanichaya N and her colleague. The objective of their study was to explore the effectiveness of an adjustable splint in patients with hallux valgus. The findings revealed that wearing an adjustable splint for 12 months in patients with moderate to severe degrees of hallux valgus resulted in a decrease in hallux valgus angle and alleviation of hallux pain, without any serious complications.

The next manuscript in this issue is conducted by Kotcharoen R and her colleague. Their objective was to identify the factors that contribute to cardiac rehabilitation uptake among patients with coronary artery disease in Thailand. The study concluded that while the existing hospital-based cardiac rehabilitation programs in Thailand are suitable for urban patients with coronary artery disease, they may be less effective for those residing in rural areas. The authors suggested that improvements should be made to the existing programs or the development of more nuanced approaches specifically tailored for rural patients.

The final manuscript in this issue is conducted by Boonsiripipat P and her colleague. Their study involved a retrospective chart review of a university hospital, aiming to determine the demographic and clinical characteristics of patients with primary knee osteoarthritis. The findings revealed that the main characteristics of knee osteoarthritis patients in this study included obesity, advanced age, female gender, civil servant medical coverage, bilateral knee pain, and mild radiographic severity. Notably, patients with a higher body mass index (BMI) were significantly more likely to receive weight reduction advice.

We hope you find this study insightful and informative. Thank you for your continued support and interest in our journal.

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

Original Article

Efficacy of Transcranial Direct Current Stimulation in the Treatment of Post-Stroke Aphasia: A Randomized Controlled Trial

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ABSTRACT

Objectives: To evaluate the efficacy of anodal transcranial direct current stimulation (tDCS) on improving language ability in patients with post-stroke aphasia

Study design: Double-blind randomized controlled trial

Setting: Department of Rehabilitation Medicine, Maharat Nakhon Ratchasima Hospital

Subjects: Post-stroke aphasia patients aged 18 years and over, with at least three months from stroke onset

Methods: Forty patients were randomly assigned to intervention and control groups. The intervention group received 2 mA of anodal tDCS over Broca's area (F5) combined with speech therapy for 20 minutes per session per day on five consecutive days. The control group received sham-tDCS combined with speech therapy in the same protocol as the intervention group. Language skills were evaluated using the Thai Western Aphasia Battery at pre-treatment, post-treatment (after the session on the fifth day of treatment), and 1-month follow-up. The accessor was blinded.

Results: Thirty-two patients completed the assigned sessions. The mean age of the patients was 52.7 (SD=11.4) years. Most of them had an ischemic stroke (71.9%). The mean difference in Thai WAB-AQ scores between the intervention and control groups at post-treatment and 1-month follow-up were -0.05 (95% CI: -4.4, 4.3) and -2.38 (95% CI: -11.7, 6.9), respectively. However, the difference between the two groups did not reach statistical significance at either time point. No serious complication was found.

Conclusions: This study did not show sufficient evidence to support anodal tDCS concurrent speech therapy with additional improvement in language ability beyond those observed in patients undergoing speech therapy alone, among those with post-stroke aphasia.

Keywords: transcranial direct current stimulation, aphasia, stroke, speech therapy, stroke rehabilitation

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Introduction

Aphasia is an impairment of language, affecting the production or comprehension of speech and the ability to read and write. The most common cause of aphasia is cerebrovascular disease. Approximately 30% of stroke patients will be diagnosed with aphasia.[1] Currently, there is no known effective treatment. The most popular treatment used today is the practice of communication with a speech-language pathologist (SLP).[2] A SLP assists the patient in recovering linguistic abilities and training the patient and family members in exercising alternative strategies for communication.

However, current speech therapy strategies have limited and variable effectiveness in improving aphasia.[2,3] Transcranial Direct Current Stimulation (tDCS) is a non-invasive brain stimulation that has been used in adjunctive therapy with rehabilitation in stroke patients for various disabilities including muscle weakness,[4] cognitive impairment,[4] dysphagia,[5] and aphasia.[6-10] Also, tDCS is a neuromodulatory technique that affects the resting membrane potentials of neurons through modulation of sodium-channel, calcium-channels, and NMDA (N-methyl-D-aspartate) receptor activity, resulting in long-term potentiation, long-term depression, and synaptic plasticity.[6,7]

Anodal tDCS over the left frontal or temporal regions effectively performs linguistic tasks. For instance, Baker et al. and Fiori et al. reported significant improvements in naming accuracy following tDCS interventions.[8,9] Campana et al. demonstrated enhanced picture description abilities among patients who received tDCS stimulation.[10] Furthermore, Vilanowa et al. indicated enhancements in articulatory accuracy following anodal tDCS application.[11] However, Fridriksson et al. and Spielmann et al. did not find a significant difference improvement in naming accuracy between the anodal tDCS group and the control group.[12,13] Polanowska et al. likewise concluded that naming accuracy and naming time had no significant difference improvement after applying anodal tDCS.[14]

Elser et al. conducted a systematic review and metaanalysis and found that tDCS was not superior to the conventional

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treatment in improving functional communication, language impairment, and cognition in patients with chronic post-stroke aphasia.[15] Biou et al. performed a systematic review of 5 meta-analyses and 48 studies and concluded that tDCS is effective for post-stroke aphasia rehabilitation.[16]

Even though there were systematic reviews, those studies had heterogenicity in the phase of stroke, polarity, and area of brain stimulation. The effectiveness of tDCS for improving aphasia is controversial. Therefore, this study aimed to investigate the efficacy of anodal tDCS combined with speech therapy in patients with post-stroke aphasia.

Methods

Study design

This study was a double-blind, randomized control trial conducted at the Department of Rehabilitation Medicine of Maharat Nakhon Ratchasima Hospital (tertiary care hospital) in Nakhon Ratchasima, Thailand, from March 2019 to September 2022. Ethical approval was obtained from the Maharat Nakhon Ratchasima Hospital Institution Review Board (approval ethical number 041/2019) and was registered in the Thai Clinical Trials Registry (TCTR 20200204007).

Participants

The participants of this study were patients with post-stroke aphasia who were diagnosed at least three months. They received treatment at the Department of Rehabilitation Medicine at Maharat Nakhon Ratchasima Hospital. The inclusion criteria included the following requirements: age 18 years or over, the first diagnosis of stroke, communication impairment that affects communication in daily life or Thai WAB-AQ score less than 93.8, the cut-off for aphasia diagnosis,[17] and willingness to provide consent to participate in the study. The exclusion criteria included the following specifications: unstable vital signs or neurological symptoms, communication impairment prior to the stroke, receiving neuromodulation therapy, including tDCS, transcranial magnetic stimulation (TMS), and acupuncture during the previous three months, and having contraindications for tDCS including a history of craniectomy or craniotomy, a history of seizure within twelve months, cochlear implants, intra-cardiac devices implanted, and metallic material implanted.[7]

The sample size calculation was based on a study by Shah-Basak et al.[18] The primary outcome variable selected was WAB-AQ score. The power of the study was set at 80%, and the significance level was 0.05. There were 18 patients required in each study group and a control group. Taking into account a 10% dropout, the number of patients was increased to 20 subjects in each group, and 40 participants were recruited in total.

Randomization

The patients were randomized to either an intervention or a control group by a research coordinator from a computer-generated random number system (http://randomization.com) for a block of four randomizations. After baseline testing, the patients received notification of their group allocation in a sealed envelope. Patients and SLPs were blinded to the intervention assignment.

Intervention

Patients in the intervention and control groups received speech therapy for 20 minutes per session per day, five sessions on consecutive days. During the speech therapy session, tDCS was applied with an anode over the left Broca's area (F5) according to the 10-20 EEG system, and the cathode on the right supraorbital area. Patients in the intervention group received an electrical current of 2 mA for all 20 minutes during the speech training session. In contrast, those in the control group received an electrical current for only 30 seconds to simulate being treated with the electricity. The tDCS method was chosen based on the previous studies[9,10,19] that assessed the effectiveness and safety of tDCS.

Outcome measurements

The clinical outcome measure was the Thai Western Aphasia Battery-Aphasia Quotient (Thai WAB-AQ) score after the session on the fifth day of the treatment (post-treatment) and one month after the last treatment session. The Thai WAB-AQ was modified from the Western Aphasia Battery Aphasia Quotient.[17] The Thai WAB-AQ score has a reliability of 0.99.[20] The scale was zero to a hundred. The one hundred scores meant normal. It consisted of 4 tasks: spontaneous speech, comprehension, repetition, and naming. The accessor was the SLP, who was blinded to the intervention assignment. The flow chart of the study is shown in Figure 1.

Statistical methods

The baseline characteristics of both groups were analyzed with descriptive statistics, shown as a number, percentage, mean, and standard deviation. The researchers used mixed-effect restricted maximum likelihood regression to compare the mean difference of Thai WAB-AQ between the two groups on the fifth day after treatment and one month after the last session. The 95-percent confidence interval, which did not overlap with 0, was statistically significant.

Result

Forty patients with post-stroke aphasia participated in the study and were randomly assigned to one of two groups: the intervention (anodal-tDCS) or the control (sham-tDCS) group. Three patients from the intervention group and four from the control group dropped out between treatments due to transportation issues. Also, one patient from the intervention group dropped out on the first day of treatment due to stress from the speech training. One month after treatment, two patients from the intervention group failed follow-up due to transportation challenges. The last observation carried

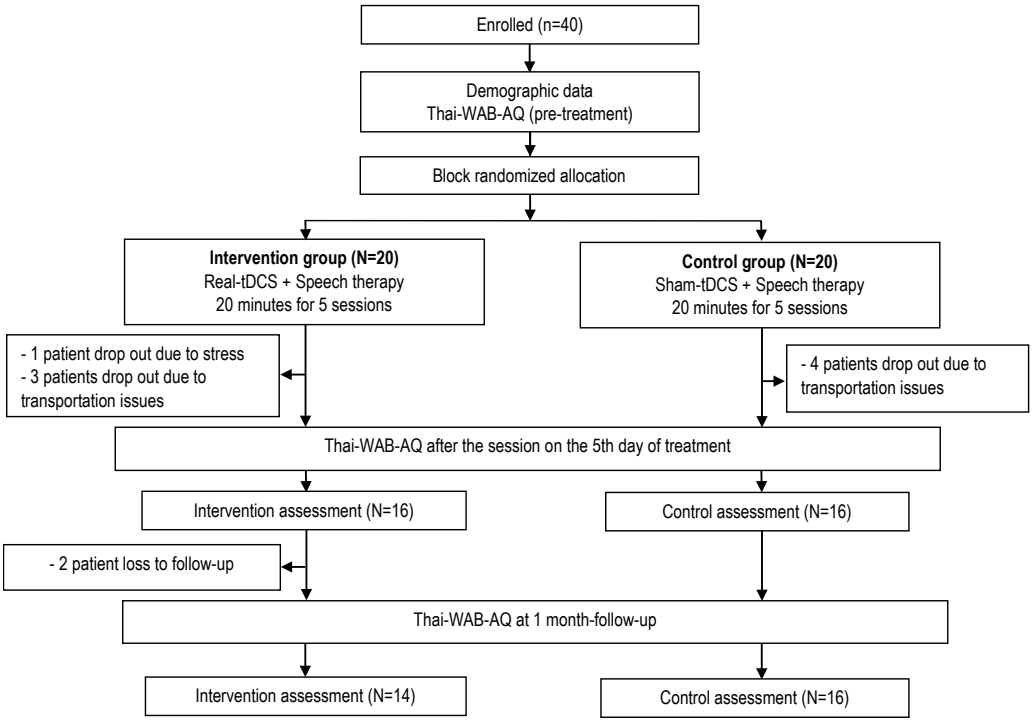

Figure1. Flow diagram of the patients through the trial

Table 1. Demographic data of the patients

Characteristics	Intervention group (n = 16)	Control group (n = 16)
Male gender[1]	9 (56.25)	12 (75)
Age (year)[2]	53.1 (10.97)	52.5 (12.26)
Education level[1]		
• Primary school	10 (62.5)	6 (37.5)
• Secondary school	5 (31.25)	10 (62.5)
• Bachelor's degree	1 (6.25)	0 (0)
Underlying disease[1]	14 (87.5)	13 (81.25)
• Hypertension	7 (43.75)	8 (50)
• Diabetes mellitus	5 (31.25)	2 (12.5)
• Dyslipidemia	1 (6.25)	1 (6.25)
• Heart disease	5 (31.25)	7 (43.75)
• Other	3 (18.75)	6 (18.75)
Duration from the onset of stroke to intervention (month)[2]	9.2 (56.25)	4.9 (2.41)
Right hand dominant[1]	15 (93.75)	15 (93.75)
Ischemic stroke[1]	11 (68.75)	12 (75)
Location[1]		
• Left MCA infarction	7 (43.75)	8 (50)
• Left frontoparietal	2 (12.5)	2 (12.5)
• Left basal ganglion	5 (31.25)	3 (18.75)
• Right MCA infarction	0 (0)	1 (6.25)
• Other	2 (12.5)	2 (12.5)
Type of aphasia[1]		
• Non-fluent	9 (56.25)	7 (43.75)
• Fluent	7 (43.75)	9 (56.25)
Speech therapy before Intervention[1]	14 (87.5)	10 (62.5)

[1]Number (%); [2]Mean (SD)

forward analytic technique was used to impute the Thai WAB-AQ scores at one month for data from patients who did not complete the 1-month follow-up. Data from patients who dropped out between the 5-day treatment sessions were excluded.

The baseline demographic data of patients are shown in Table 1. Gender, age, education level, underlying disease, dominant hand, type of lesions, location of lesions, and type of aphasia were similar between the two groups. However, the intervention group had a longer mean duration from the

onset of stroke to the treatment than the control group. Specifically, the mean time duration from the onset of stroke was 9.2 months for the intervention group, whereas it was 4.9 months for the control group.

Thai WAB-AQ Score

The intervention groups had slightly higher mean scores of Thai WAB-AQ at baseline than the control group, with 45.44 (SD=28.24) in the intervention group and 43.76 (SD=24.61) in the control group. Post-treatment and one month after treatment, the mean scores of the intervention groups were 51.61 (SD=27.54), 52.12 (SD=27.35), and the mean scores of the control group were 49.97 (SD=28.04), and 52.81 (SD=29.38) (Figure 2) as shown in Table 2. The mean score of Thai WAB-AQ at post-treatment and one month after treatment in both intervention and control groups was statistically significantly higher than the baseline.

After adjusting the baseline of the Thai WAB-AQ score, the adjusted mean difference score between the intervention group and control group were -0.05 (95% CI, -4.37, 4.26) at post-treatment and -2.38 (95% CI, -11.71, 6.95) at one month after treatment (Table 2). However, the difference between the two groups did not reach statistical significance at either time point (Figure 2b).

Spontaneous speech, comprehension, repetition, and naming scores improved post-treatment and one month after treatment compared to baseline. However, there was no statistically significant difference between the groups at both times (Table 2). The side effects of tDCS treatment observed in this study were skin redness in 2 patients, which resolved within 15 minutes. No serious complication was found.

Table 2. Mean score and mean score difference of Thai WAB-AQ score at pre-treatment, post-treatment, and 1-month follow-up between intervention and control groups

Group	The mean score (SD)			Adjusted mean difference changed score, Intervention group-control group (95% CI) at post-treatment	Adjusted mean difference changed score, Intervention group-control group (95% CI) at 1 month
	Pre-treatment	Post-treatment	1 month-follow up		
Thai WAB – AQ					
Intervention	45.44 (28.42)	51.61 (27.54)	52.12 (27.35)	-0.05 (-4.37, 4.26)	-2.38 (-11.71, 6.95)
Control	43.76 (24.61)	49.97 (28.04)	52.81 (29.38)		
Spontaneous speech					
Intervention	8.25 (5.79)	10.13 (5.30)	10.00 (4.47)	0.38 (-1.18, 1.94)	-1.31 (-4.38, 1.76)
Control	8.13 (5.24)	9.63 (5.90)	11.19 (6.60)		
Comprehension					
Intervention	6.45 (2.64)	6.81 (2.66)	6.76 (2.89)	0.00 (-0.50, 0.49)	-0.05 (-0.85, 0.75)
Control	6.03 (2.81)	6.41 (2.58)	6.42 (2.76)		
Repetition					
Intervention	4.91 (3.74)	5.21 (3.69)	5.04 (3.54)	-0.30 (-0.66, 0.07)	0.40 (-1.30, 0.50)
Control	4.38 (3.61)	4.99 (3.79)	4.92 (3.85)		
Naming					
Intervention	3.11 (3.44)	3.65 (3.48)	3.83 (3.48)	-0.07 (-0.61, 0.46)	0.05 (-1.11, 1.22)
Control	3.35 (2.99)	3.96 (3.48)	4.02 (3.39)		

Mean difference changed score = changed score from baseline in the intervention group – changed score from baseline in the control group.

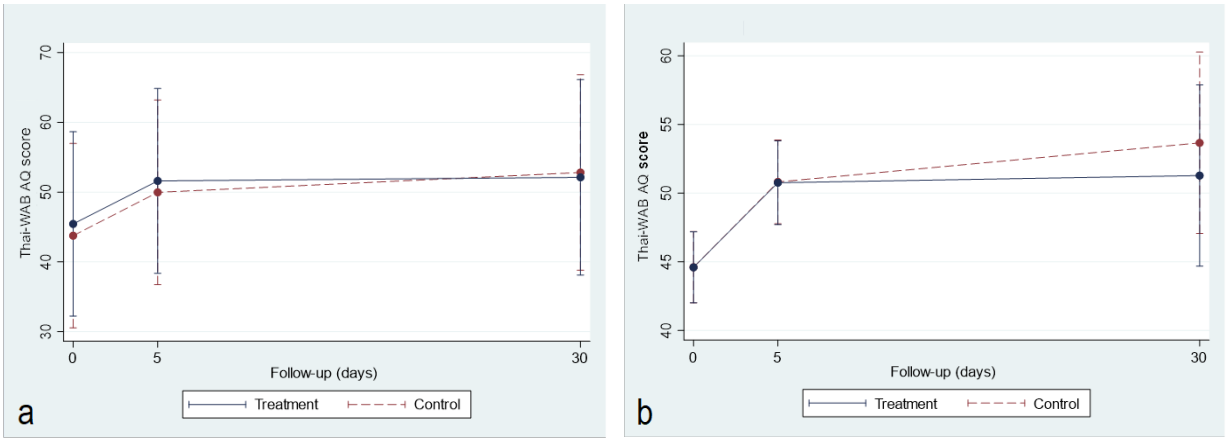

Figure 2. The chart shows the mean score of Thai-WAB AQ at pre-treatment, post-treatment (5 days), and 1-month follow-up (30 days) of intervention and control groups. (a) unadjusted (b) after adjusting the baseline of the Thai WAB score.

Discussion

According to the findings of this study, patients with post-stroke aphasia who received a dosage of 2 mA of anodal tDCS over Broca's area (F5) combined with speech therapy for 20 minutes per session per day for five consecutive days improved in Thai WAB-AQ score at post-treatment and one month after treatment. However, there was no statistically significant difference when compared to the sham-tDCS group. The findings agreed with some previous studies, Polanowska et al.[14] Otal et al.[21] and Fridriksson et al.[12] that showed no significant improvement in language ability between the tDCS group and the control group. However, Fiori et al.[9] Silva et al.[22] Shah-Basak et al.[18] and Baker et al.[8] demonstrated the effectiveness of tDCS in improving the language abilities of patients with post-stroke aphasia. The different results are caused by numerous factors, including the time from onset of the stroke to treatment,[23] the severity of aphasia,[23,24] the dose, and the protocol of tDCS that may influence the effectiveness of tDCS in treating aphasia.

In this study, the mean stroke duration was 9.2 months in the intervention group, whereas it was only 4.9 months in the control group. Both groups showed improvement in language ability after the intervention. However, there was no significant difference between the groups. The improvement in the control group may be associated with spontaneous recovery, which happened in the first six months.[23] Maas MB et al. found that 74% of patients with stroke had the complete resolve of aphasia in six months.[25]

Aphasia severity is a strong predictor of response to the therapy.[24] In this study, the severity of aphasia was assessed using the Thai WAB-AQ. The mean baseline Thai WAB-AQ score of the intervention groups was 45.4, which was classified as a severe degree.[17] This study did not show the superiority of tDCS over the sham group in terms of effectiveness. On the other hand, Shah-Basak et al. conducted a cross-over randomized control trial in patients with a moderate degree of aphasia, with a mean baseline WAB score of 53.3. They reported that tDCS can improve the WAB score significantly compared to the sham group.[18] This difference in results can be attributed to the fact that the patients in the study by Shah-Basak et al. had less severe aphasia, which has a high recovery rate after therapy.[26] Therefore, the severity of aphasia is a crucial factor to consider when evaluating the effectiveness of therapeutic interventions.

This study utilized a dosage of 2 mA of tDCS over Broca's area (F5) combined with speech therapy, with 20 minutes per session, for five days. The dosage was adapted from the study by Fiori et al., who used 1 mA of anodal tDCS at the left Broca's area, 20 minutes per session per day, for five days. Their finding showed that this dose can enhance the naming accuracy in patients with aphasia.[9] However, our study found no significant difference in the improvement of language ability between the tDCS group and the sham group. There existed a wide range of doses of tDCS which showed the effective improvement of language ability, including 2 mA, 30 min, 10 days,[27] 2 mA, 20 min, 10 days,[18] 1 mA, 20 min, 5 days,[8, 9] or 1 mA, 20 min 1 day.[28] Nevertheless, some previous studies showed no effect of tDCS despite selecting the high dose of tDCS. For example, Fridriksson et al. administered 1 mA, 45 minutes 15 days of anodal tDCS,[12] and Polanowska et al. used 1 mA, 10 min 15 days of tDCS.[14] Even though the intensity of tDCS can be precisely determined, the amount of current that reaches the affected site may vary among individuals due to various factors such as the size and shape of the skull, scalp characteristics, and hair length. The amount of current at the target site may differ in each patient and not achieve the therapeutic effect in some cases.[29]

The selection of polarity of tDCS has been a controversial issue. Anodal stimulation at the affected site was selected in this study because it is understood to be effective and safe. Inhibiting the unaffected hemisphere by the cathode might be harmful when it is compensatory.[30] Furthermore, Rosso et al. conducted a meta-analysis. They found that the improvement of naming accuracy among individuals with post-stroke aphasia following anodal stimulation was more remarkable compared to cathodal stimulation.[31] Meinzer et al. also found that functional communication significantly improved more in the anodal tDCS group immediately after treatment and six months after treatment than in patients treated with sham tDCS.[32] However, Silva et al. applied the cathodal tDCS over the right Broca's area (F8) with a dose of 2 mA, 20 minutes per session on five consecutive days: the same dose but different polarity as our study. The improvement in correct naming was found to be significant in the tDCS group.[22] Fregni et al. reported that enhancing excitability at the affected site is more difficult than diminishing excitability at the unaffected site.[33] Thus, this may be why this study showed no significant difference between the tDCS and the sham groups.

In this study, patients with various brain lesions were enrolled, and Broca's area (F5) was selected as the stimulation site for all patients using tDCS. This decision was based on the effective nature of tDCS in a wide area. Fiori et al. also chose the left Broca's area and found a significantly different improvement in verb naming in the tDCS group compared to the sham group.[9] However, direct electrode placement on the lesion site would result in a favorable therapeutic outcome. Baker et al. selected areas for anodal tDCS based on functional magnetic resonance imaging (fMRI) activity during language tasks. Research demonstrated a significant improvement in the naming accuracy of treated items with tDCS compared to sham tDCS.[8] Nevertheless, Fridriksson et al. also placed the anodal electrode at the target area based on fMRI. However, significantly different improvements in correct naming were not found between the tDCS and sham groups.[12] The target area applying the electrode is still considered controversial. Therefore, future studies should be investigated.

Thai-WAB-AQ was selected to be the assessment tool in this study due to the reliability used in the Thai context with its focused questions, scoring system, and questionnaires based on the patient's daily life. In addition, previous studies[8,18] using this assessment tool detected the effectiveness of tDCS in improving language ability. Unfortunately, this assessment tool did not detect highly sensitive indicators such as response time. Polanowska et al. found that the anodal tDCS group obtained larger effect sizes in naming time than the sham tDCS group.[14] Silva et al. discovered a significant difference in the meantime for correct responses with strategy between the tDCS group and the sham group.[22] Also, Thai-WAB-AQ had a lengthy evaluation process, which lasted approximately 30 minutes. Some patients reported fatigue, and their decreased cooperation during the final assessment sessions could have compromised the results' accuracy.

Several limitations occurred during this study. First, many patients dropped out of this study. Therefore, more than the number of samples included in this study would be required to demonstrate the superiority of anodal-tDCS over sham-tDCS. Second, the patients in this study showed heterogeneous clinical features in terms of time from the stroke onset, type and severity of aphasia, and brain lesion site. This characteristic was seen in the actual situation in clinical practice. However, it made the result restricted in applied generalizability. Third, the assessment tool needed to be more sensitive to detect the differences between the two groups. The tool should have a response time to language tasks, particularly in naming. Finally, the one-month duration may have been inadequate to detect the therapeutic effect of tDCS. A longer-term follow-up study may reveal a greater degree of improvement.

Conclusions

This study did not show sufficient evidence to support anodal tDCS concurrent speech therapy with additional improvement in language ability beyond those observed in patients undergoing speech therapy alone, among those with post-stroke aphasia.

Disclosure

The authors declare no conflicts of interest.

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Original Article

Efficacy of Rhythmic Auditory Stimulation on Balance in Children with Cerebral Palsy: A Randomized Controlled Trial

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ABSTRACT

Objectives: Evaluate efficacy of rhythmic auditory stimulation (RAS) on balance in children with cerebral palsy.

Study design: Randomized controlled trial

Setting: Sri-Sangwan School, Bangkok, Thailand

Subjects: Children with cerebral palsy, GMFCS levels I to III

Methods: Participants were randomly allocated into RAS and control groups. All participants underwent a physical therapy involving exercises and gait training for 3 weeks. RAS group received gait training with RAS. We measured Timed Up and Go-In Children (TUG-IC), Pediatric Balance Scale (PBS), Gross Motor Function Measure (GMFM-66), and gait velocity.

Results: 22 cerebral palsy aged 7-15 years were divided into control and RAS, 11 participants per group. Results revealed improvement of TUG-IC, PBS, and GMFM-66 in both groups. The median (95% CI) difference between before and after training of TUG-IC were 1.51 (-16.35, 21.77) second in control and 0.90 (-29.38, 25.76) second in RAS. The differences in PBS were 1.5 (0.03-3.96) in control and 1 (-3.84, 1.84) in RAS. The change of GMFM-66 was 3.5 (0.38, 5.61) in control and 3 (-3.78, 3.78) in RAS. Whereas gait velocity only increased in control group. RAS showed no statistically significant improvement in TUG-IC, PBS, and GMFM-66. While control group only significantly increased PBS and GMFM-66 ($p = 0.047$, $p = 0.027$), no significant difference in TUG-IC or gait velocity. Comparison between RAS and control revealed no significant difference in TUG-IC, PBS, GMFM-66, or gait velocity.

Conclusions: The addition of RAS to physical therapy may not improve efficacy of training beyond effects of physical therapy alone.

Keywords: cerebral palsy, gait, music, physical therapy modalities, postural balance

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Introduction

Cerebral palsy is a group of neurological disorders that affect muscle tone, movement, and posture caused by non-progressive injury to the developing brain. Possible causes of cerebral palsy include infections, brain hypoxia, brain injuries, toxins or teratogenic agents, and genetic disorders.[1,2] The reported incidence of cerebral palsy is 1.5-3.5 out of 1,000 live births.[3,4] These conditions result in problems in ambulation, balance, and coordination between the upper and lower extremities, impacting daily routine, family relationships, and school activities and consequently affecting individuals' mental and emotional state.[2,3,5,6]

Regarding the difficulties in ambulation, balance, and coordination between the upper and lower extremities mentioned above, many previous studies have examined ambulation and movement in children with cerebral palsy. These studies have revealed various abnormal gait patterns, including asymmetrical gait, shortened step or stride length, slow gait velocity, loss of balance ability, uncontrollable body movements, and rhythm perception impairment.[7,8]

There are currently several approaches to treating children with cerebral palsy that aim to rehabilitate patients to support their ability to help themselves and maintain their physical ability as much as possible. The rehabilitative approach for each patient will be carefully considered regarding their abnormality. However, using more than one method together is common because there is no evidence that any method is clearly better than the others.[9]

Rhythmic auditory stimulation (RAS) aims to improve movement and gait patterns by offering auditory cueing to the patients. The auditory rhythms during RAS promote motor cortex area functioning, which positively affects gait and balance.[9-15] Studies in various countries have examined the outcome of gait patterns using RAS in children and adults with movement disorders caused by neurological diseases, stroke, Parkinson's disease, cerebral palsy, and traumatic brain injuries. It has been reported that RAS improves gait ability in patients, including steps per minute, stride length, gait velocity, and symmetrical gait pattern.[9-15]

In addition to improving gait patterns, previous studies reported that RAS enhanced balance in adults with stroke, Parkinson's disease, and cerebral palsy.[15-17] However, no previous studies have examined whether RAS improves balance in children with cerebral palsy. Therefore, the current

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study examined the efficacy of rhythmic auditory stimulation on balance in children with cerebral palsy.

Methods

Study design

This study was approved by the Human Research Ethics Committee, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand, and was registered on ClinicalTrials.gov (NCT05455970).

Participants

Children with cerebral palsy were recruited from Sri-Sangwan School in Bangkok, Thailand. Inclusion criteria were used to select patients who had been diagnosed with cerebral palsy, aged 7-15 years, with gross motor function classification system (GMFCS)[18] levels I to III, and the ability to follow commands, and for whom both the patient and their guardian provided written consent to participate in the study. Exclusion criteria were used to exclude patients who had spinal surgery or lower extremities surgery or received chemodenervation injection targeting the lower extremities within six months before participating in the study, patients who suffered from spinal or pelvic bone injury within six months before participating in the study, patients who received intrathecal baclofen pump implantation, patients who had another neurological deficit with severe movement disorder, and cases in which the patient and their guardian did not give consent.

Due to none of the previous studies between RAS and children with cerebral palsy, the sample size of this study was calculated based on data from a pilot study, three children per group, and the fact that this study aims to compare the means of the control versus the experimental group. The sample size was calculated using Timed Up and Go-In Children (TUG-IC) test scores with a mean difference of 5.31 and standard deviation of 3.39 as a variable by setting the alpha level at 0.05, a beta level at 0.2 and applying an estimated patient dropout rate of 20%. The results indicated a total required sample size of 22 patients divided into two groups of 11.

Randomization

Participants were divided into a control group and an RAS group by blocks of four randomization means with a computer program. Group allocations were placed in a sealed envelope and assigned to participants by blinded physical therapists at Sri-Sangwan School.

Materials

1. Metronome program
2. Time Up and Go-In Children (TUG-IC) test[19]
3. Pediatric Balance Scale (PBS) test[20]
4. The Thai version of Gross Motor Function Measurement-66 (GMFM-66)[21]

Intervention

After randomization, the researchers recruited patients and obtained consent after providing information about the study procedures to patients and their guardians. General information regarding age, gender, weight, height, underlying disease, records of surgery, records of medicine used, and GMFCS level was collected and assessed by the researchers.

Before undergoing the rehabilitation program, the participants were examined by a blinded outcome assessor to evaluate TUG-IC, PBS, GMFM-66, and gait velocity.

Participants from both groups underwent a rehabilitation training program involving stretching and strengthening exercises of hip and knee muscles such as gluteus medius, gluteus maximus, quadriceps, hamstrings, and gastrocnemius muscles. The program contained three sets of exercises, each containing ten movements with a 3-minute break between sets.[22,23] The control group then underwent gait training by ground walking training in the 30 meters-ambulation practice area for 30 minutes per day, five days a week, for three weeks in total, with partial weight bearing and permission to use walking aid equipment during training. In the RAS group, the rhythmic tempo was calculated by determining the number of steps per minute (cadence) for each participant that resulted in beat per minute and using the metronome to make the rhythm for cueing during ambulation training for 30 minutes per day, five days a week, for three weeks in total. The frequency and duration of training refer to previous study of RAS training in children with cerebral palsy.[7]

Participants from both groups received training from Sri-Sangwan School's physical therapists team, who had expertise in rehabilitation training and movement training in children with cerebral palsy. Each participant was received the same protocol and looked after by a team of physical therapists to ensure their safety. Patients could take breaks during training if they were fatigued.

Three weeks after completing rehabilitation training, each participant was re-assessed on the TUG-IC, PBS, GMFM-66, and gait velocity. All participants were examined by the same assessor at the beginning and the end of the training, as shown in Figure 1.

Outcome measurements

The current study sought to evaluate the balance in children with cerebral palsy. The primary outcome was TUG-IC scores, which assessed functional balance and mobility in children. The secondary outcomes were the pediatric balance scale (PBS), gross motor function measurement-66 (GMFM-66), and gait velocity, which represent functional mobility and gait stability.

Time Up and Go-In Children (TUG-IC) test.[19]

The participant sits straight with their back against a chair and their hands on their lap. When the researcher gives a signal, the participant stands up, walks straight ahead on a flat surface for 3 meters, goes around a specified object,

and walks back to the starting point. The time is measured (in seconds) from standing up from the chair to returning to the beginning sitting posture. During the test, the participant walks at their average speed and repeats it three times to determine the average score, with a 1-minute break between trials. The participant is allowed to use a walking aid. The reliability for the TUG-IC was high, with intraclass correlation coefficients (ICC) ranging from 0.970-0.995.

Pediatric Balance Scale (PBS) test[20,24]

The participant performs 14 sitting and standing postures, including sitting to standing, standing to sitting, transfers, standing unsupported, sitting unsupported, standing with eyes closed, standing with feet together, standing with one foot in front of the other, standing on one foot, turning 360 degrees, turning to look behind, retrieving an object from the floor, placing an alternate foot on a stool, reaching forward with an outstretched arm. Each posture was assessed on a 0-4-point scale, with a total possible score of 56 points. The PBS has high reliability with ICC > 0.9.

Gross Motor Function Measurement-66 (GMFM-66)[21]

The participant performs five movement activity categories to assess gross motor function: lying and rolling, sitting, crawling and kneeling, standing, walking, running, and jumping. There are 66 postures in total. Each posture is assessed on a 0-3-point scale, with a total possible score of 186 points.

Gait velocity[25]

The participant walks straight on a flat floor for 14 meters at their self-selected comfortable speed. The starting and finishing points are 2 and 12 meters, respectively. The time taken to walk 10 meters is calculated to determine the gait velocity (kilometers per hour).

Statistical methods

We analyzed participants' general information using descriptive statistics, and data were presented as the number, percentage, mean, standard deviation (SD), median, and Interquartile range (IQR) for gender, GMFCS, age, TUG-IC, and gait velocity. We conducted comparisons of the following variables before and after training using STATA version 16, the Wilcoxon signed-rank test: TUG-IC, PBS, GMFM-66, and gait velocity. We compared differences in variable data between the RAS and control groups before and after training using quartile median regression, with a value of $p < 0.05$ considered to indicate statistical significance.

Results

In the present study, 22 eligible participants completed the training program (11 in the control and 11 in the RAS groups). The baseline characteristics of the patients included gender, GMFCS, age, topography, TUG-IC, PBS, GMFM-66, and gait velocity. The results revealed that most patients were male, the average GFMCS level was level III, and the average age was 1-11 years. The median TUG-IC, PBS, GMFM-66, and the mean gait velocity between groups at baseline showed no significant differences, as shown in Table 1.

As shown in Table 2, a comparison between median TUG-IC scores before and after the training program revealed improvements of 1.51 and 0.90 seconds in the control and RAS groups, respectively; however, these differences did not reach significance within groups ($p = 0.77$ and $p = 0.90$, respectively).

The median differences in PBS scores between before and after training in the control and RAS groups were 1.5

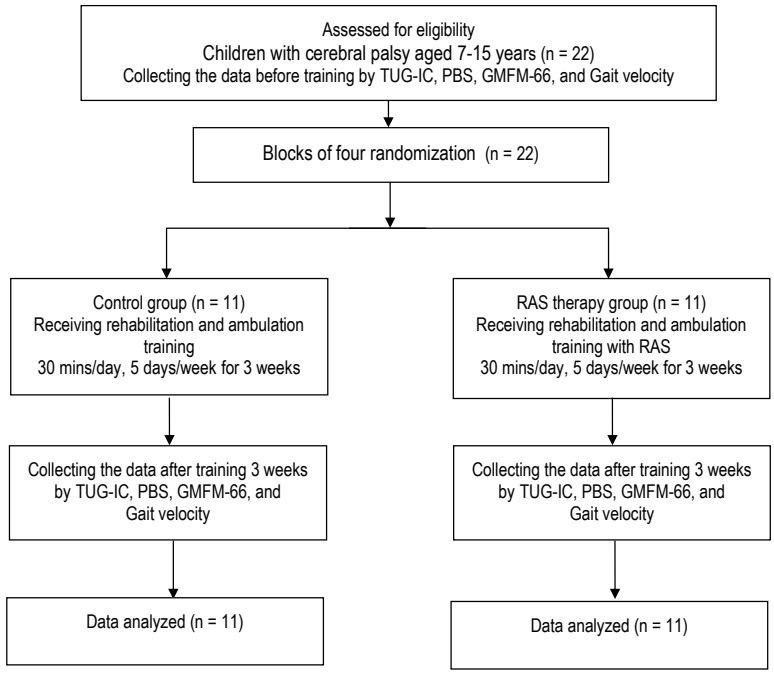

Figure 1. Protocol of research flow diagram

Table 1. Demographic and clinical characteristics of participants

Characteristics	Control (n = 11)	RAS (n = 11)	*p*-value
Gender, No (%)			0.55
Male	8 (72.73)	7 (63.64)	
Female	3 (27.27)	4 (36.36)	
GMFCS, No (%)			0.56
1	1 (9.09)	0 (0)	
2	3 (27.27)	4 (36.36)	
3	7 (63.64)	7 (63.64)	
Topography, No (%)			0.56
Spastic diplegia	7 (63.64)	8 (72.73)	
Spastic hemiplegia	4 (36.36)	3 (27.27)	
Age[1], year	11.24 (2.12)	10.30 (2.08)	0.29
TUG-IC[2], second	26.18 (11.09, 61.95)	41.98 (11.94, 53.02)	0.57
PBS[2]	18 (9.5, 31)	23 (10, 35)	0.82
GMFM-66[2]	123.5 (94, 146.5)	115 (90, 149)	0.83
Gait velocity[1], km/hr	2.22 (1.12)	2.07 (0.99)	0.73
Cadence[1], step/min	83.79 (34.78)	77.82 (19.86)	0.29

[1]Mean (standard deviation); [2]Median (interquartile range)

RAS, Rhythmic auditory stimulation; GMFCS, gross motor function classification system; TUG-IC, Time Up and Go-In Children; PBS, Pediatric Balance Scale; GMFM-66, Gross Motor Function Measurement-66

Table 2. Outcome measurement difference

Characteristics	Control (n = 11)	RAS (n = 11)	*p*-value
ΔTUG-IC[1], second	1.51 (−0.80, 11.45)	0.9 (-1.00, 8.38)	0.50
ΔPBS[1]	1.5 (0.00, 3.00)*	1 (1.00, 2.00)	0.75
ΔGMFM-66[1]	3.5 (0.00, 4.00)*	3 (1.00, 5.00)	0.49
ΔGait velocity[1], km/hr	0.02 (-0.16, 0.27)	-0.15 (-0.44, 0.04)	0.50

*Significant difference in outcome measurement between before and after training. PBS; $p = 0.047$, GMFM-66; $p = 0.027$

[1]Median (interquartile range)

RAS, Rhythmic auditory stimulation; GMFCS, gross motor function classification system; TUG-IC, Time Up and Go-In Children; PBS, Pediatric Balance Scale; GMFM-66, Gross Motor Function Measurement-66

and 1, respectively, and the median differences in GMFM-66 scores between before and after training in the control and RAS groups were 3.5 and 3, respectively. This result indicated that both PBS and GMFM-66 exhibited improvements in both groups after training, with significant increases in the control group ($p = 0.047$ and $p = 0.027$ for PBS and GMFM-66, respectively). The differences in the RAS group did not reach statistical significance ($p = 0.47$, $p = 1.00$ for PBS and GMFM-66, respectively).

Unlike other outcomes, only the median differences between before and after training of gait velocity in the control group were improved by 0.02 km/hr. In the RAS group, the median gait velocity was decreased by 0.15 km/hr after training. However, there was no significant difference between before and after training in the RAS or control groups ($p = 0.97$, $p = 0.66$, respectively).

Comparisons of TUG-IC, PBS, GMFM-66, and gait velocity before and after training revealed no significant differences in either group.

The current results indicated that the control group showed significant increases in PBS and GMFM-66 scores after training, whereas no significant changes were observed in TUG-IC or gait velocity. In contrast, the RAS group showed no significant differences between before and after training in any of the outcomes. Comparisons of the control and RAS groups revealed no significant differences between groups in TUG-IC, PBS, GMFM-66, or gait speed.

Discussion

There were previous studies of a rhythm-based approach for improving gait patterns in patients with cerebral palsy in both children and adults. However, only Efraimidou et al.[15] examined the effects of music and rhythms on the balance of adult athletes with hemiplegic cerebral palsy. The results revealed increased balance ability using the TUG and Berg balance scale (BBS), significantly improving the music and rhythmic movements training group. This previous finding differs from the results of the current study, which indicated that TUG-IC improved after training in both groups. Several differences between the Efraimidou et al.[15] study and the current study could have contributed to the lack of significant changes. First, the participants in Efraimidou's study were adult athletes with hemiplegic cerebral palsy between the ages of 22 and 50, with GMFCS levels I-II.

In contrast, in the current study, the participants were children with cerebral palsy between the ages of 10 and 11, and 65% of participants had spastic diplegia and GMFCS level III. Thus, the patients in the current study had lower ambulation abilities than those in the previous study. Moreover,

Efraimidou used rhythms for training at 90 beats per minute, in conjunction with rhythmic auditory stimulation walking practice at 70 beats per minute before the actual training. In the current study, due to younger participants, the rhythms were calculated from the pace of each participant from 30-147 steps per minute, and no rhythmic auditory stimulation practice was performed before the actual training. This difference may have improved the ability of the patients in Efraimidou's study to walk during RAS training, resulting in a significant change after training.

The differences in median TUG-IC scores before and after training in the control and RAS groups were 1.51 and 0.90 seconds, respectively. However, the difference between groups did not reach significance. Carey et al.[19] reported that variation in TUG-IC scores has a minimum clinically significant difference (MCID) of 0.22-5.31 seconds. Therefore, training in both groups can improve the efficiency of functional balance in children with cerebral palsy. The median PBS score before and after training in this study in the control and RAS groups increased by 1.5 and 1, respectively, with a significant change in the control group but not the RAS group. However, according to Chen et al.[24], the MCID for variation in PBS has a range of 3.66-5.83. Thus, the current results revealed that only physical therapy training resulted in a statistically significant improvement in balance, but this improvement is not clinically significant.

The current study used GMFM-66 assessment to detect developmental changes in movement. After training, GMFM-66 showed an increase in both groups, with a significant difference in the control group but no significant difference in the RAS group. According to Oeffinger et al.[26], the MCID of GMFM-66 is 0.8. Hence, patients in both groups' current study tended to have a clinically significant effect after training, although the GMFM-66 improvement in the RAS group did not reach statistical significance.

In the current study, as mentioned above, gait velocity was decreased after training in the RAS group. In contrast, a study by Kwak et al.[7] reported that RAS training improved gait performance in children with spastic cerebral palsy GMFCS level I-III compared with the gait training exercise, with significant improvements in gait velocity, step length, and symmetrical gait pattern. The factors causing this discrepancy between the present findings and those of Kwak's study may be related to differences in the RAS techniques used in each study. In Kwak's study, the rhythms were calculated from each participant's pace, and the rhythm rate was increased by 5% in the first week, 10% in the second week, and 15% in the third week. In contrast, in the current study, we used rhythms that were calculated from the pace of each participant and fixed the rhythm for the whole session. Gait velocity is enhanced by increasing cadence or stride length. However, the current study aimed to improve balance without increasing cadence, and the decrease in gait velocity may represent an increase in gait stability as in Katz-Leurer et al.[27]

In summary, the results showed improvement in functional balance in children with cerebral palsy after receiving physical therapy programs in both the control and RAS groups, with more improvement in the control group. RAS is a multiple-stimulation method using auditory-motor synchronization. The children should have the ability and attention to follow the rhythm. This problem caused the children in the control group to concentrate on ambulation training rather than RAS. Nonetheless, no significant efficacy difference between RAS and physical therapy after training exists.

Limitations

More than half of the participants in the RAS group were unable to follow rhythmic cueing at the beginning of each session, and one of three participants could not maintain the rhythm's speed for 30 minutes. Therefore, to avoid muscle fatigue, participants in the RAS group took more breaks than the control group, decreasing training time. In the control group, participants could adjust the speed and rhythm by themselves.

Recommendations

Children with cerebral palsy most commonly exhibit problems in ambulation, and a practice period before implementing new techniques may improve outcomes. In this study, there is no pre-exercise auditory stimulation, unlike other previous studies. Therefore, future studies should provide pre-training auditory stimulation. In some previous studies, the speed of walking and frequency of cadence may have been elevated during therapy, and such practice should be integrated with future studies.

Conclusion

Adding RAS to physical therapy may not improve training efficacy compared with physical therapy alone.

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Original Article

Functional Outcome of Patients with Post-Acute Traumatic Spinal Cord Injury after a 6-month Home-Based Rehabilitation Program and its Related Factors

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ABSTRACT

Objectives: The study aimed to evaluate the effectiveness of home-based rehabilitation programs on the functional outcomes of patients with traumatic spinal cord injuries in the post-acute phase and analyze factors associated with improved functional outcomes.

Study design: Prospective cohort study

Setting: Phatthalung Hospital, Thailand

Subjects: Patients with traumatic spinal cord injuries had a home-based rehabilitation program and 6-month follow-up at a rehabilitation outpatient clinic from April 2022 to January 2023.

Methods: The demographic and medical information was retrieved from the medical record. The Spinal Cord Independence Measure version III was used to evaluate patients' functional outcomes at the program's start and the end of the 6-month follow-up period. The Thai-HADs questionnaire was assessed at the 6-month follow-up period. The chi-square and Fisher's exact tests were used to evaluate the factors related to improved functional outcomes.

Results: A total of 76 patients participated in this study, with 76.3% of patients being men and mean (SD) age of 47.49 (14.85) years. The SCIM scores of 63.16% of patients increased throughout the follow-up period. Age, body mass index, neurological level of injury, level of paralysis, complications related to spinal cord injuries, frequency of encounter with therapists, frequency of self-exercise, and depressive symptoms were statistically significant factors associated with improved functional outcomes.

Conclusions: Home-based rehabilitation has benefits for patients with traumatic spinal cord injuries. Many factors are associated with improved functional outcomes. Healthcare workers and community support can help patients reach the highest level of independence and better reintegrate into their families and communities.

Keywords: functional independence, spinal cord injury, home care, rehabilitation

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Introduction

Spinal cord injury (SCI) is a dangerous disorder that can result in temporary or permanent disability and neurological defects. It impacts not only the patient's quality of life but also the family, community, and healthcare system.[1] The estimated incidence of traumatic spinal cord injury in developed countries was 10.4-130.6 cases per million people annually.[2,3] There are few epidemiologic studies of people with spinal cord injuries and the number of patients who received rehabilitation in Thailand, as no national data for the whole country exists.

Most motor function recovery occurs in the first six months after injury.[4] The neurological level and capacity of spared muscle groups to perform specific tasks like activities of daily living (ADL) influence the positive predictor for good functional goals and predicted outcomes.[5] Rehabilitation goals after SCI include maximizing physical independence, becoming independent in the direction of care, and preventing secondary complications.[6] Starting rehabilitation as soon as possible is encouraged. In 2019, the Ministry of Public Health implemented a health service system called intermediate care (IMC), aimed at patients with spinal cord injuries as one of the issues ensuring access to a six-month continuous rehabilitation program. The IMC program includes an intermediate-intensive IPD program, an OPD-based program, and home health care.[7] With difficult transportation, financial problems, and the limitation of inpatient rehabilitation services in rural areas, home-based rehabilitation programs were prescribed to patients.

Various people or environmental elements may influence functional outcomes, including age, complications, family support, and financial situation.[8] A prior study found that the physical environment, social factors (culture, economy, and healthcare system), the severity of the disability, and secondary complications all impact how successfully home-based rehabilitation patients perform.[9] Numerous studies have addressed difficulties such as poor continuity of care, limited access to public facilities, a lack of accessibility owing to architecture, and living independently.[10-17]

This study aimed to evaluate the effectiveness of home-based rehabilitation programs on the functional outcomes of patients with traumatic spinal cord injuries at the end of the 6-month follow-up period. In addition, this study aims to

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evaluate the factors associated with improved functional outcomes.

Methods

Study design

The Ethics Committee of Phatthalung Hospital approved this prospective cohort study research, clinical trial registration number 05/2022.

Participants

From April 2022 to January 2023, all patients with traumatic spinal cord injuries of any age and duration from onset within three months who consulted the Rehabilitation Medicine Department at Phatthalung Hospital were enrolled in the study. They participated in a home-based rehabilitation program, were able to encounter a therapist at an outpatient clinic every two weeks, and completed a 6-month follow-up program. All participants signed informed consent and assent papers. Patients were excluded if they failed to attend the 6-month follow-up visit or passed away while the study was ongoing. Patients who missed more than two consecutive outpatient appointments with a therapist were considered dropouts.

Several studies have revealed that 80-90% of patients with traumatic spinal cord injuries may have seen improved functional results during the first six months after their injury.[4,5,8,9,18] The sample size calculation was based on the previous studies by with Stata version[14,19] which used a two-sample comparison of proportions to compare the functional outcomes of the two separate groups (the ratio of increased functional score to remaining/decreased score was 9:1). For an alpha level of 0.05, a power of 80%, a one-sided test, and an estimated drop-out rate of 20% (10% to cover loss to follow-up and an additional 10% to cover exclusion for other reasons). We, therefore, included 76 cases in the study.

Materials

The Spinal Cord Independence Measure III (SCIM III) is a clinician-rated tool that was developed specifically to measure the level of independence in overall daily life activities for individuals with SCI.[20, 21] It comprised 19 items across three subscales: self-care (feeding, grooming, bathing, and dressing), respiratory and sphincter management, and mobility. Mobility is subdivided into 'room and toilet' and 'indoors and outdoors'. The total score ranges between 0 and 100, where 0 indicates total dependence, and 100 indicates complete independence.

The Thai version of the hospital anxiety and depression scale (Thai-HADs), a self-administered questionnaire, was employed to determine the anxiety and depression symptoms of the participants.[22] It comprised 14 items: seven for anxiety assessment and seven for depression assessment. Each item was on a four-point scale ranging from 0 to 3. A score of 8-10 suggested borderline anxiety or depressive symptoms, and a score of 11 indicated clinical anxiety or depression.

Study protocol

1. After receiving approval from the hospital's Ethical Review Board, those who met the inclusion criteria were asked to participate in the study.
2. After signing the informed consent form, the patients were registered, and the following baseline variables from their medical records were collected: age, gender, etiology, level of paralysis (tetraplegia and paraplegia), completeness of injury, other underlying diseases, complications, and health insurance scheme.
3. The rehabilitation program included the following;

- Physical and occupational therapy: 0.5-hour sessions with each therapist in an outpatient clinic every two weeks. Breathing exercises, ROM exercises, mobility in bed, transfer, ambulation, ADL, and assistive or adaptive equipment application were taught to the patient and primary caregiver.
- The physiatrist reviewed and changed the rehabilitation program at the outpatient clinic every four weeks. A physiatrist advised about dietary and fluid management, a bowel training program, a scheduled voiding program, and skin care.
- The rehabilitation nurse advised the abdominal massage, clean intermittent self-catheterization (CISC) training, and ulcer care.
- Patients were instructed to do a home exercise program (as prescribed by therapists) for at least 30 minutes twice daily while being monitored or assisted by a primary caregiver.
- They had to keep a logbook record to guarantee adherence to the home program. On a weekday, patients could phone the therapist with questions or concerns.
- A physiatrist evaluated the SCIM III score at the start of the program (SCIMinitial) and the end of the 6-month follow-up period (SCIMfollowup). SCIM III score changes were classified into two categories: SCIMup (patients whose SCIM score increased at the 6-month follow-up period) and SCIMdown (patients whose SCIM score decreased or unchanged at the follow-up period).
- The Thai-HADs questionnaire was assessed at the 6-month follow-up period. Patients scoring higher than seven were considered to have depressive symptoms and will be referred to the psychology department.

Outcome measurements

The primary purpose of this study was to evaluate the effectiveness of home-based rehabilitation programs on the functional outcomes of patients with traumatic spinal cord injuries at the end of the 6-month follow-up period using SCIM III. Moreover, the secondary purpose was to evaluate the factors related to improved functional outcomes.

Statistical analysis

Demographic and clinical data were reported as percentages, mean, and standard deviations (SD). The overall SCIM III score and its subdomains were observed at the program's

start and the end of the 6-month follow-up period, and the Wilcoxon signed-rank tests were used to analyze the statistical significance of the median change. The chi-square and Fisher's exact tests were used to find factors associated with improved functional outcomes in patients' demographic and clinical characteristics.

Statistical significance was set at $p < 0.05$. Statistical analysis was conducted using Stata version 14.0.

Results

From April 2022 to January 2023, 81 individuals with traumatic SCI were consulted and participated in this study at the Rehabilitation Medicine Department. During the 6-month follow-up period, four people failed to follow up, and one died (6%). They resulted in 76 patients for analysis, as shown in Figure 1.

Table 1 displays the clinical and demographic features of the 76 patients. Most (76.3%) were men. Range: 18-78 years; mean (SD) age: 47.49 (14.85) years. 47.37% of cases had average body mass indices. The three most common causes of injury were assault (15.79%), falls (32.89%), and transport (42.11%). Most patients are classified as having neurological level of injury (NLI) type D (46.06%). 43.42% had comorbid diseases; the three most common were hypertension (69.69%), dyslipidemia (51.51%), and diabetes mellitus (36.36%). At the 6-month follow-up period, 90.79% of patients had a medical history of spinal cord injury complications; the three most common were pressure injury (84.06%), musculoskeletal issues (43.48%), and urinary tract infection (26.08%). 57.89% never miss a two week therapy appointment. 64.47% reported having done the home program every day. 52.63% had feelings of depression. 47.37% had feelings of anxiety. Only 30.26% had enough income to cover their expenses and had savings. Moreover, 53.95% opted for the health insurance scheme through the disability scheme under universal health coverage.

SCIM III was used to measure the functional outcomes. As shown in Table 2, the Wilcoxon signed-rank test was used to examine differences in total score and all subdomains at the start of the program (SCIMinitial) and the end of the 6-month follow-up (SICM follow-up).

Patients in the SCIMup group had a rise in their SCIM score after the 6-month follow-up period, whereas those in

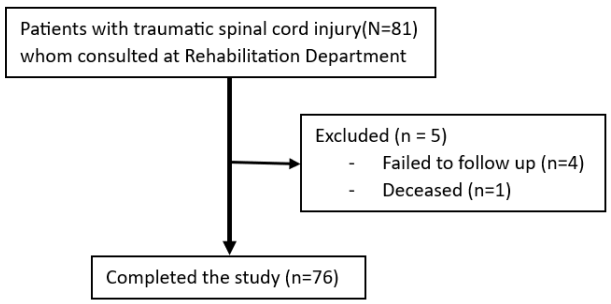

Figure 1. Schematic flow diagram of the study

Table 1. Demographics and clinical characteristics of patients with spinal cord injuries

Characteristics	Value (N = 76)
Gender	
Male	58 (76.32)
Age (yrs)[1]	47.49 (14.85)
Body mass index (BMI)[2]	
Underweight	19 (25.00)
Normal	36 (47.37)
Overweight	21 (27.63)
Cause of injury[2]	
Transport	32 (42.11)
Falls	25 (32.89)
Sports and leisure	5 (6.58)
Assault	12 (15.79)
Others	2 (2.63)
Neurological level of injury (NLI) according to ASIA impairment scale (AIS)[2]	
C1-8; ASIA A, B, C	18 (23.68)
T1-S5; ASIA A, B, C	23 (30.26)
All D	35 (46.06)
Level of paralysis[2]	
Paraplegia	42 (55.26)
Tetraplegia	34 (44.74)
Comorbid diseases (n = 33)[2]	33 (43.42)
Hypertension	23 (69.69)
Dyslipidemia	17 (51.51)
Diabetes mellitus	12 (36.36)
Cardiovascular	7 (21.21)
Psychiatric	2 (6.06)
Complication (n = 69)[2]	69 (90.79)
Pressure injury	58 (84.06)
Musculoskeletal problems	30 (43.48)
Urinary tract infection	18 (26.08)
Respiratory impairment	14 (20.29)
Pain	9 (13.04)
Frequency of encounter with the therapist (every 2 weeks)[2]	
Never missed session	44 (57.89)
Occasionally (not drop out)	32 (42.10)
Frequency of home program (logbook diary)[2]	
Every day	49 (64.47)
Every other day	13 (17.11)
Uneven	14 (18.42)
Thai-HADs (depression)[2]	
Feeling of depression	40 (52.63)
Thai-HADs (anxiety)[2]	
Feeling of anxiety	36 (47.37)
Income adequacy[2]	
Not enough	17 (22.37)
Enough for basic needs only	36 (47.37)
Enough for needs and have savings	23 (30.26)
Health insurance scheme[2]	
Universal health coverage (UHC)	16 (21.05)
Self-pay	6 (7.89)
Civil servant medical benefit scheme (CSMBS)/ Social security scheme (SSS)	13 (17.11)
Disability scheme under universal health coverage	41 (53.95)

[1]Mean (standard deviation, SD); [2]number (%)

the SCIMdown group had a decrease or no change in their SCIM score.

According to the study's findings, the SCIMup group had statistically significant increases in all subdomains and the total SCIM score (p 0.05). In addition, 28 patients (36.84%) were in the SCIMdown group, with a statistically significant decrease or unchanged score in all items (p 0.05).

The chi-square and Fisher's exact tests have been used to evaluate the relationship between factors and an improved functional outcome, as shown in Table 3. Age, body mass index (BMI), neurological level of injury (NLI), level of paralysis, spinal cord injury complications, frequency of sessions with therapy, self-exercise frequency, and depressive symptoms were found to be statistically significant factors associated with improved functional outcomes.

Discussion

This study aims to assess the effectiveness of home-based rehabilitation programs on patients with traumatic spinal cord injuries who underwent a 6-month rehabilitation period at the Rehabilitation Department of Phatthalung Hospital regarding functional outcomes.

At the start of the program, the median SCIM score of all patients was 32.71, and it got statistically significantly higher to 58.89 at the end of the 6-month follow-up period. As in all subdomains, the score at the end of the 6-month follow-up period also showed significant increases. This data may indicate that a home-based rehabilitation program would benefit people with traumatic spinal cord injuries.

In contrast to earlier studies where patients receiving hospital-based programs enhanced their functional results by as much as 80-93%, this study found that 63.16% of patients improved their functional outcomes throughout the home-based program.[4,7,10,15] Early, intensive rehabilitation therapy following the acute phase is associated with good functional improvement.[16-18] Functional recovery following SCI is anticipated to happen most quickly during inpatient rehabilitation due to spontaneous neurological recovery and the intensity of training.[23,24] Staying in a rehabilitation center was positively associated with improved rehabilitation outcomes.[25,26] To assist patients in achieving better functional outcomes. This study required patients to visit their therapist at the outpatient clinic every two weeks and document their home program adherence in their logbooks. However, the improvements in functional independence were not as big as in the hospital-based program. That would result from home-based programs' limitations, such as environmental barriers to exercise at home, caregivers, and the inadequate intensity of the home program.

In this study, 36.84% of patients were grouped in the SCIMdown group, with a statistically significant lower total score, respiration and sphincter subdomain, and room and toilet subdomain from the program's start. While the self-care subdomain and mobility indoor and outdoor subdomain were statistically significantly unchanged from the program's start. The finding could explain this that 82.15% of SCIMdown patients were classified as having C1-8 ASIA A, B, and C (NLI), which affect all motor functions of muscle below the level of the cervical spine, including certain aspects of upper extremity function, trunk function, lower extremity function, and other motor functions related to all subdomains. Also, the respiratory and sphincter subdomain and mobility subdomain correspond to the functions of the cervical NLI. Respiratory impairment, musculoskeletal problems (joint stiffness, swelling, and pain), neurogenic bowel or bladder issues, transfer or ambulation difficulties, and other spinal cord injury sequelae

Table 2. Comparing SCIM III scores at the start of the program (initial) and at the end of the 6-month follow-up (follow-up).

Items of SCIM	Overall (n = 76)		SCIMup (n = 48)		SCIMdown (n = 28)	
	Mean (95% CI)	*p*-value	Mean (95% CI)	*p*-value	Mean (95% CI)	*p*-value
Total score		0.001*		0.001*		0.003*
Initial	32.71(30.61-41.76)		41.68 (10.14-44.38)		35.43 (11.73-38.55)	
Follow up	58.89(26.18- 60.59)		68.94 (12.57-86.27)		31.13 (9.39-36.69)	
Self-care		0.001*		0.001*		0.003*
Initial	8.04(6.43-10.05)		8.21 (3.29-10.07)		8.37(2.44-10.78)	
Follow up	14.79(9.47-18.03)		14.98(2.84-19.43)		8.37(3.64-10.56)	
Respiration & sphincter		0.001*		0.001*		0.003*
Initial	14.73(13.50-24.44)		20.36(3.66-23.15)		18.11(5.99-28.06)	
Follow up	28.23(17.28-35.58)		30.23(4.43-36.99)		17.02 (5.35-22.78)	
Room & toilet		0.001*		0.010*		0.000*
Initial	3.12(2.68-7.43)		3.93(2.06-6.09)		2.86(1.42-4.57)	
Follow up	7.48(6.04-11.84)		8.00(2.33-9.26)		2.50(1.31-3.34)	
Mobility indoor & out-door		0.001*		0.002*		0.040*
Initial	4.96(3.14-7.57)		3.56(1.63-6.93)		9.81(1.02-11.83)	
Follow up	16.28(11.32-25.37)		15.73(0.56-23.78)		9.81(1.20-11.09)	

The data were analyzed using Wilcoxon signed rank test (statistic significant at $p < 0.05$)

SCIMup (patients whose SCIM score increased at the end of the 6-month follow-up period)

SCIMdown (patients whose SCIM score decreased/unchanged at the end of the follow-up period)

Table 3. Factors associated with improved functional outcome

Factors	Group		*p*-value
	SCIMup (n = 48)	SCIMdown (n = 28)	
Gender			
Male	37 (77.08)	21 (75.00)	0.837*
Age (years)			0.024*
40 or less	19 (39.58)	11 (39.29)	
41-60	23 (47.92)	12 (42.86)	
More than 60	6 (12.50)	5 (17.85)	
Body mass index (BMI)			0.027*
Underweight	13 (27.08)	6 (21.43)	
Normal	27 (56.25)	9 (32.14)	
Overweight	8 (16.67)	13 (46.43)	
Neurological level of injury (NLI)			0.009**
C1-8; ASIA A, B, C	17 (35.42)	23 (82.15)	
T1-S5; ASIA A, B, C	21 (43.75)	3 (10.71)	
All D	10 (20.83)	2 (7.14)	
Level of paralysis			0.008
Paraplegia	32 (66.67)	10 (35.71)	
Tetraplegia	16 (33.33)	18 (64.29)	
Comorbid disease			0.301**
None	25 (52.08)	16 (57.14)	
1-2 diseases	14 (29.17)	4 (14.29)	
3 or more	9 (18.75)	8 (28.57)	
Complications related to spinal cord injuries			0.029**
None	18 (37.50)	5 (17.86)	
1-2 complications	21 (43.75)	9 (32.14)	
3 or more	9 (18.75)	14 (50.00)	
Frequency of encounter with the therapist (every 2 weeks)			0.038*
Never missed session	31 (64.58)	13 (46.43)	
Occasionally (not drop out)	17 (35.42)	15 (53.57)	
Frequency of self-exercise (logbook diary)			0.032*
Everyday	34 (70.84)	15 (53.57)	
Every other day	7 (14.58)	6 (21.43)	
Uneven	7 (14.58)	7 (25.00)	
Thai-HADs (depression)			0.004*
Feeling of depression	20 (41.67)	20 (71.43)	
Thai-HADs (Anxiety)			0.102**
Feeling of anxiety	20 (41.67)	16 (57.14)	
Income adequacy			0.326*
Not enough	10 (20.83)	7 (25.00)	
Enough for basic needs only	23 (47.92)	13 (46.42)	
Enough for needs and have savings	15 (31.25)	8 (28.57)	
Health insurance scheme			0.413**
Universal health coverage (UHC)	11 (22.92)	5 (17.86)	
Self-pay	4 (8.33)	2 (7.14)	
Civil servant medical benefit scheme (CSMBS)/Social security scheme (SSS)	10 (20.83)	3 (10.71)	
Disability scheme under universal health coverage	23 (47.92)	18 (64.29)	

*The data were presented as numbers (percent) and analyzed using the Chi-square test, **Fisher's exact test (statistic significant at $p < 0.05$)
SCIMup (patients whose SCIM score increased at the end of the 6-month follow-up period)
SCIMdown (patients whose SCIM score decreased/remained unchanged at the end of the follow-up period)

are all possible. Prior studies discovered that patients who experienced complications had secondary complications that were considered to have negatively impacted functional outcomes.[10,15,17] As this study found, 82.14% of patients in the SCIMdown group had complications from spinal cord injury, compared to only 47.92% in the SCIMup group.

After using the Chi-square test and Fisher's exact test to evaluate the relationship between factors and improved functional outcomes, there were eight factors with statistically significant relationships to improved functional outcomes at the 6-month follow-up: age, body mass index (BMI), neurological level of injury (NLI), level of paralysis, complications related

to spinal cord injuries, frequency of encounter with a therapist, frequency of self-exercise, and depressive symptoms.

The elderly population's neurological recovery fails to improve functional mobility, which is related to reduced cardiovascular endurance and other medical conditions. It has been reported that older patients with SCI have less potential than younger patients to translate neurological improvements into functional recovery.[27,28] An injury at a younger age can result in better functional outcomes.[29,30] According to a previous study, people aged 35-55 showed the most remarkable improvement. In contrast, those aged 70 and older showed the least.[31] As the percentage of young patients in the SCIMup group was higher in this study than in the SCIMdown group, it is recommended that age appropriate individualized treatment techniques for patients be employed to meet their needs better and achieve their rehabilitation goals.

Previous studies indicated that being overweight was one of the risk factors for more significant spinal cord complications, mobility problems, and community transportation barriers.[23,29,32,33] In this study; the SCIMdown group had a higher percentage of overweight patients than the SCIMup group. Thus, the SCIM score's function related to the mobility subdomain is diminished.

The most significant predictor of functional recovery was the neurological level of injury (NLI).[5] Patients with high levels of SCI have poorer potential for neurological recovery. Patients with lower levels of injury have better outcomes for traumatic spinal cord lesions.[5,8] Patients with lower neurological levels of the lesion (thoracic and lumbar compared to cervical) are six times more likely to see improvement in their Functional Independence Measure (FIM) score.[33] In this study, 82.15% of patients in the SCIMdown group were classified in C1-8 ASIA A, B, and C, compared to only 35.42% in the SCIMup group. The greater the severity of spinal cord damage, the smaller the capacity of the spared muscle group. The muscles needed to perform specific tasks in activities of daily living (ADL) were diminished, which was related to difficulty maintaining function.

Five quantitative studies identified a variety of health complications, including pain, pressure injury, neurogenic bladder, urinary tract infection (UTI), spasticity, contracture, tightness, and sleep problems, as critical factors in reducing mobility and community participation in individuals with spinal cord injuries.[31,34-37] According to Jansen MP et al.'s study, the majority of patients in the home-based program who had problems had to return to the inpatient section for treatment, which negatively influenced functional outcomes.[38] Similarly to this study, 82.14% of the SCIMdown group experienced spinal cord injury sequelae due to their inability to enhance functional outcomes.

According to this study, more frequent therapy sessions are related to better functional outcomes. In the SCIMup group, 64.58% of patients never missed a session, compared to 46.43% in the SCIMdown group. These findings agree with prior studies, which found that patients with the same level of injury who participated more actively in rehabilitation sessions had higher functional outcomes than those who were less active.[38,39] The skills and knowledge obtained from the rehabilitation team are more impactful on independent functional mobility when they can be applied in a community setting.[40-43] When the patients visited the therapist or physiatrist, they likely obtained program revisions that personalized and appropriated themselves.

The World Health Organization (WHO) recommends at least 150 minutes per week of moderate-intensity aerobic activity (or 75 minutes per week of vigorous-intensity aerobic activity) and muscle-strengthening activities twice weekly.[44] The International Spinal Injury Society (ISCoS) recommends that for cardiorespiratory fitness and muscle strength benefits, adults with SCI should engage in at least 20 minutes of moderate to vigorous intensity aerobic exercise 2 times per week, and three sets of strength exercises for each major functioning muscle group at a moderate to vigorous intensity two times per week (a strong recommendation). Moreover, for cardiometabolic health benefits, adults with SCI should engage in at least 30 minutes of moderate-to-vigorous-intensity aerobic exercise three times per week (a conditional recommendation).[45] People with SCI most frequently experience intrapersonal (e.g., a lack of energy, motivation, or knowledge) and environmental or organizational (e.g., a lack of accessible or affordable fitness facilities, equipment, and knowledgeable staff).[46,47] Those chronically inactive or unable to reach standard exercises are also at risk for poor metabolic and cardiovascular health and secondary problems such as pressure injury, infections, and depression.[48-50] In this study, patients in the SCIMup group revealed that 70.84% of patients claimed to do daily home exercises daily, compared to 53.57% in the SCIMdown group. Noncompliance with a home program or inadequate self-exercise may impact functional outcomes.

Depression is the most frequent psychiatric condition following a spinal cord injury, with a wide range of prevalence estimates from 8.8% to 60% among inpatients and those in the community.[51] Previous research found a relationship between depression and functional independence.[51,53,54] Because traumatic SCI can suddenly deteriorate function, untreated depressive symptoms may persist continuously and have a negative impact on health-related quality of life.[32,33,38,51] This includes secondary conditions that result in less functional gains, decreased functional independence, increased secondary complications, and reduced life expectancy.[52,53] Short-term rehabilitation goals should include early diagnosis and treatment of depressive symptoms within 2-4 weeks. In this study, only 41.67% of patients in the SCIMup group re-ported having depressive symptoms, compared to 71.43% in the SCIMdown group. Depression symptoms might interfere with a person's capacity to participate in activities and make them less motivated to participate in rehabilitation programs.

Therefore, several variables, such as age, body size and weight, associated injuries and complications, motivation, family support, premordid lifestyle, educational background, financial situation, healthcare system, and community facility could affect functional outcomes in patients who received home-based rehabilitatio.[5,8,15,17,53] Opportunities at home and in the community, barriers to accessing rehabilitation care, and a lack of health centers to treat secondary complications may limit home-based rehabilitation. In this study, 66.67% of patients in the SCIMup group versus 35.71% in the SCIMdown group had paraplegia. This study proposed home-based rehabilitation program may be more suitable for paraplegia patients than tetraplegia patients.

Limitations of this study were

1. Some patients were excluded from this study because they could not adhere to the follow-up protocols during the program, which was carried out in a provincial hospital. With the development of telemedicine, medical staff can interact with patients in their homes via communication technologies (such as smartphones or realtime video feeds over the Internet). Future studies should include this intervention as part of home-based rehabilitation.

2. Because this study was conducted in a home-based rehabilitation environment, essential factors such as program maintenance, caregiver concerns, and community integration were not addressed. Future research should be considered as a result.

Conclusions

In conclusion, patients with severe spinal cord injuries who attended home-based rehabilitation revealed improved functional outcomes. From this study, factors related to improved functional outcomes were age, body mass index (BMI), neurological level of injury (NLI), level of paralysis, complications related to spinal cord injuries, and depressive symptoms. The frequency of encounters with therapists and self-exercise sessions are additional environmental factors. The program should be considered for patients with paraplegia or those with lower neurological levels of lesions who require a maintenance therapy program. However, in the home-based program, the physiatrists should be concerned about the comprehensive care and investigation for neurogenic bladder, e.g., cystometry or ultrasound kidneys, ureters, and urinary bladder (KUB), or renal function evaluation. Also, early detection of secondary complications and depressive symptoms is essential for early treatment and assessment of other factors related to improved functional outcomes in planning for better recovery.

Disclosure

The authors declare that they have no conflicts of interest.

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Original Article

An Observational Longitudinal Study Investigating the Effectiveness of Adjustable Splint on Individuals with Hallux Valgus

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ABSTRACT

Objectives: To explore the effectiveness of an adjustable splint to decrease hallux valgus angle and pain at the first metatarsophalangeal joint. In addition, to discover complications and participants' satisfaction

Study design: Prospective cohort analytical study design

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

Subjects: Thirty-eight patients with hallux valgus deformity at moderate to severe degrees (hallux valgus angle 30°- 50°) were recruited from March to May 2021.

Methods: The participants were asked to use an adjustable splint for 6 hours daily for 12 months and continue their current treatment regimen. They were also asked to record the duration of wearing the splint and complications in a logbook every week. Hallux valgus angle measured from radiography and pain numeric rating scale (pain NRS) were evaluated at baseline, 6 months, and 12 months after getting the splint.

Results: Thirty-two participants returned for follow-up at the end of the study. Per protocol and intention to treat, analyses showed a decreased hallux valgus angle and pain at the first metatarsophalangeal joint with a statistically significant difference (p = 0.001). The satisfaction scores with the adjustable splint were high in every domain. No participant had serious complications. The common complication was splint slip (33.3%).

Conclusions: Wearing an adjustable splint for 12 months in patients with moderate to severe degrees of hallux valgus could decrease hallux valgus angle and pain at the first metatarsophalangeal joint without serious complications.

Keywords: foot deformity, hallux valgus, pain, adjustable splint, orthotic device

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Introduction

Hallux valgus is a common forefoot problem. This deformity is described as a static subluxation of the first metatarsophalangeal joint, characterized by lateral deviation of the first toe and medial deviation of the first metatarsal bone.[1] This condition is a slow progressive deformity.[2]

The severity of hallux valgus can be classified into mild, moderate, and severe degrees from clinical presentations (such as degree of the first toe rotation) and hallux valgus angle from radiography.[3]

The causes of hallux valgus deformity are multifactorial such as age,[4] female,[5] pes planus,[6] tightness of the Achilles tendon,[7] degenerative of the first metatarsophalangeal joint, ligamentous hyperlaxity, first-ray hypermobility,[8] and cerebral palsy. Family history is a major risk factor. Improper shoe-wearing behaviors, especially pointed, high-heeled shoes, are also important causes.[9,10] Hallux valgus occurs in women 15 times more than in men.

Many problems occur with the hallux valgus deformity, such as pain at the first metatarsophalangeal joint, friction between bunion and shoe, friction at the first web space, neuropathic pain from over-stretching of medial cutaneous nerve, bursitis, callus, metatarsalgia and overriding of the second toe on the first toe.

The primary objectives of treating individuals with hallux valgus are to alleviate symptomatic pain and correct or prevent the progression of the deformity. Conservative treatment options include wearing properly fitting shoes with a wide toe box, as well as utilizing foot orthoses. Previous studies have demonstrated the effectiveness of total contact orthoses with fixed toe separators in relieving pain,[11,12] improving toe alignment, and enhancing walking ability.[11] Other conservative measures encompass soft tissue stretching, muscle strengthening exercises, and therapeutic modalities. Various orthoses such as toe separators, hallux valgus splints, and hallux valgus straps have been prescribed.

In a previous study conducted by Chadchavalpanichaya N, it was found that wearing a custom-mold room temperature vulcanizing silicone toe separator for a duration of one year resulted in a decrease in hallux valgus angle and alleviation of big toe pain in patients with a moderate degree of hallux valgus.[13] However, this device required customization by a

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skilled orthotist and came at a cost of approximately 50 USD per piece. This posed a challenge for patients seeking access to the device. For more convenience, many physicians prefer to prescribe prefabricated orthotic devices. The study from Kandang C discovered that wearing a prefabricated silicone toe separator for a year can decrease the progression of the hallux valgus angle. However, this prefabricated device is suitable only for patients with mild to moderate hallux valgus.[14] Another study from Chadchavalpanichaya N and Chueluecha C revealed that wearing a prefabricated elastic hallux valgus strap for a year can decrease pain at the first metatarsophalangeal joint. However, this device cannot decrease the progression of the hallux valgus angle more than using only wide-toe box shoes.[15]

An alternative prefabricated orthotic device is an adjustable hallux valgus splint. This device is made of plastic and lined with soft foam to provide cushioning. This splint has two soft bands for strapping it with a foot and a big toe. Since this orthotic device has a joint, it can be adjusted along the angle of hallux deformity.

The study from Plaass C revealed that wearing an adjustable hallux valgus splint in patients who had big toe pain for three months can decrease the pain. This orthosis cannot decrease the hallux valgus angle.[16] Another study from Moulodi N compared the effectiveness of an adjustable hallux valgus splint and a non-adjustable one.[17] The study presented that wearing an adjustable splint can decrease the hallux valgus angle and pain at the first metatarsophalangeal joint when walking more than wearing a non-adjustable one. However, this study collected the data after wearing the splint for only a month and used a goniometer instead of a radiograph for monitoring hallux valgus angle. Furthermore, the average age of the population in this study was 22 years old. This age group is not the expected population in clinical practice.

However, no study reports the effectiveness of an adjustable hallux valgus splint to decrease the hallux valgus angle progression in patients with a moderate to severe degree of hallux valgus.

Therefore, the primary objective of this study was to determine the effectiveness of the adjustable hallux valgus splint in decreasing the hallux valgus angle progression in individuals diagnosed with moderate to severe degree hallux valgus. In addition, this study would also monitor pain at the first metatarsophalangeal joint, related complications, patient compliance, and satisfaction with the adjustable hallux valgus splint.

Methods

The study protocol was reviewed and approved by the Institutional Review Board at Siriraj Hospital, Bangkok, Thailand (Si 1063/2020).

Study design

Prospective cohort analytical study design

Participants

Thirty-eight patients who had hallux valgus and visited the Foot Clinic, Siriraj Hospital from March to May 2021 were recruited to participate in this study. A physiatrist performed a foot examination and provided the clinical diagnosis and severity of hallux valgus.

Inclusion criteria

- Age not less than eighteen years old
- Having moderate to severe degree of hallux valgus (hallux valgus angle: 30°– 50°)
- Be detected hallux valgus for more than 5 years.

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

Exclusion criteria

- Having acute inflammation of the first metatarsophalangeal joint
- Having limitation of the first metatarsophalangeal joint ROM
- Having active foot numbness or foot ulcer
- Having ulcer or maceration at the first web space
- Continuous usage of any type of hallux valgus strap or toe separator in a past year
- History of hallux valgus surgery
- Having a condition that cannot answer the questionnaire

Sample size calculation

To determine the proper sample size, the Independent Student's t-test was utilized, taking into account the results of a previous study.[13] Based on a power of 0.80 to detect a significant difference with a 5% type I error (p = 0.05, two-sided), and a clinically significant difference in hallux valgus angle of 5°,[13-15] a sample size of 33 patients was calculated for this study. Ultimately, a sample of 38 participants was recruited, with a predictable 15% drop-out rate.

Materials

An adjustable splint selected for this study was a dynamic bunion splint, universal size Tynor Orthotics® brand. (Figure 1) It is made of plastic with a joint, and a cushioned pad provides cushioning for enhanced comfort. There are two soft straps for strapping a splint with a big toe and foot. It is easy to use and maintain.

Study protocol

An information sheet with verbal explanation was provided to the patients, and a signed informed consent form was obtained before the study.

In the beginning, demographic data such as age, gender, type/ height of daily-used shoes, side of foot deformity, duration of hallux valgus, as well as problems related to hallux valgus such as pain at the first metatarsophalangeal joint, toe friction, and paronychia were collected. Then, a physiatrist

performed a foot examination to record the point of tenderness and callus.

After that, the participants were recommended how to use an adjustable splint and asked to wear it every day for at least six hours per day during daytime and/or nighttime and recommended to wear proper shoes: low-heel shoes with a wide-and-deep toe box. The participants were also asked to record the duration of wearing the adjustable splint and complications caused by the device in a weekly logbook. They were instructed to contact the research team directly if any complications, such as abrasion, pain, or discomfort, occurred.

The primary outcome was the hallux valgus angle, which was assessed at baseline, 6-month, and 12-month follow-up. The hallux valgus angle was measured with a weight-bearing anteroposterior radiograph. (Figure 2)[1] It was measured by two well-trained physiatrists who did not assess the participants. The angles evaluated by the two assessors were averaged and used for further analyses.

The secondary outcomes were the first metatarsophalangeal pain, friction at the bunion, friction at the first web space, compliance, complications related to the adjustable splint, and the participant's satisfaction. At baseline, 6-month follow-up, and 12-month follow-up, pain and friction experienced within the last 24 hours were scored from 0 (no pain/ friction) to 10 (worst pain/ friction). Patient compliance was measured with daily usage of the adjustable splint, which was then averaged as weekly use and recorded in the logbook. Any complications caused by the device were also recorded. At the end of the study, patient satisfaction in five sub-domains - pain reduction, convenience in wearing, cosmetic appearance, maintenance, durability, and overall satisfaction, were recorded. The NRS was scored as 0 (dissatisfaction) to 10 (most satisfaction).

Statistical analysis

All statistical analyses were performed using PASW Statistics (SPSS) 18.0 (SPSS, Inc., Chicago, IL, USA), and a *p*-value of less than 0.05 was considered a statistically significant difference. Age, body mass index, hallux valgus angle, and patient compliance using the adjustable splint (hours/day) were calculated by means and standard deviations (SD). The median (IQR) was calculated for the duration of hallux valgus problem (months), the first metatarsophalangeal pain, friction at the bunion, friction at the first web space, and patient satisfaction (NRS from 0 to 10). Gender, daily-used shoes, sides, hallux valgus problems, foot examination results, and any complications from the adjustable splint usage were calculated as a number and percentage.

As measured in degrees, the primary outcome of hallux valgus angle was reported by both per protocol (PP) and intention-to-treat (ITT) analysis. A repeated-measures analysis of variance (ANOVA) was used to analyze the differences between baseline, 6-month, and 12-month follow-up. The Friedman test was performed to determine the secondary outcomes of pain at the first metatarsophalangeal joint. Bonferroni correction for multiple comparisons was used to analyze the difference of the data at baseline, 6-month, and 12-month follow-up.

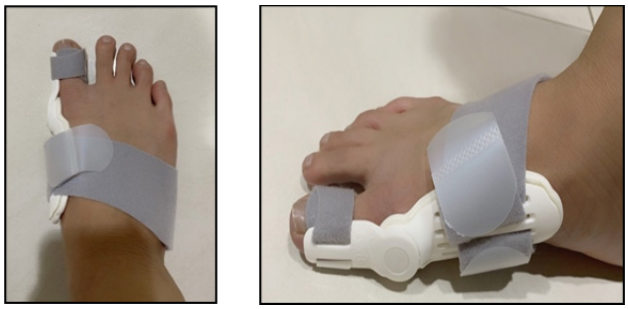

Figure 1. An adjustable splint, universal size; Tynor Orthotics® brand.

Results

Thirty-eight participants joined in the study. Thirty-three and 32 participants returned to follow-up at the hospital six months and twelve months, respectively. Five participants dropped out at 6-month follow-up: one of them due to pain, one of them due to itching, two of them due to the COVID-19 situation, and one of them lost contact. Thirty-three participants answered the questionnaires, but 32 returned to x-ray at the 12-month follow-up because one participant denied going to the hospital due to COVID-19. (Figure 3)

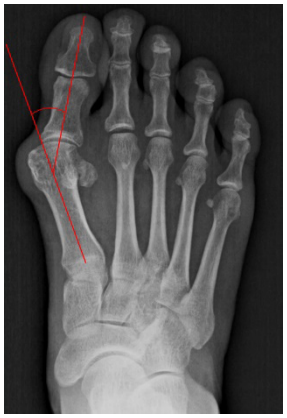

Figure 2. The hallux valgus angle measures were demonstrated on weight-bearing anteroposterior radiographs.

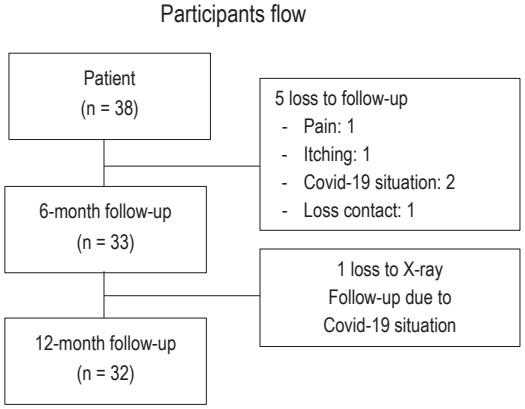

Figure 3. Participant flow

The characteristic data and foot problems of the participants are shown in Table 1. Most participants were females (97.4%) with a mean age of 63.5 years. Nearly all of the patients had hallux valgus on both sides. The median duration was 10 years. Thirty participants wore closed shoes (78.6%), and 27 were used to wearing narrow-toe box shoes (71.1%).

The top four most common problems from hallux valgus were callus (65.7%), friction at the bunion or friction at the first web space (57.8%), shoes-fitting problems or difficulty in finding comfortable shoes (52.6%), and pain at bunion from shoe compression (50%). The hallux valgus associated findings were callus at the first metatarsal head (73.7%), calluses at the medial side of the big toe (57.9%), and tenderness at the first metatarsal head (13.2%).

Table 1. Demographic data (38 patients)

Characteristics	
Age (years)[1]	63.5 (9.8)
Gender[2]	
Female	37 (97.4)
Body mass index (kg/m^2)[1]	23.2 (3.57)
Hallux valgus problem	
Duration[3]	10 (7.8, 20)
Side[2]	
Right	1 (2.6)
Bilateral	37 (97.4)
History type of used shoes[2]	
Closed toe box	30 (78.9)
Opened toe box	8 (21.1)
Wide toe box	11 (28.9)
Narrow toe box	27 (71.1)
Shoe height (inch)[2*]	
Low heel	17 (44.7)
1-2 inch	15 (39.5)
2-4 inch	4 (10.5)
> 4 inch	2 (5.3)
Complications related hallux valgus[2*]	
Pain	
Pain at bunion from shoe compression	19 (50.0)
Pain at the first metatarsophalangeal joint	8 (21.0)
Redness/ friction	22 (57.8)
Bursitis	0 (0.0)
Paronychia	4 (10.5)
Callus	25 (65.7)
Overriding toe	9 (23.6)
Cosmesis problems	14 (36.8)
Shoe fitting problems	20 (52.6)
Foot examination 2[*]	
Tenderness at	
1st metatarsal head	5 (13.2)
2nd-5th metatarsal head	1 (2.6)
Callus at	
The medial side of big toe	22 (57.9)
First metatarsal head	28 (73.7)
Tip of 2nd-5th toes	1 (2.6)
2nd-5th metatarsal heads	0 (0.0)

[*]Some patients had more than one problem.
[1]Mean (SD), [2]number (%), [3]median (interquartile range)

Primary outcome

The results demonstrated the decrease of hallux valgus angle at baseline, 6-month, and 12-month follow-up and were reported in both per protocol (PP) and intention-to-treat (ITT) analysis, as shown in Table 2. From the PP analysis, the means (SD) of the hallux valgus angle were 36.77 (6.03) at baseline, 35.87 (6.37) at a 6-month and 34.94 (6.39) at a 12-month follow-up with statistically significant difference ($p < 0.001$). From the ITT analysis, means (SD) of the hallux valgus angle were 36.55 (5.60) at baseline, 35.71 (6.03) at a 6-month and 34.95 (6.04) at a 12-month follow-up with statistically significant difference ($p < 0.001$), as well.

Secondary outcomes

Regarding pain and friction, based on the PP and the ITT analyses, the result showed a statistically significant decrease in pain at the first metatarsophalangeal joint, friction between bunion and shoes, and friction between the first web space at 6-month and 12-month follow-up when compared with the baseline ($p = 0.001$) as shown in table 3.

Regarding compliance with the usage of the adjustable splint, the data from the participants' logbook showed that the compliance was higher than being recommended, with a mean (SD) of 6.60 (1.50) hours per day and 6.5 (0.70) days per week (43.9 (11.7) hours per week).

Table 4 indicates that 15 (45.5%) participants had minor complications while using the device. They did not register them as serious complications. The most reported complication was quickly slipping a device from the first toe.

The satisfaction scores with the adjustable splint were high in every domain. The median (IQR) overall satisfac-

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

	Per protocol		*p*-value	Intention to treat		*p*-value
Hallux valgus angle (degrees) Mean (SD)	Baseline (n=38)	36.77 (6.03)	< 0.001[a]	Baseline (n=38)	36.55 (5.60)	< 0.001[a]
	Month 6 (n=33)	35.87 (6.37)		Month 6 (n=38)	35.71 (6.03)	
	Month 12 (n=31)	34.94 (6.39)		Month 12 (n=38)	34.95 (6.04)	

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

Table 3. Pain at the first metatarsophalangeal joint, friction between bunion and shoe, friction between 1st webspace measured by numeric rating scale (0 as lowest symptoms, 10 as the most severe symptoms) at month 0, month 6 and month 12 follow-up

	Per protocol			*p*-value	Intention to treat			*p*-value
	Baseline (N=38)	Month 6 (N=33)	Month 12 (N=32)		Baseline (N=38)	Month 6 (N=38)	Month 12 (N=38)	
Hallux valgus pain	3 (0-3)	0 (0-1)	0 (0-1)	< 0.001	2.5 (0-3)	0 (0-1.3)	0 (0-1)	< 0.001
Friction between bunion and shoe	3 (2-5)	2 (1-3)	2 (1-2)	< 0.001	3 (2-5)	2 (1-3)	2 (1-2.3)	< 0.001
Friction between 1st webspace	2.5 (0.3-5)	2 (0.3-3)	2 (0.3-3)	< 0.001	2.5 (0-5)	2 (0-3)	1.5 (0-3)	< 0.001

Median (interquartile range); *p*-value analyzed by Friedman test, statistically significant at $p < 0.05$

Table 4. Complications and problems of using the hallux valgus adjustable splint

Complications	N (%)
No	18 (54.5)
Yes	
Easily to slip	11 (33.3)
Discomfort or mild pain at the bunion	3 (9.0)
Rash	1 (2.6)

N (%): number of participants = 33

Table 5. Satisfaction with an adjustable splint (n = 33)

Type median (interquartile range)	Satisfaction score
Pain reduction	7 (6-8)
Convenience in wearing/ easy to use	9 (7.5-9)
Cosmesis appearance	8 (7-9)
Maintenance	9 (8-9)
Durability	7 (7-8)
Overall	8 (7-8)

Measured by a numeric rating scale (0 as dissatisfied, 10 as the most satisfied)

tion score was 8 (7-8). The two subdomains with the highest scores were easy to use and maintain, as shown in Table 5.

Discussion

Over time, hallux valgus angle usually progresses due to the instability of the first metatarsophalangeal joint and the weakness of soft tissue around the joint. The previous study from Chadchavalpanichaya N showed that recommending the patient to wear wide toe box shoes does not prevent such deformity as this study followed the hallux valgus angle of those who had a moderate degree of hallux valgus for 12 months and found significantly increased hallux valgus angle in the control group.[13]

Regarding the hallux valgus angle, the results of the present study showed that wearing an adjustable splint can decrease the hallux valgus angle by about 1.8°. The findings align with the research of Moulodi N et al.[17] The study presented that wearing a splint can decrease the hallux valgus angle by up to 2-3°. However, this study collected the data using a goniometer instead of a radiograph to monitor hallux valgus angle. Moreover, the average age of the population was 22 years old. This finding is not the common population in clinical practice.

Regarding the hallux valgus angle and pain at the first metatarsophalangeal joint, the previous study from Chadchavalpanichaya N revealed that wearing a custom-mold room temperature vulcanizing silicone toe separator for a year can decrease the hallux valgus angle and pain in patients who had a moderate degree of hallux valgus.[13] But this device had to be custom-made by a skilled orthotist. Furthermore, it costs about 50 USD per piece. This problem makes it difficult for patients to get this device. Therefore, our current study aimed to evaluate the effectiveness of an adjustable splint as an alternative solution. These splints are readily available at drug stores or online stores and are priced at a more affordable rate of around 10 USD. Our assumption is that both the custom-molded device and the adjustable splint have a similar effect in reducing hallux valgus angle and pain. This is achieved by allowing the soft tissues and nerves on the medial and lateral aspects of the big toe to return to a more anatomical position. As a result, the splints prevent the shortening of soft tissues on the lateral aspect of the big toe and the overstretching of soft tissues and nerves on the medial aspect, ultimately leading to a reduction in pain at the big toe and the first metatarsophalangeal joint.

Regarding complication, when compared with the custom-mold toe separator,[15] our study showed a higher rate of complications, especially in easily slipping a device from the first toe. Because of using the device for a while, the strap lost its tightness. Although this device has to be changed every six months, it still costs less than the custom-made one.

Regarding satisfaction, the subdomains with the highest scores were easy to use and maintain. An adjustable splint selected for this study was a dynamic bunion splint with a joint. This component provides the splint to move with the big toe when the patient walks. Since it is made of plastic, it is lightweight and easy to maintain. Since the splint can reduce pain at the first metatarsophalangeal joint and be easy to use, compliance with the splint was higher than recommended (6 hours). When comparing the participant's compliance with the orthosis between the custom-mold toe separator and this device,[13] the present study shows the exact compliance.

Although wearing an adjustable splint can decrease the hallux valgus angle less than the clinically significant difference angle (5°). This device is still one of the treatments of choice in clinical practice. The hallux valgus angle usually progresses overtime because of the instability of the first metatarsophalangeal joint and the weakness of soft tissue around the

joint. The devices that can decrease the progression of hallux valgus angle are still beneficial.

The present study had some limitations. By way of its design, it was a cohort analytical study that had no control group. For more substantial evidence, a randomized controlled trial study should be conducted.

Conclusions

Wearing an adjustable splint for 12 months in patients with moderate to severe degrees of hallux valgus could decrease hallux valgus angle and pain at the first metatarsophalangeal joint without serious complications.

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Original Article

Factors Contributing to Cardiac Rehabilitation Uptake Among Patients with Coronary Artery Disease in Thailand: A Nationwide Cross-Sectional Study

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ABSTRACT

Objectives: This study aimed to identify factors contributing to cardiac rehabilitation (CR) uptake among patients with coronary artery disease (CAD) in Thailand.

Study design: A descriptive survey study

Setting: Data collection took place at an urban and a rural hospital.

Subjects: Patients were eligible for the study if they had been referred for CR by the medical staff during their in-patient stay.

Methods: Data were collected from June 2018 to July 2019. Patients with CAD attending either the urban or the rural hospital completed the Cardiac Rehabilitation Barriers Scale (CRBS) questionnaire which surveyed barriers to CR uptake.

Results: The mean age of the 138 respondents was 64 years with 68.8% aged 60 or older; 70% were male, and 67.4% were CR attendees. Patients aged 60-69 were found to have the highest uptake of CR. Rural patients with CAD differed from those from urban areas in having a lower level of education (X^2 (2, n = 67) = 14.58, p = 0.001, *phi*= 0.466) and lower family income (X^2 (2, n = 67) = 9.60, p = 0.008, *phi* = 0.379). Rural patients with fewer years of formal education and those who were farmers were less likely to attend CR. Rural patients reported more barriers to CR than did urban participants. The main barriers to CR uptake for rural patients were distance from and transportation to the clinic.

Conclusions: While the existing CR hospital-based programs in Thailand may be appropriate for urban patients with CAD, they are less useful for patients living in rural areas. Existing CR programs should be modified to include more nuanced approaches to CR suitable for rural patients.

Keywords: rehabilitation, cardiac rehabilitation, secondary prevention, cardiovascular diseases, barrier, attendance

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Introduction

Coronary artery disease (CAD), also referred to as coronary heart disease (CHD), is mainly caused by coronary atherosclerosis, which results from the coronary arterial wall response to an inflammatory process.[1] CAD is the leading cause of death globally, with annual mortality from CAD approximately 9.1 million worldwide,[2] which is almost a half the total number of deaths (18.6 million) in 2019 from cardiovascular diseases (CVD).[2] Globally, it is estimated that in 2019, 197.2 million people were living with CAD, and that the number of people with CAD increased by 103.5% from 1990 to 2019.[2]

Although CAD mortality in Western countries has dropped dramatically in recent decades as a result of greater emphasis on primary prevention and the improvement of diagnosis and treatment of CAD, developing countries continue to present challenges for public health.[3] In Thailand, the Ministry of Public Health (MOPH) reported CAD mortality of 20,786 for the year 2019,[4] making it the major cause of death among the Thai population. There were 337,441 hospital admissions due to CAD in 2019.[4] According to a report by Kiatchoosakun, Sutra, and Thepsuthammarat (2012),[5] CAD represents the highest disease burden for Thais. The authors also reported that CAD impacts not only patients' quality of life, but also affects the national budget and the healthcare system.

Currently, there are a number of standardized approaches for the prevention or treatment of CAD, e.g., pharmacology therapy, coronary revascularization (Percutaneous Coronary Intervention (PCI) and Coronary Artery Bypass Grafting (CABG).[6] Primary prevention for CAD is defined as prevention of the first occurrence of CAD and includes the assessment and management of cardiovascular risk factors such as maintaining a desirable body weight, eating healthy food, exercising regularly, and not smoking.[7] Secondary prevention, an essential part of contemporary care of patients with

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CVD, refers to healthcare designed to prevent recurrence of cardiovascular events, e.g., heart attack or stroke and complications of CVD in patients diagnosed with CVD. Such prevention involves medical care, modification of behavioral risk factors, psychosocial care, education, and support for self-management, all of which need to be delivered in a variety of settings.[8]

Cardiac rehabilitation (CR) is recommended worldwide as a secondary prevention for patients with CAD, as it improves cardiovascular health outcomes.[9,10] CR has been defined as "the sum of activities required to influence favorably the underlying cause of the disease, as well as to provide the best possible physical, mental and social conditions, so that patients may by their own efforts preserve, or resume when lost, as normal a place as possible in the life of the community."[11]

There is extensive evidence supporting the effectiveness of CR: restoring and maintaining physical functioning of the heart, a significant reduction in morbidity and mortality from cardiac causes, better psychosocial well-being, and improved quality of life.[10,12]

As a result of the effectiveness of CR, it is now recognized in evidenced based guidelines for patients with CAD. The European Society of Cardiology,[13] the American Heart Association, and the American College of Cardiology[7] have all given CR a Class I recommendation, the highest level of recommendation for specific treatments, meaning that there is evidence that CR is beneficial, useful and effective for patients with CAD.

Although the benefits of CR are considerable, CR uptake overall is poor worldwide, with reported rates of attendance at CR sessions by patients recommended to attend ranging from 20% to 50% internationally.[13, 14] Many factors contribute to CR uptake and adherence, including demographic variables, psychological factors, medical conditions, access to programs, and sociocultural factors.[15,16] In Thailand, the CR uptake rate is low, with estimates that only approximately 18.3% of eligible patients attend.[17] However, little is known about the reasons for the poor patient uptake at CR programs in Thailand. The present study aimed to identify factors contributing to low CR uptake among patients with CAD in Thailand as the healthcare system differs from those of most Western countries and because cultural and religious beliefs strongly influence people's lives and health.

Method

Design

This was an urban and rural center cross sectional study.

Participants

The population consisted of patients diagnosed with CAD who were eligible to attend a CR program based on the current guidelines in Thailand.[18] Patients were eligible to participate in the study if they had been referred for CR by the medical staff during their in-patient stay. A question regarding their intention to attend future CR (yes/no/waiting) was asked. Patients waiting to attend their first CR session were excluded from the study as they may or may not actually attend CR.

The majority of patients with CAD were undergoing coronary artery bypass grafting or percutaneous coronary intervention, or were patients with CAD who had developed heart failure.

Data collection

All recruited patients had been discharged after their initial admission and were returning to outpatient clinics between 2018 and 2019 at either the urban hospital or the rural hospital. Data collection took place between June 2018 and July 2019. Patients were excluded if they had a documented cognitive impairment. Participants were recruited in the outpatient clinic using a convenience sampling approach. The researcher presented the self-administered survey questionnaires after providing a verbal explanation of the survey tool. Once completed, the survey questionnaires were retained in a sealed box to ensure anonymity.

Ethical considerations

The study protocol was approved by the Human Research Ethics Committees of University of Queensland (approval number 2017001672), the urban hospital (reference number MURA2018/339 and protocol number ID 05-61-24), and the rural hospital (reference number HE621143).The study conforms to the Helsinki Declaration. All participants gave written consent to participate in the study.

Table 1. Overview of the phase two CR program delivery in a rural and an urban hospitals

Phase 2 Intensive physical and aerobic exercise (walking, running, cycling) as circuit conditioning delivered in the outpatient CR center.
Three programs are available and the number of sessions were determined by the risk of the patients including
Program 1: high risks= 18 sessions (6-9 weeks), 2-3 times a week
Program 2: moderate risks= 10 sessions (3-5 weeks), 2-3 times a week
Program 3: low risks= 12 sessions, monthly
60 minutes duration each session
Content of the session: warm up (10-15 minutes), exercising (15-30 minutes), and cool down
Educational activities 2–3 times per week
Psychological counselling
The CR programs are standardized and based on international guidelines; therefore, deliver the same benefits across different sites.

CR, cardiac rehabilitation

Questionnaire

The questionnaire consisted of one question ("yes/no/waiting") to determine if the participant was currently attending phase II CR plus 14 demographic questions and a Thai language version of the Cardiac Rehabilitation Barriers Scale (CRBS) questionnaire. The researchers obtained permission to use the CRBS questionnaire from the authors.[19] The CRBS was chosen because it has been used to identify multidimensional barriers to CR uptake as reported in literature reviews. It was practical for the purpose of the present study, and the reliability and validity of the questionnaire had previously been demonstrated.[19,20]

The CRBS questionnaire is comprised of four subscales with a total of 21 items rated on a five point Likert type scale, ranging from 1=strongly disagree to 5=strongly agree. Higher scores represent stronger barriers to CR participation or adherence. The CRBS consists of perceived need for CR/healthcare factors (nine items), logistical factors (five items), conflicts with work schedule/time (three items), and comorbidities/functional status (four items).[19] For the present study, the CRBS questionnaire was translated into Thai and the face validity of the translation was determined by a panel of experts and a back-translation approach combined with a bilingual test.[21] The back-translation technique allows detection and correction of discrepancies between source- and target language versions, while a bilingual test can evaluate an instrument's clarity, comprehensiveness, appropriateness, and cultural relevance with future subjects.[21] The CRBS back-translation process was performed by two qualified bilingual translators, both having a NATTI (National Accreditation Authority for Translators and Interpreters) certificate. The original version of the CRBS was initially forward-translated from English into Thai. Then, the CRBS Thai version was back-translated blindly into an English version.

Once the translation process was completed, the two versions in English were compared and evaluated by the researcher. The researcher and the translators reviewed the source version and the back-translation of the CRBS for equivalences, and adapted them to the most fitting meaning in Thai. The version was reviewed for linguistic and cultural quality by the researcher and the translators.[21] Discrepancies were resolved by consensus to achieve conceptual equivalence with the original questionnaire.

An expert panel then conducted a face validity check of the CRBS to determine whether the language was considered to be appropriate for Thai people and to assess the questionnaire language for clarity. Then, the translated CRBS was sent to experts to ensure the appropriateness of the language based on Thai local information, context, and culture.[22]

A cardiologist, a cardiac surgeon, a cardiac rehabilitation physician, and two clinical nurses who specialize in CR were chosen as the experts in this study as they are responsible for referring patients to CR programs as well as providing ongoing care and management to patients diagnosed with CAD. During face validation, all experts recommended that "my doctor" in item CRBS[16] should be modified to "my cardiologist" and "cardiac surgeons" or "cardiac rehabilitation doctors" as appropriate. Aside from this item, the experts found the length, readability, and clarity of the translated CRBS satisfactory.

Data handling

To review data across commonly accepted categories used by the National Economic and Social Development Board, and Ministry of Education, age and education were collapsed into categorical variables as shown in Table 2.

Employment status was also collapsed into four categories, consistent with the main categories of employment status among the Thai population. The distance patients travelled from their home to CR settings in Thailand was grouped into three categories (Table 2).

Data analysis

Data were entered into SPSS version 21.0 (IBM SPSS software) for statistical analysis. For purposes of comparison, "attendees" was defined as individuals who had attended one or more rehabilitation sessions, and "non-attendees" as those who had been invited to attend but did not do so. The Chi-square test for independence was used to detect the relationship between categorical variables (sociodemographic characteristics and CR attendance) at both hospitals and within each hospital. Post hoc tests were conducted using Chi-square tests when appropriate. The independent samples t-test was used to compare the mean scores of continuous variables. Statistical significance was set at 0.05 for all tests in the analysis with two sided *p* values.

Results

Demographic Characteristics

Of the 180 patients who were approached, 138 met the eligibility criteria. A total of 71 participants from the urban hospital, and 67 participants from the rural hospital were

Table 2. Categories for collapsed continuous and categorical variables

Variable	Category (coding)
Age (years)	< 60 (1) 60-69 (2) ≥ 70 (3)
Educational level	< 6 years (1) 6-12 years (2) More than 12 years or tertiary (3)
Employment status	Employed (1) Unemployed (2) Retired (3) Farmer (4)
Distance from patients' homes (kilometer)	≤ 100 (1) > 100, but ≤ 200 (2) > 200 (3)

included. Of the participants, 95 were CR attendees and 43 were CR non-attendees. The average age of the participants was 64 years (range 41-88). Of the participants, 96% were Thai and 4% were Lao. There were more males (70%) than females (30%). Almost 95% of the participants were Buddhist, with 3% and 2% of the participants Christian and Muslim, respectively.

The demographics of the participants are shown in Table 3. The majority of the participants were 60 years or older, married, and had a moderate family income. Approximately half of the participants had a tertiary educational and almost 20% were farmers. Approximately 10% said they had to travel a long distance from their home to the CR location. CR attendees had a higher educational level, employment rate, and family income compared to CR non-attendees.

At the urban hospital (Table 4), there was no statistically significant association between any of the demographic variables and CR attendance among patients with CAD. However, at the rural hospital (Table 5), a Chi-square test for independence indicated that there were significant differences in educational level (X^2 (2, n = 67) = 14.58, p = 0.001, *phi* = 0.466), employment status (X^2 (3, n = 67) = 10.25, p = 0.017, *phi* = 0.391), and family income (X^2 (2, n= 67) = 9.60, p = 0.008, *phi* = 0.379) with CR attendance among patients with CAD. Post hoc comparisons revealed that patients with fewer years of education and those who were farmers were less

Table 3. Demographics of CR Attendees and CR Non-Attendees (n = 138)

Demographic variables	Total (n = 138)	CR attendees (n = 95)	CR non-attendees (n = 43)	*p*-value[a]
Age (years)				0.101
< 60	43 (31.2)	31 (32.6)	12 (27.9)	
60-69	54 (39.1)	41 (43.2)	13 (30.2)	
≥ 70	41 (29.7)	23 (24.2)	18 (41.9)	
Educational level (years)				< 0.001
< 6	42 (30.4)	18 (18.9)	24 (55.8)	
6-12	23 (16.7)	19 (20.0)	4 (9.3)	
Tertiary or more than 12	73 (52.9)	58 (61.1)	15 (34.9)	
Marital status				0.492
Single	5 (3.6)	4 (4.2)	1 (2.3)	
Married	110 (79.7)	75 (79.0)	35 (81.4)	
Widowed	19 (13.8)	12 (12.6)	7 (16.3)	
Divorced	4 (2.9)	4 (4.2)	0	
Employment status				0.001
Employed	41 (29.7)	32 (33.7)	9 (20.9)	
Unemployed	28 (20.3)	19 (20.0)	9 (20.9)	
Retired	42 (30.4)	34 (35.8)	8 (18.6)	
Farmer	27 (19.6)	10 (10.5)	17 (39.5)	
Family income a month (Thai baht)				0.046
< 10,000	17 (12.3)	9 (9.5)	8 (18.6)	
10,000-20,000	36 (26.1)	21 (22.1)	15 (34.9)	
> 20,000	85 (61.6)	65 (68.4)	20 (46.5)	
Health insurance				0.076
Universal health coverage scheme	44 (31.9)	24 (25.3)	20 (46.5)	
Civil servant medical benefit scheme	71 (51.4)	52 (54.7)	19 (44.1)	
Social security scheme	11 (8.0)	9 (9.5)	2 (4.7)	
Voluntary payment	12 (8.7)	10 (10.5)	2 (4.7)	
CR cost per session (Thai baht)				0.958
< 1,000	52 (37.7)	36 (37.9)	16 (37.2)	
1,000-2,000	56 (40.6)	39 (41.0)	17 (39.5)	
≥ 2,000	30 (21.7)	20 (21.1)	10 (23.3)	
Distance from patients' homes to CR (kilometers)				0.609
≤ 100	72 (52.2)	52 (54.7)	20 (46.5)	
> 100, but ≤ 200	48 (34.8)	32 (33.7)	16 (37.2)	
> 200	18 (13.0)	11 (11.6)	7 (16.3)	
Time travelling from patients' homes to CR (minutes)				0.192
≤ 60	64 (46.4)	49 (51.6)	15 (34.9)	
≥ 90, but ≤ 180	55 (39.9)	34 (35.8)	21 (48.8)	
≥ 200, but ≤ 300	17 (12.3)	10 (10.5)	7 (16.3)	
> 300, but ≤ 360	2 (1.4)	2 (2.1)	0	

*Values are presented as number (%); [a]Chi-square test; CR, (cardiac rehabilitation)

A recommended living family income of 313–336 Thai Baht a day is based on the daily minimum wage nationwide (Ministry of Labor, 2020).

likely to attend CR, while patients with higher educational levels and who had a higher family income were more likely to attend CR.

Cardiac Rehabilitation Barriers Scale (CRBS) findings

The criterion validity of the CRBS and of mean scores for CRBS items for both cohorts are presented below.

Criterion Validity of the CRBS

Mean total and subscale CRBS scores for CR attendees and CR non-attendees for both hospitals combined are shown in Table 6. CR attendees and CR non-attendees had the highest mean CRBS subscale for logistical factors. There was a significant difference in the CRBS mean total scores between CR attendance for CR non-attendees (M = 2.60, SD = 0.36) and CR attendees (M = 2.41, SD = 0.52); t (138) = -2.44, p = 0.016, two tailed. The magnitude of the difference in the means (mean difference = -0.19) was small to moderate (eta^2 = 0.04). However, a statistically significant difference in CR attendance was found only for the CRBS healthcare/perceived need subscale for CR non-attendees (M = 2.46, SD = 0.41) and CR attendees (M = 2.21, SD = 0.48); t (138) = -2.96, p = 0.004, two tailed. The magnitude of the difference in the means (mean difference = -0.25) was moderate (eta^2 = 0.06).

Table 4. Demographics of CR Attendees and CR Non-Attendees at the Urban Hospital (n = 71)

Demographic variables	CR attendees (n = 55)	CR non-attendees (n = 16)	p-value[a]
Age (years)			0.290
< 60	14 (25.5)	3 (18.8)	
60-69	22 (40.0)	4 (25.0)	
≥ 70	19 (34.5)	9 (56.2)	
Educational level (years)			0.291
< 6	8 (14.5)	5 (31.3)	
6-12	14 (25.5)	4 (25.0)	
Tertiary or more than 12	33 (60.0)	7 (43.7)	
Marital status			0.741
Single	2 (3.6)	1 (6.25)	
Married	44 (80.0)	14 (87.5)	
Widowed	8 (14.6)	1 (6.25)	
Divorced	1 (1.8)	0	
Employment status			0.535
Employed	14 (25.5)	3 (18.8)	
Unemployed	13 (23.6)	6 (37.5)	
Retired	28 (50.9)	7 (43.7)	
Family income a month (Thai Baht)			0.774
< 10,000	6 (10.9)	1 (6.3)	
10,000-20,000	9 (16.4)	2 (12.5)	
> 20,000	40 (72.7)	13 (81.2)	
Health insurance			0.218
Universal health coverage scheme	12 (21.8)	6 (37.5)	
Civil servant medical benefit scheme	32 (58.2)	10 (62.5)	
Social security scheme	5 (9.1)	0	
Voluntary payment	6 (10.9)	0	
CR cost per session (Thai Baht)			0.713
< 1,000	27 (49.1)	9 (56.2)	
1,000-2,000	16 (29.1)	3 (18.8)	
≥ 2,000	12 (21.8)	4 (25.0)	
Distance from patients' homes to CR (kilometers)			0.185
≤ 100	34 (61.8)	7 (43.8)	
> 100, but ≤ 200	18 (22.7)	6 (37.5)	
> 200	3 (5.5)	3 (18.7)	
Time travelling from patients' homes to CR (minutes)			0.058
≤ 60	33 (60.0)	7 (43.8)	
≥ 90, but ≤ 180	19 (34.6)	6 (37.5)	
≥ 200, but ≤ 300	1 (1.8)	3 (18.7)	
> 300, but ≤ 360	2 (3.6)	0	

*Values are presented as number (%); [a]Chi-square test; CR, cardiac rehabilitation

A recommended living family income of 313–336 Thai Baht a day is based on the daily minimum wage nationwide (Ministry of Labor, 2020).

Table 5. Demographics of CR attendees and CR non-attendees at the rural hospital (n = 67)

Demographic variables	CR attendees (n = 40)	CR non-attendees (n = 27)	*p*-value[a]
Age (years)			0.059
< 60	17 (42.5)	9 (33.3)	
60-69	19 (47.5)	9 (33.3)	
≥ 70	4 (10.0)	9 (33.3)	
Educational level (years)			0.001
< 6	10 (25.0)[b]	19 (70.4)[c]	
6-12	5 (12.5)[b]	0[b]	
Tertiary or more than 12	25 (62.5)[b]	8 (29.6)[c]	
Marital status			0.173
Single	2 (5.0)	0	
Married	31 (77.5)	21 (77.8)	
Widowed	4 (10.0)	6 (22.2)	
Divorced	3 (7.5)	0	
Employment status			0.017
Employed	18 (45.0)[b]	6 (22.2)[b]	
Unemployed	6 (15.0)[b]	3 (11.1)[b]	
Retired	6 (15.0)[b]	1 (3.7)[b]	
Farmer	10 (25.0)[b]	17 (63.0)[c]	
Family income a month (Thai baht)			0.008
< 10,000	3 (7.5)[b]	7 (25.9)[b]	
10,000-20,000	12 (30.0)[b]	13 (48.2)[b]	
≥ 20,000	25 (62.5)[b]	7 (25.9)[c]	
Health insurance			0.353
Universal health coverage scheme	12 (30.0)	14 (51.9)	
Civil servant medical benefit scheme	20 (50.0)	9 (33.3)	
Social security scheme	4 (10.0)	2 (7.4)	
Voluntary payment	4 (10.0)	2 (7.4)	
CR cost per session (Thai baht)			0.900
< 1,000	9 (22.5)	7 (25.9)	
1,000-2,000	23 (57.5)	14 (51.9)	
> 2,000	8 (20.0)	6 (22.2)	
Distance from patients' homes to CR (kilometers)			0.863
≤ 100	18 (45.0)	13 (48.1)	
> 100, but ≤ 200	14 (35.0)	10 (37.0)	
> 200	8 (20.0)	4 (14.8)	
Time travelling from patients' homes to CR (minutes)			0.342
≤ 60	16 (40.0)	8 (29.6)	
≥ 90, but ≤ 180	15 (37.5)	15 (55.6)	
≥ 200, but ≤ 300	9 (22.5)	4 (14.8)	
> 300, but ≤ 360	0	0	

*Values are presented as number (%); [a]Chi-square test; [bc]Post-hoc tests for Chi-square tests; CR, (cardiac rehabilitation)
A recommended living family income of 313–336 Thai Baht a day is based on the daily minimum wage nationwide (Ministry of Labor, 2020).

Correlation of CRBS Scores and CR Attendance (n=138)

The mean scores of CR attendees were compared to CR non-attendees for each of the CRBS items both overall and for urban and rural hospitals. The most commonly reported barriers for both cohorts were "transportation problems," "distance," and "family responsibilities," followed by CR cost, and a lack of knowledge of CR.

Consistent with the methodology of Shanmugasegaram et al. (2012), an independent samples t-test was conducted to compare the CRBS mean item scores of CR attendees and CR non-attendees (Table 7). There were statistically significant differences in mean item scores for "other health problems," not being contacted by the rehab program with small to moderate effect size. "My doctor did not feel it was necessary" and "taking too long to start the CR program" showed a significant difference in mean item score with moderate to large effect size as shown in Table 7.

CRBS Scores for the urban hospital

The mean scores for CRBS items of CR attendees were compared to scores for CR non-attendees at the urban hospital. "Transportation problems" was the most frequently reported barrier for CR attendees, while "family responsibilities" had the highest CRBS mean score for CR non-attendees. Both CR non-attendees and CR attendees had CRBS mean

Table 6. Comparison of Mean Scores on the CRBS between CR attendees and CR non-attendees (n = 138)

Demographic variables	CR attendees (n = 95)		CR non-attendees (n = 43)		*p*-value[a]
	Mean	SD	Mean	SD	
Scale total	2.41	0.52	2.60	0.36	0.016
Subscales					
Healthcare/perceived need	2.21	0.48	2.46	0.41	0.004
Logistical	2.84	0.88	2.91	0.67	0.635
Work/time conflicts	2.45	0.84	2.67	0.68	0.124
Comorbidities/functional status	2.29	0.72	2.46	0.72	0.207

CRBS, Cardiac Rehabilitation Barriers Scale; CR, cardiac rehabilitation; SD, standard deviation

[a]Independent sample t-tests.

Table 7. CRBS Scores of CR Attendees and CR non-attendees of both hospitals (n = 138)

CRBS items	Total (n = 138)	CR attendees (n = 95)	CR non-attendees (n = 43)	MD	*Eta*^{2}	*p*-value[a]
CRBS_01… of distance	3.22±1.30	3.14±1.35	3.42±1.16	-0.28	0.010	0.240
CRBS_02… of cost	2.93±1.20	2.83±1.23	3.16±1.09	-0.33	0.016	0.133
CRBS_03… of transportation problems	3.29±1.23	3.29±1.29	3.28±1.12	0.23	0.000	0.945
CRBS_04… of family responsibilities	2.98±1.10	2.96±1.15	3.02±1.01	0.07	0.000	0.749
CRBS_05… I didn't know about CR	2.80±1.01	2.79±1.08	2.79±1.08	-0.05	0.000	0.798
CRBS_06… I don't need CR	2.42±1.05	2.34±1.11	2.62±0.88	-0.28	0.015	0.147
CRBS_07…I already exercise at home, or in my community	2.68±1.03	2.60±1.07	2.60±1.07	-0.26	0.013	0.171
CRBS_08… severe weather	1.88±1.03	1.98±1.02	1.67±1.04	0.30	0.009	0.109
CRBS_09… I find exercise tiring or painful	2.52±0.94	2.55±0.98	2.47±0.83	0.08	0.001	0.635
CRBS_10… travel	2.49±0.97	2.41±0.99	2.66±0.91	-0.25	0.014	0.174
CRBS_11… of time constraints	2.59±1.07	2.48±1.10	2.84±0.97	-0.35	0.023	0.073
CRBS_12… of work responsibilities	2.47±0.99	2.45±1.03	2.51±0.91	-0.06	0.000	0.747
CRBS_13… I don't have the energy	2.30±0.96	2.22±0.96	2.49±0.94	-0.27	0.017	0.129
CRBS_14… other health problems prevent me from going	2.29±0.87	2.17±0.81	2.56±0.96	-0.39	0.038	0.023
CRBS_15… I am too old	2.26±1.12	2.23±1.13	2.33±1.09	-0.09	0.002	0.648
CRBS_16… my doctor did not feel it was necessary	2.06±0.72	1.94±0.69	2.33±0.71	-0.39	0.062	0.003
CRBS_17… many people with heart problems don't go, and they are fine	2.13±0.70	2.12±0.74	2.16±0.57	-0.05	0.001	0.713
CRBS_18… I can manage my heart problem on my own	2.30±0.93	2.28±0.98	2.33±0.85	-0.05	0.000	0.778
CRBS_19… I think I was referred, but the rehab program didn't contact me	2.10±0.79	1.98±0.73	2.37±0.85	-0.39	0.049	0.010
CRBS_20… it took too long to start the outpatient program after referral	2.03±0.73	1.84±0.61	2.45±0.80	-0.61	0.125	< 0.001
CRBS_21… I prefer to take care of my health alone, not in a group	2.06±0.77	2.01±0.83	2.17±0.62	-0.16	0.008	0.278

[*]Values are presented as mean± standard deviation; [a]Independent sample t-tests; mean difference; Eta^2, eta square

A recommended living family income of 313–336 Thai Baht a day is based on the daily minimum wage nationwide (Ministry of Labor, 2020).

scores of 2.5 or more in five items, and CR non-attendees had higher CRBS means in 10 items. However, only the item, "taking too long to start the CR program after referral," showed a significant difference in mean score between CR attendees and CR non-attendees. The *eta*^{2} statistic (0.12) indicated a moderate to large effect size (Table 8).

CRBS Scores for the Rural Hospital

As shown in Table 9, CR non-attendees had higher mean scores on CRBS items than CR attendees, with the exception of the items related to "transportation problems," "family responsibilities," a lack of knowledge of CR, "severe weather," and "finding exercise tiring or painful." "Distance" was the most frequently reported barrier for CR non-attendees, but the highest reported CRBS mean score for CR attendees was for "transportation problems." CR non-attendees and CR attendees had mean CRBS item scores of 3 or more for distance, cost, and transportation problems.

An independent samples t-test was conducted to compare the CRBS mean item scores for CR attendees and CR non-attendees at the rural hospital (Table 9). There were significant differences in the CRBS item mean scores for "severe weather," "other health problems," "the rehab program didn't contact me," and the preference to "manage my heart problem

Table 8. CRBS Scores of CR Attendees and CR Non-Attendees at the Urban Hospital (n = 71)

CRBS items	CR attendees (n = 55)	CR non-attendees (n = 16)	MD	*Eta*^{2}	*p*-value[a]
CRBS_01… of distance	2.78±1.29	2.94±1.34	-0.16	0.002	0.674
CRBS_02… of cost	2.44±1.05	2.38±0.96	0.06	0.000	0.835
CRBS_03… of transportation problems	3.04±1.26	2.88±1.20	0.16	0.003	0.651
CRBS_04… of family responsibilities	2.82±1.23	3.25±1.18	-0.43	0.021	0.218
CRBS_05… I didn't know about CR	2.65±1.16	2.81±1.11	-0.16	0.003	0.630
CRBS_06… I don't need CR	2.24±1.07	2.19±0.83	0.05	0.000	0.867
CRBS_07… I already exercise at home, or in my community	2.69±1.20	2.94±1.06	-0.25	0.007	0.461
CRBS_08… severe weather	2.36±1.11	2.63±1.15	-0.26	0.009	0.414
CRBS_09… I find exercise tiring or painful	2.29±0.96	2.19±0.91	0.10	0.002	0.702
CRBS_10… travel	2.35±0.93	2.31±0.95	0.03	0.000	0.903
CRBS_11… of time constraints	2.29±1.05	2.25±1.00	0.04	0.000	0.890
CRBS_12… of work responsibilities	2.24±0.96	1.94±0.77	0.30	0.018	0.259
CRBS_13… I don't have the energy	2.13±1.02	2.31±0.95	-0.19	0.006	0.518
CRBS_14… other health problems prevent me from going	2.05±0.83	2.19±1.05	-0.13	0.004	0.596
CRBS_15… I am too old	2.18±1.11	2.00±0.89	0.18	0.006	0.504
CRBS_16… my doctor did not feel it was necessary	1.84±0.76	2.00±0.89	-0.16	0.007	0.471
CRBS_17… many people with heart problems don't go, and they are fine	1.98±0.73	1.81±0.40	0.17	0.011	0.380
CRBS_18… I can manage my heart problem on my own	2.27±1.06	2.13±1.06	0.14	0.003	0.654
CRBS_19… I think I was referred, but the rehab program didn't contact me	1.89±0.74	2.06±0.99	-0.17	0.008	0.453
CRBS_20… it took too long to start the outpatient program after referral	1.80±0.73	2.50±0.97	-0.70	0.124	0.003
CRBS_21… I prefer to take care of my health alone, not in a group	2.13±0.96	2.06±0.68	0.07	0.000	0.803

[*]Values are presented as mean± standard deviation; [a]Independent sample t-test

CR, cardiac rehabilitation; CRBS, Cardiac Rehabilitation Barriers Scale; MD, mean difference; E*ta*^{2}, eta squared

Table 9. CRBS Scores of CR Attendees and CR Non-Attendees at the Rural Hospital (n = 67)

CRBS items	CR attendees (n = 40)	CR non-attendees (n = 27)	MD	*Eta*^{2}	*p*-value[a]
CRBS_01… of distance	3.63±1.31	3.70±0.95	-0.08	0.001	0.777
CRBS_02… of cost	3.38±1.28	3.63±0.88	-0.26	0.014	0.338
CRBS_03… of transportation problems	3.65±1.25	3.52±1.01	0.13	0.003	0.651
CRBS_04… of family responsibilities	3.15±1.00	2.89±0.89	0.26	0.018	0.278
CRBS_05… I didn't know about CR	2.98±0.95	2.85±0.66	0.12	0.006	0.533
CRBS_06… I don't need CR	2.48±1.15	2.88±0.82	-0.41	0.042	0.096
CRBS_07…I already exercise at home, or in my community	2.48±0.88	2.81±0.83	-0.34	0.037	0.117
CRBS_08… severe weather	1.45±0.55	1.11±0.32	0.34	0.133	0.002
CRBS_09… I find exercise tiring or painful	2.90±0.93	2.63±0.74	0.27	0.024	0.211
CRBS_10… travel	2.50±1.09	2.88±0.83	-0.38	0.033	0.140
CRBS_11… of time constraints	2.75±1.13	3.19±0.79	-0.44	0.050	0.067
CRBS_12… of work responsibilities	2.75±1.06	2.85±0.82	-0.10	0.003	0.659
CRBS_13… I don't have the energy	2.35±0.86	2.59±0.93	-0.24	0.018	0.278
CRBS_14… other health problems prevent me from going	2.33±0.76	2.78±0.85	-0.45	0.074	0.026
CRBS_15… I am too old	2.30±1.18	2.52±1.16	-0.22	0.008	0.456
CRBS_16… my doctor did not feel it was necessary	2.08±0.57	2.52±0.51	-0.44	0.140	0.002
CRBS_17… many people with heart problems don't go, and they are fine	2.30±0.72	2.37±0.57	-0.07	0.003	0.672
CRBS_18… I can manage my heart problem on my own	2.30±0.85	2.44±0.69	-0.14	0.008	0.468
CRBS_19… I think I was referred, but the rehab program didn't contact me	2.10±0.71	2.56±0.69	-0.46	0.094	0.012
CRBS_20… it took too long to start the outpatient program after referral	1.90±0.38	2.42±0.70	-0.52	0.157	0.001
CRBS_21… I prefer to take care of my health alone, not in a group	1.85±0.58	2.23±0.59	-0.38	0.094	0.012

[*]Values are presented as mean± standard deviation; [a]Independent sample t-test.

CR, cardiac rehabilitation; CRBS, Cardiac Rehabilitation Barriers Scale; MD, mean difference; E*ta*^{2}, eta squared

on my own" between CR attendees and CR non-attendees with a moderate to large effect size. However, statistically significant differences were also found with large effect size in the mean item scores for "my doctor did not feel it was necessary" and "it took too long to start the outpatient program after referral."

Distance was the most frequently reported barrier at both hospitals. CR attendees and CR non-attendees at the rural

hospital had higher CRBS mean item scores than those of CR attendees and CR non-attendees at the urban hospital in 18 and 17 items out of 21, respectively. CR non-attendees at the rural hospital had CRBS mean item scores of 2.5 or more in 16 items, while CR non-attendees at the urban hospital had CRBS mean item scores of 2.5 or more for only seven items.

Discussion

The majority of the CR participants in this study were 60 years or older and male.

Patients aged 60-69 had the highest rate of CR attendance, and patients over 70 years had the lowest rate of CR attendance. These results accord with an Australian study where CR attendance rates dropped sharply after 70 years of age among patients with CAD.[23] Contrary to our study, previous research studies have found that CR attendees were younger than non-attendees.[16,24,25] In the Thai context, there are some possible reasons why patients aged 60-69 had a higher rate of CR attendance than those under 60. These could include that the majority of the participants were retired and had more free time to attend CR, they may have had financial security sufficient for costs associated with traveling to CR settings, and they may have had strong family support (almost 80% of CR attendees were married).

Consistent with other studies, our study found that women were less likely than men to attend CR programs,[16,26] although other studies have reported no significant gender difference in CR uptake when the gender difference in enrolment rates after a referral is taken into account.[27] In the Thai context, women have a crucial role as the caretaker of family members and feel an obligation to feed other family members before joining CR.[28] This may affect the decision of female patients not to attend CR at the hospital. This is supported by studies which show that family commitments for women are a key barrier preventing them from attending CR.[15,29]

Barriers to CR uptake

This study demonstrated that educational level, distance and transportation, work commitments and the farming season, knowledge of CR and its benefits, family responsibilities, and CR costs were the key concerns related to CR uptake among patients with CAD in the Thai context.

Consistent with the findings of several international studies, patients with a higher education level were more likely to attend CR.[16,30] The majority of CR non-attendees at the rural hospital had fewer years of education than those at the urban hospital, reflecting a huge gap in accessing the Thai educational system between the urban and rural areas of the country. This education gap may result in reduced ability of patients in rural areas to access, understand and appraise health information, including information about CR.

In agreement with other international studies undertaken in Europe, Japan and Indonesia, distance to travel for CR was a common barrier to attendance, especially in rural areas.[16,25,31,32,33] In Thailand, the number of CR programs is limited. Throughout the northeast of Thailand, for example, only one CR setting currently provides a CR program which provides for 22 provincial areas of Thailand and the nearby countries of Laos, Cambodia, and Vietnam. The majority of CR rural non-attendees lived more than 100 kilometers from the location of the CR program.

In line with previous studies, our study demonstrated that transportation difficulties, including heavy traffic and lack of parking, have been associated with low CR uptake[16, 31,34] In remote areas of Thailand's northeast, the transportation system is not well developed. Road systems are often inadequate, some patients do not own cars, and public transport is extremely limited. However, transportation is a problem not only for rural people, but is also a barrier for urban dwellers.[35] This could be because of traffic congestion which is common in some urban areas, particularly in Bangkok.

Consistent with the findings of some international studies, an association was found between patients' knowledge of CR and CR uptake.[9,36] This study found that CR attendees, especially younger CR attendees with higher educational levels, had more practical knowledge of CR and its benefits. Despite this knowledge, however, some patients still did not attend CR, possibly because the perceived benefit was not high enough or because the barriers to attendance were too great.

These results are consistent with international studies which have found that some currently employed patients did not attend CR due to work responsibilities.[15,37,38] A novel finding of the present study is the extent to which specific work demands in rural and urban areas differ. At the rural hospital, 63% of CR non-attendees were farmers, which could explain why they did not attend CR during the rice planting or harvesting periods. Rural Thai people are heavily dependent on agriculture as their main source of income.[39] Their farming activities also rely on natural conditions such as weather and seasons.

Urban and rural female patients who did not work outside the home had responsibilities such as cooking for their family members which must be considered before joining CR. These duties led to a reluctance to attend CR programs. This finding accords with that of some international studies that women's decision to attend CR is influenced by their family obligations.[29, 31] This could also be explained culturally, e.g., the Buddhist belief that women and wives play important roles in household duties and as caretakers to support other family members. Thai women live in a patriarchal social structure where they undertake most of the family care.[40] Men or husbands take responsibility as a head of the house to provide the means to feed the family members.[40]

Although the CR program itself was covered by the healthcare system, costs related to CR attendance, including food, parking, transportation, and accommodation, were the responsibility of patients. The finding that cost was a barrier is consistent with previous studies.[15,25,31] However, those studies were conducted in urban settings, where income tends to

higher than in rural populations.[15] In Thailand, patients in both urban and rural areas have similar issues related to CR costs. These CR costs might be linked to the lack of CR facilities located in some provincial areas, resulting in patients having to travel some distance from their home to participate in CR programs.

Study limitations

The findings of this study should be interpreted with caution. First, the study sample was a convenience sample, the study consisted mainly of male Thai participants, and the findings are specific to only two tertiary hospitals in Thailand which may limit the generalizability of the findings. Second, the majority of the participants were elderly, had comorbidities, and had had follow-ups with many different physicians which may have introduced recall bias. However, efforts were made to minimize recall bias by asking patients to recall only shorter periods. Third, data collection took place in two CR settings, although these tertiary CR settings did appear to be the representative of the urban and rural areas of Thailand.

Conclusions

Distance, transportation, and CR costs are the key obstacles affecting patients' decision to attend CR in Thailand. Notably, differences in work commitments in rural and urban areas also affected CR uptake. Men and the elderly were found to be the majority of the CR participants. Most importantly, this study shows that rural participants differ from the urban cohort in some aspects. There may be additional barriers which may not have been identified, so further research with a larger sample may be able to identify factors related to CR uptake among patients with CAD throughout the country. The upshot is there is a need to improve the current CR programs and to create more nuanced approaches to CR for rural and remote populations.

Disclosure

The authors have no conflicts of interest to disclose.

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Original Article

The Clinical Characteristic and Management of Knee Osteoarthritis in the Outpatient Rehabilitation Department at Siriraj Hospital, A Descriptive Study

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ABSTRACT

Objectives: To determine the relationship between demographic, clinical characteristics and management of patients with primary knee osteoarthritis

Study design: Retrospective chart review

Setting: Outpatient Rehabilitation Department of Siriraj Hospital

Subjects: 300 patients diagnosed with primary knee osteoarthritis.

Methods: Data was collected from the medical records of patients diagnosed with knee osteoarthritis (OA) knee with ICD-10 codes M17.0, 17.1, or 17.9 at Siriraj Hospital's Outpatient Rehabilitation Department in 2018, the year before the start of the COVID-19 pandemic.

Results: The study involved 300 patients diagnosed with primary knee OA. The mean age was 69.8 years (SD = 9.6) and 89% were female. The median BMI was 25.3 kg/cm^2. Most (67%) used civil servant medical coverage. Of the patients, 88.9% had bilateral knee pain and limited walking, and 66.9% of the patients who underwent roentgenographic study of the knees had early radiographic changes (Kellgren and Lawrence (KL) grades 0-1). The hospital records showed topical analgesics was the most commonly prescribed drugs (51.3%), followed by glucosamine sulfate (21.7%) which was associated with significantly milder radiographic changes (p = 0.004). Half the patients received educational information on knee OA and advice on appropriate exercises. Provision of weight reduction advice was associated with patients with higher body mass index (p < 0.001). Hospital-based physiotherapy was prescribed for nearly half the patients (43%). Non-pharmacological prescriptions were not significantly associated with radiographic severity.

Conclusions: The main characteristics of knee osteoarthritis patients in this study included obesity, elderly, female gender, civil servant medical coverage, bilateral knee pain, and mild radiographic severity. Weight reduction advice was given more frequently to patients with a higher BMI, and glucosamine sulfate was prescribed more often for patients with mild radiographic severity.

Keywords: *steoarthritis knee, clinical characteristics, management, glucosamine sulfate

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Introduction

Osteoarthritis (OA) is a disease characterized by degeneration of the joints resulting in biomechanical and biochemical changes.[1] It is a common problem worldwide, and its prevalence is increasing in high, middle, and low-income countries.[2-4] According to global burden of disease studies conducted in 2017, knee OA was the third most prevalent disease in 2017, becoming a major health disorder and the second most frequent cause of disability globally.[5] In terms of years lived with disability (YLD), the percentage change in counts and age-standardized rates, in 2007-2017, knee OA was also the third from most common cause in the musculoskeletal disease group.[2, 5]

According to previous studies in Thailand, the prevalence of osteoarthritic is high, particularly in women, and increases with age.[3,4] Patients with knee OA experience knee pain, joint stiffness, swelling, deformity, and crepitus, leading them to seek hospital treatment. Interestingly, clinical presentations do not differ between rural and urban Thais, although urban patients have more treatment options.[6]

Healthcare utilization has dramatically increased as the world's life expectancy has increased, leading to more patients with knee osteoarthritis visiting healthcare providers.[6] Economic impacts of arthritis are high, particularly in Southeast Asia, including Thailand, where urbanization and population growth are driving increases in the prevalence of OA.[2, 7]

Treatment for knee osteoarthritis typically falls into three main categories: non-pharmacological, pharmacological, and surgical treatments.[1, 8] It is recommended that patients receive a combination of treatment modalities, including education, which is currently the core of international recommendations.[1, 8-11]

In Siriraj Hospital, knee osteoarthritis is the second most common problem in the outpatient rehabilitation clinic. The number of patients has doubled over the past decade, requiring more economic support. This study aimed to examine the

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amount of outpatient care provided by this department, including remedies used. The study aimed to approximate the annual resource utilization for the treatment of knee osteoarthritis and to determine the association between the radiologically measured severity of osteoarthritis and the prescribed treatment. This basic information can be used to monitor services provided and for resource utilization planning. This narrative study can also serve as a foundation for future studies in this field.

Methods

Study design

A retrospective chart review was conducted in a university hospital in Bangkok, Thailand, with approval from the Institutional Review Board, Faculty of Medicine, Siriraj Hospital (585/2564).

Participants

Patients were eligible if they had been diagnosed with knee OA, with diagnostic codes of the International Classification of Diseases, Tenth Revision (ICD-10)[12] of M17.0 (Bilateral primary osteoarthritis of knee), M17.1 (unilateral primary osteoarthritis of knee), or 17.9 (Knee arthritis, unspecified), and were outpatients at the Rehabilitation Department, Siriraj Hospital between January 1, 2018 and December 31, 2018, the year before the COVID-19 outbreak. Data for 2019-2022 are not included in this study because the hospital services data for that period may not reflect routine hospital care practices.

All patients' charts were included if the data met the clinical criteria for knee OA knee developed by the American College of Rheumatology (ACR): pain in the knee plus at least three of the following: age > 50 years, stiffness < 30 min, crepitus, bony tenderness, bony enlargement, and no palpable warmth.[13] The exclusion criteria were preexisting conditions that can cause secondary arthritis, including trauma, infection, neoplasm, and metabolic diseases such as gout and hemochromatosis.

Outcome measurements

The demographic characteristics of participants, including age, sex, health care coverage, body weight, and body mass index (BMI), were analyzed according to the WHO Asian body mass index reference.[14] BMI is divided into five groups: less than 18.5, 18.5-22.9, 23-24.9, 25-29.9, and 30 kg/cm^2 or more, representing underweight, normal, overweight, obesity, and extreme obesity, respectively. The study also assessed clinical characteristics such as knee pain, side of knee pain, history of functional limitation, signs of crepitus, and radiologic severity assessed using the Kellgren Lawrence radiographic grading scale[15] which was used for rating the severity of radiographic findings in this study: Grade 0 (none) definite absence of radiographic features, Grade 1 (doubtful) doubtful osteophyte lipping and possible joint space narrowing (JSN), Grade 2 (minimal) definite osteophytes, possibly JSN, Grade 3 (moderate) moderate multiple osteophytes, definite JSN, sclerosis, Grade 4 (severe) large osteophytes, marked JSN, severe sclerosis.

The types and number of treatments for each patient during each visit were identified and counted. Non-pharmacologic treatments included home-based and hospital-based physical therapy (PT), acupuncture, knee support, provision of gait aids, recommending specific exercise practices, weight control advice, provision of information about the nature of the disease and the joint protection program, and orthopedic consultation.[1,2]

Pharmacological treatments are divided into symptomatic rapid-acting drugs for osteoarthritis (SYRADOA), e.g., acetaminophen, oral nonsteroidal anti-inflammatory drugs (NSAIDs), topical analgesics (methyl salicylate cream), oral opioids, and the combination of acetaminophen and opioids.[8,9] Symptomatic slow-acting drugs for osteoarthritis (SYSADOA) include glucosamine sulfate, diacerein, and intra-articular injections such as intra-articular hyaluronic, steroids, and platelet-rich plasma injections.

Statistical methods

The statistical analysis used R version 4.1.1. The demographic data was assessed for the normality of continuous variables distribution using the Kolmogorov-Smirnov test, with a statistical significance set at ≤ 0.05. Continuous variable data are presented as mean and standard deviation (SD) or median, while discrete variable data is expressed as a percentage. In addition, we used the Chi-squared test or Fisher's exact test to examine the relationship between discrete variables and radiologic severity grade.

Results

Of 318 charts were randomly selected from the total 1,200 charts with coded M 17.0, 17.1, or M 17.9, the researchers confirmed that the data from 310 charts met the clinical criteria of knee OA developed by the American College of Rheumatology (ACR).[13] Ten additional charts were excluded because of wrong coding: no clinical data about knee OA or knee pain were found in those charts. No charts were excluded because of evidence of secondary knee osteoarthritis. Among the remaining 308 charts, another eight were excluded because of incomplete data (Fig.1). Of the 300 charts with complete data which met ACR clinical criteria of knee OA, 124 (41.3%) were coded M17.0 (bilateral primary osteoarthritis of the knee), 5 (1.7%) were coded M17.1 (unilateral primary osteoarthritis of the knee), and 171 (57.0%) were coded 17.9 (arthritis of the knee, unspecified).

Characteristics of the participants

The study involved 300 patients who made a total of 809 visits to the outpatient rehabilitation department at Siriraj Hospital in 2018. All patients were diagnosed with primary OA knee. The mean age of the patients was 69.8 (SD=9.6), with 89% female and 11% male. The median BMI was 25.3

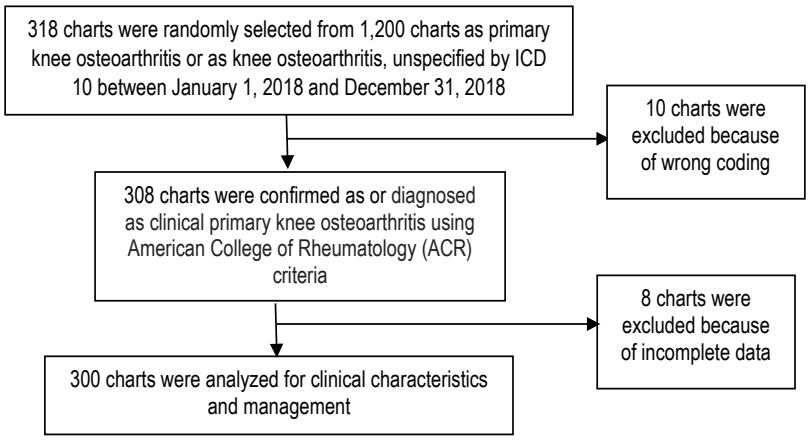

Figure 1. Chart review flow sheet

kg/cm^2, with 40.3% of patients being obese (BMI range 25-29.9 kg/cm^2). Most patients (67%) had civil servant medical benefit schemes as their health care coverage. Almost all patients (96.9%) experienced clinical knee pain. Most (88.9%) of the patients had bilateral knee pain and (92.6%) had crepitus. Most patients (86.1%) had functional limitations when walking. Over two-thirds of patients (68%) underwent a radiographic study, with most (69.9%) being classified as having Kellgren Lawrence (KL)[14] grade 0 or 1 (Table 1).

From the hospital records, topical analgesics (51.3%) were the most frequent pharmacological treatment, followed by glucosamine sulfate (22.3%) (Table 2). In addition, in almost half of the patients (42.7%), there were records regarding counseling on osteoarthritis knowledge. Over one-third were prescribed hospital-based physiotherapy as a non-pharmacological treatment (Table 2).

The association between the level of body mass index (BMI) and weight control prescribed by physicians was statistically significant ($p < 0.001$). For example, 21.1 percent of the patients with a BMI of 30 or more had a record of receiving weight reduction advice, while 2.5% of the patients with a BMI of 25-29.5 had a record of receiving advice.

The association between radiologic severity grading and treatment prescription is presented in Table 3. As analyzed by Fisher's exact test, glucosamine sulfate was statistically significantly associated with severity ($p = 0.004$). This drug was prescribed for patients with lower Kellgren Lawrence grades more frequently than for those with more severe grades. There was no significant association between radiological grading and non-pharmacological treatments, e.g., knee support, gait aid, and PT programs. (Table 3)

Discussion

Knee osteoarthritis (OA) is a common degenerative joint disease affecting millions worldwide. Accurate diagnosis and appropriate management are crucial to providing effective treatment to patients. While clinical diagnosis based on symptoms, medical history, and physical examination can be reasonably accurate, radiographic imaging plays a vital role in confirming the diagnosis and assessing the severity of knee OA.[16]

This study included charts with the diagnostic code 17.9 (arthritis of knee, unspecified) for screening purposes based

Table 1. Baseline characteristics of patients (n = 300)

Variable	Population Number (%)
Sex – female - number (%)	267 (89.0)
Age (years) - mean (SD)	69.8 (9.6)
Body weight (kg) - median (IQR)	60 (54.7, 66.7)
BMI[16] (kg/cm^2) - change to number (%)	
< 18.5	4 (1.3)
18.5-22.9	74 (24.7)
23.0-24.9	63 (21.0)
25.0-29.9	121 (40.3)
≥ 30.0	38 (12.7)
Health care coverage - number (%)	
Civil Servant Medical Benefits Scheme	200 (67)
Social security scheme	28 (9)
Universal coverage scheme	72 (24)
Clinical characteristics - number (%)	
Knee pain	279 (96.9)
Side of knee pain	
One side	28 (11.1)
Both	224 (88.9)
Crepitus	126 (92.6)
Functional limitations - number (%)	
Walking	124 (86.1)
Sitting on floor	2 (1.4)
Stair climbing	11 (7.6)
Others	7 (4.9)
Investigations - number (%)	
Radiographic study	204 (68)
Severity (Grading by Kellgren Lawrence score[13])	
Grade 0	22 (10.8)
Grade 1	120 (59.1)
Grade 2	54 (26.6)
Grade 3	7 (3.4)
Grade 4	0 (0)

Km, kilogram; cm, centimeter

on the pilot study in which the researchers found that the officials responsible for assigning codes usually relied on the information in the patient's chart. In cases where the physician's notes indicated "right" or "left" knee osteoarthritis or knee arthritis without specifying "primary," the coding was classified as 17.9 (Knee arthritis, unspecified). To ensure greater accuracy of the results, the researchers reviewed the charts and applied the ACR criteria to confirm primary osteoarthritis of knee.

The analysis found that approximately half (57%) of the medical records with clinical data that met the ACR criteria for primary knee osteoarthritis contained the M 17.9 code (knee arthritis, non-specific). This finding suggests that at team meetings, physicians should emphasize the significance of using precise terminology within the coding system.

Acknowledging that coding is not infallible and can sometimes lead to inaccuracies or misinterpretations is essential. Therefore, it is crucial to exercise caution and consider the limitations of relying solely on coded data to determine the actual diagnosis. Additional measures, such as thorough chart reviews and clinical evaluations, may be necessary to ensure a more accurate diagnosis.

Among the 204 patients who underwent an X-ray examination, 22 cases exhibited negative findings (Kellgren Lawrence grade 0). Negative X-ray findings in knee OA patients can be the result of several factors. First, X-rays may fail to capture early-stage OA, where structural changes and joint space narrowing may not be evident.[17] In such cases, alternative imaging modalities such as MRI or ultrasound might be more sensitive for detecting early cartilage degeneration or soft tissue abnormalities. Second, patients with knee OA symptoms but negative X-ray findings could have other conditions mimicking OA, such as inflammatory arthritis, meniscal tears, or ligamentous injuries. A comprehensive clinical evaluation, including a detailed medical history, physical examination, and, potentially, additional diagnostic investigations, is crucial to identifying alternative diagnoses and ensuring appropriate management.

Regarding clinical characteristics, this study's results are similar to a previous study by Kuptniratsaikul on the epidemiology of OA knee among elderly patients residing in an urban area of Bangkok.[5] Our study found similarities in the average age, gender, and bilateral knee distribution of patients. This

Table 2. Pharmacologic and non-pharmacologic treatment (n = 300)

Treatment	Number (%) (N = 300)
Pharmacologic treatment	
Acetaminophen	23 (7.7)
Oral NSAIDs	46 (15.3)
Topical analgesics	154 (51.3)
Oral opioids	6 (2.0)
Combined acetaminophen-opioids	45 (15.0)
Glucosamine sulfate	67 (22.3)
Diacerein	0 (0.0)
Intra-articular corticosteroids	0 (0.0)
Intra-articular hyaluronic acid	0 (0.0)
Intra-articular platelet-rich plasma	0 (0.0)
Non-pharmacologic treatment	
Advised PT home program	17 (5.7)
PT program at the hospital	129 (43)
Knee support	49 (16.3)
Specific exercise practice	113 (37.7)
Weight control advice	14 (5.3)
Education	128 (42.7)
Orthopedic consultation	4 (1.3)

NSAID, nonsteroidal anti-inflammatory drugs; PT, physical therapy

Table 3. Association between radiologic grading and treatment prescriptions

	Grade 0 N = 22	Grade 1 N = 120	Grade 2 N = 54	Grade 3 N = 7	*p*-value
Pharmacologic treatment					
Acetaminophen	3 (13.6)	7 (5.8)	4 (7.4)	1 (14.3)	0.317[a]
Oral NSAIDs	2 (9.1)	20 (16.7)	8 (14.8)	1 (14.3)	0.893[a]
Topical analgesics (methyl salicylate cream)	11 (50.0)	64 (53.3	24 (44.4)	5 (71.4)	0.501[a]
Oral opioids	2 (9.1)	1 (0.8)	0 (0.0)	0 (0.0)	0.079[a]
Combined acetaminophen-opioids	2 (9.1)	17 (14.2)	7 (13.0)	1 (14.3)	0.98[a]
Glucosamine sulfate	22 (100.0)	28 (23.3)	13 (24.1)	4 (57.1)	0.004[a]
Non-pharmacologic treatment					
Advice on PT home program	2 (9.1)	4 (3.3)	4 (7.4)	1 (14.3)	0.174[a]
PT program at the hospital	8 (36.4)	60 (50.0)	25 (46.3)	2 (28.6)	0.518[a]
Knee support	2 (9.1)	18 (15.0)	12 (22.2	2 (28.6)	0.35[a]
Gait aid prescription	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	-
Specific exercise advice	8 (36.4)	46 (38.3)	20 (37)	3 (42.9)	1[a]
Weight control advice	1 (4.5)	9 (7.5)	4 (7.4)	0 (0.0)	1[a]
Education	12 (54.5)	51 (42.5)	25 (46.3)	3 (42.9)	0.751[a]
Orthopedic consultation	0 (0.0)	0 (0.0)	2 (4.0)	2 (28.6)	0.06[a]

[a]Fisher's Exact Test, NSAID, nonsteroidal anti-inflammatory drugs; PT, physical therapy
Values are reported as numbers (percentage)

finding may be due to the possibility that some patients visiting our clinic may have been from the Bangkok metropolitan area.

This study found that the most commonly prescribed medication was topical analgesics which accounted for half of the cases. Analysis of the association between radiologic grading and drug prescription found no statistically significant association (p = 0.317). This finding may be due to doctors' concerns about the potential side effects of oral medications and the patient's preferences.

The second most commonly prescribed drug was glucosamine sulfate. We found a positive association between glucosamine sulfate and mild film grading (Table 3). In general, the effectiveness of glucosamine for knee OA remains a topic of debate. Some studies have suggested that glucosamine may provide pain relief and potentially slow down the progression of the disease, while others have found no significant benefits compared to a placebo. The conflicting results may be due to variations in study design, patient populations, dosages, and formulations of glucosamine. Guidelines from the American College of Rheumatology,[8] Osteoarthritis Research Society International (OARSI),[10] and the Thai Rheumatism Association[11] presented no substantial evidence supporting using glucosamine sulfate to improve OA knee and do not recommend glucosamine as a first-line treatment for knee OA.

Conversely, the European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ESCEO) publications in 2014 and 2019, included a strong recommendation for the use of prescription crystalline glucosamine sulfate (pCGS) and chondroitin sulfate as step one in long-term background therapy for management of knee OA.[9,18] The combination of these treatments was only weakly recommend. A research article by Meng et al. published in 2022 reported that the combined use of glucosamine and chondroitin is effective and is superior to other treatments for knee OA.[19] However, the authors of that systematic study and meta-analysis also concluded that more studies are needed due to the uneven trial quality of the previous research. More high-quality trials are needed to further investigate the actual clinical advantages of the combination.[18]

While numerous studies have been conducted on glucosamine for knee OA, including randomized controlled trials (RCTs), more specific RCTs are needed that focus exclusively on patients with clinical knee OA with negative X-ray findings (KL = 0). The prescription of glucosamine sulfate for this group of patients should be reevaluated.

Further work is needed to identify specific reasons for choosing a given medication as various factors can influence the physicians' decision and thus affect patient outcomes. Patient requirements as well as physician beliefs and experience can influence the prescription of specific medications. Additionally, patients recently diagnosed with osteoarthritis knee have easy access to information on the latest technology, including medical knowledge, and may search for alternative medicines online.

Among the 809 medical records from 300 patients, there were no recorded cases of the use of more invasive therapy such as intra-articular steroid hyaluronic acid or platelet-rich plasma (Table 2). Similarly, there was no record of prescription of gait aids (Table 3), although that could result from the fact that most of the cases in this study had only mild knee OA.

Regarding non-pharmacological prescribing, including provision of patient education about the nature of the disease, joint protection programs, and exercise recommendations, the patient records show that half the patients received information on exercise (Table 2). However, failure to record provision of that advice may have resulted in underreporting the number of cases receiving such information. We found a statistically significant association between provision of weight control information and BMI. The records also show that physicians advised weight reduction for patients with a higher BMI (p < 0.001) (Table 3)

Hospital-based physiotherapy was the preferred treatment for 43% of the 300 patients diagnosed with primary OA knee who had made a median of three hospital visits. Although more patients with mild radiologic severity came to the hospital for treatment than those with greater radiologic severity, there was no significant association between the level of severity and the number of hospital visits. A goal for the future is to reduce patient dependence on outpatient PT programs and to promote sustainable self-management of knee OA.[18]

As expected, patients who failed to respond to conservative treatments or who had severe radiologic grading were referred to the orthopedic department. This study found radiologic severity tended to increase the number of orthopedic consultations, but the association was not statistically significant.

There are several limitations to our study. First, numerous instances of information missing from an incomplete database may have resulted in less robust results. Second, poor handwriting may have resulted in some information being difficult to understand. Third, this study conducted only univariable analysis. Hence, the associations between two variables might be due to the effect of confounders. Another limitation is that data related to routine care from the 2018 chart review prior to the COVID-19 pandemic might be different from the routine care after the onset of the pandemic. Finally, our study was a retrospective chart review. Future prospective studies are suggested to improve the accuracy of the findings. We also recommend including pain scores, starting patient records at the first visit, maintaining the follow-up records, and specifying the quantity of medications. These information that could be valuable for future studies.

Conclusions

This study found that patients in the rehabilitation department at Siriraj Hospital were predominantly elderly, female, obese, and had civil servant medical coverage. The most common clinical characteristics were bilateral knee involvement, limitation in walking, and mild radiologic grades (KL 0 and 1). The records showed that half of the patients received education on osteoarthritis, and that weight reduction advice was given to patients with higher BMI. The most common treatments were topical analgesics, glucosamine sulfate, and hospital-based physical therapy programs. Glucosamine sulfate was significantly more frequently prescribed in cases with milder radiologic severity. Non-pharmacological prescriptions were not significantly associated with OA knee severity.

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