ASEAN Journal of Rehabilitation Medicine

e-ISSN 2673-0863

ASEAN J Rehabil Med
Volume 34, Number 2
May - August 2024
Formerly known as J Thai Rehabil Med

ASEAN Journal of Rehabilitation Medicine (ASEAN J Rehabil Med)

(Formerly Journal of Thai Rehabilitation Medicine)

Publication frequency

"ASEAN J Rehabil Med" publishes three issues a year: (1) January-April, (2) May-August, and (3) September-December.
It is our policy that there is NO publication charge.

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The main access its content is https://www.tci-thaijo.org/index.php/aseanjrm/

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Ownership and publisher

Thai Rehabilitation Medicine Association

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Notes from the Editor-in-Chief

I am delighted to welcome readers to the second issue of the ASEAN Rehab Med Journal for the year 2024. This issue features two randomized controlled trials that compare the effects of new interventions for musculoskeletal pain. Additionally, this issue includes the publication of three descriptive research studies that aim to establish the usage of diagnostic tools commonly employed in the field of rehabilitation. Furthermore, this issue presents a qualitative study that may not be familiar to the medical community but proves to be valuable, particularly when considering psychosocial factors as important aspects of the outcomes.

The first paper, Tongthong V and her colleagues conducted a randomized, single-blinded, non-inferiority clinical trial to compare the effectiveness of high-intensity laser therapy (HILT) and radial extracorporeal shock wave therapy (rESWT) in patients with chronic plantar fasciitis. They found that HILT and rESWT for this group of patients have the same pain reduction effect at 3 and at 7 weeks. Regarding foot function, rESWT helps improve ADL at 3 weeks but not in HILT. Both treatments improve overall foot function at 7 weeks.

Next, Amornpinyokiat T conducted a randomized controlled trial to compare the pain numeric rating scale and Oswestry Disability Index between telerehabilitation and conventional rehabilitation in patients with chronic low back pain. She found that telerehabilitation is not superior to conventional rehabilitation in reducing chronic pain, disability-related low back pain and is an option for individuals who can access the telerehabilitation service.

Aranyavalai T and her colleagues conducted a cross-sectional descriptive study to translate and culturally adapt the Fall Risk for Older People – Community Setting (FROP-Com) assessment tool for older Thai people and to evaluate the instrument's internal consistency and reliability. They concluded that the FROP-Com assessment tool displayed positive reliability and internal consistency for assessing risk factors among Thai older people.

Puprasert C and her colleagues conducted a cross-sectional study to establish the average values of cross-sectional area in the sural, fibular, and tibial nerves by ultrasonography and to investigate correlations with demographic data and nerve conduction studies and offered normative values and differentiate aberrant neural structures.

Harnphadungkit K and Raksit Phitsa-ard R conducted a cross-sectional study of 140 participants with carpal tunnel syndrome diagnosed by electrodiagnosis and fond that the patients' quality of life are correlated with the subjective symptom severity, functional severity, anxiety, and the inability to participate in leisure activities, but not electrophysiologic severity.

The last article, Kotcharoen R and her colleagues conducted a qualitative study to explored factors affecting cardiac rehabilitation uptake among patients with coronary artery disease in Thailand. They found that religious and cultural factors impact the uptake of cardiac rehabilitation among these group of patients. The authors concluded that a creation of culturally-based programs should be considered a priority, as should identifying potential approaches to successful delivery of program in rural areas of the country.

I extend my sincere thanks to all readers, authors, reviewers, and the editorial board for their hard work and support. I also hope to have your continued support for the upcoming issues.

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

Original Article

Comparative Effectiveness of High-Intensity Laser Therapy and Radial Extracorporeal Shock Wave Therapy in Chronic Plantar Fasciitis: A Randomized, Single-Blind Clinical Trial

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ABSTRACT

Objectives: To compare the effectiveness of high-intensity laser therapy (HILT) and radial extracorporeal shock wave therapy (rESWT) in reducing pain and improving foot function in patients with chronic plantar fasciitis (PF)

Study design: A randomized, single-blinded, non-inferiority clinical trial

Setting: Sirindhorn National Medical Rehabilitation Institute, Nonthaburi, Thailand

Subjects: Fifty-two patients suffering from chronic PF

Methods: Participants were randomly assigned to receive a total of 9 sessions of HILT or a total of 3 sessions of rESWT. Outcome measures were the visual analog scale (VAS) and the Thai version of the Foot and Ankle Ability Measure (FAAM) at 0, 3, and 7 weeks.

Results: There was no statistically significant difference between the two groups in VAS at baseline. The FAAM and VAS of both groups showed significant improvement at 3 and 7 weeks ($p < 0.05$). For instance, the FAAM scores of the rESWT group had significant improvement at 3 and 7 weeks ($p < 0.05$), while the FAAM scores of the HILT group had significant improvement only at 7 weeks ($p < 0.05$). There was no statistically significant difference in the VAS and total FAAM scores between the two groups. However, the rESWT group showed significant improvement compared to the HILT group in the ADL subgroup of FAAM at 3 weeks ($p < 0.05$).

Conclusions: HILT and rESWT for chronic PF have no statistical different pain reduction effect at 3 and at 7 weeks. Regarding foot function, rESWT helps improve ADL at 3 weeks but not in HILT. Both treatments improve overall foot function at 7 weeks.

Keywords: chronic plantar fasciitis, high-intensity laser therapy, radial extracorporeal shock wave therapy, physical therapy

ASEAN J Rehabil Med. 2024; 34(2): 48-55.

Introduction

Plantar fasciitis (PF) is a common foot disorder affecting 10% of adults during their lifetime. It accounts for 25% of all foot disorders in athletic populations, e.g., it affects up to 17.4% of runners. The pathology of PF is still unknown. Previous studies have reported secondary degenerative changes due to repetitive trauma in the plantar fascia without inflammation.[1,2] The usual symptoms include pain in the inner part of the heel that worsens with activities that include bearing weight and after periods of rest or non-weight-bearing.

PF has three phases: acute, subacute, and chronic. Acute PF pertains to the first 4 to 6 weeks following the onset. Subacute PF typically lasts 6 to 12 weeks. Chronic PF is diagnosed in individuals experiencing symptoms for beyond three months. Refractory PF is characterized as chronic PF that has not responded to conservative therapy for more than 6 months.[3] PF typically persists for an extended duration, with around 45% of individuals still enduring discomfort a decade later, resulting in extensive utilization of healthcare resources and a notable economic impact.[4,5]

Although previous studies have reported that 90% of PF patients achieved symptom resolution within 3-6 months with conservative treatment, the resolution of symptoms in some patients may take up to 18 months.[6,7] The 2010 updated clinical practice guidelines for heel pain recommended conservative treatments such as foot padding, orthotic insoles, anti-inflammatory medication, stretching exercises, orthotic devices, night splints, corticosteroid injections, botulinum toxin injections, physical therapy, cast immobilization, and extracorporeal shock wave therapy (ESWT) before considering surgical options.[8] Aside from surgical treatment, ESWT is one of the third-line treatments for PF which should be considered in chronic PF patients whose symptoms do not improve with other conservative treatments.[8] ESWT methods involve hyperstimulation analgesia, neovascularization stimulation, and collagen synthesis in degenerative tissues.[9] Nevertheless, there are still significant disadvantages and a lack of clarity regarding ESWT. Initially, common side effects include experiencing discomfort both during and after the treatment. According to a recent study, 20% of patients encountered

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Received: June 6, 2023 Revised: November 24, 2023 Accepted: November 28, 2023

adverse effects such as temporary skin redness and ecchymosis when undergoing ESWT treatment.[10] Secondly, contradicting results in many studies make it unclear to determine which type of ESWT, radial-ESWT or focused-ESWT, is superior.[9] Most studies have demonstrated the efficacy of ESWT for PF using a weekly routine of 3 to 5 sessions. However, there is currently no established standard protocol for using ESWT to treat chronic PF.[3]

HILT is a new, painless treatment option. The use of HILT has been studied in many musculoskeletal disorders with favorable results,[11] including PF and calcaneal spur.[12] HILT's effects are due to its anti-inflammatory, anti-edema, and analgesic mechanisms. HILT can access and activate more extensive and profound regions of the fascia compared to a high-power laser.[13,14] However, HILT application protocols so far have been heterogeneous.[11]

A recent study investigating HILT and rESWT effects on PF showed that both interventions successfully reduced pain. However, HILT seemed to be more effective in improving foot function.[15] This study's population of interest is distinct from that of Thammajaree et al. as it specifically targets persistent PF, a condition more frequently encountered in clinical settings. This study aims to examine the efficacy of HILT in comparison to rESWT for treating chronic PF and assess the immediate and intermediate effects of both treatments.[15]

Methods

Study design

This study was a randomized closed-label trial conducted at the outpatient department of Sirindhorn National Medical Rehabilitation Institute (SNMRI), Nonthaburi, Thailand, from May 2020 to December 2022. The Sirindhorn National Medical Rehabilitation Institute ethical committee approved the trial protocol (63006/ April 2020) and it was registered in the Thai Clinical Trials Registry (TCTR20201226001/ December 2020).

Participants

Patients who met the following inclusion criteria were recruited: 1) age ≥ 18 years, 2) pain and tenderness at the medial tubercle of the calcaneus which was worse with the initial step in the morning or after an extended period of rest and decreasing initially after the first steps but exacerbated with increased activity, 3) unresponsiveness to conservative treatments for at least three months.[7] The exclusion criteria included: 1) receipt of HILT or rESWT within the previous three months, 2) receipt of steroid injections within one month, 3) a diagnosis of other foot pathologies, e.g., foot or ankle fracture, fixed foot deformity, 4) a diagnosis of systemic inflammatory arthritis, e.g., rheumatic disease, 5) a diagnosis of neuropathy of the heel, e.g., polyneuropathy, entrapment disorder, 6) other acute pathology, e.g., wounds or signs of inflammation, and 7) patients who were not able to communicate. All participants provided written informed consent.

Sample size

The number of participants included in this study was determined based on the studies of Yesil et al., 2019[13] and Yinilmez et al., 2018.[16] The visual analog scale (VAS) was selected as the primary data source. According to the results, Yesil et al. used the mean difference score of VAS on HILT, 2.4, which had a standard deviation of 1.2. Additionally, Yinilmez et al. used the mean difference score of VAS on ESWT, which was 1 with a standard deviation of 2. The sample size was based on a power of 80% (beta 0.2), a dropout rate of 20%, and a statistical significance (alpha 0.05) of 95% (p = 0.05). As a result, 52 patients were required, with 26 patients per group using the sample size formula based on a randomized, single-blinded, non-inferiority clinical trial.

The sample size formula: is

$$n_{trt} = \frac{(z_{1-\frac{\alpha}{2}} + z_{1-\beta})^2 \left[\sigma_{trt}^2 + \frac{\sigma_{con}^2}{r}\right]}{\Delta^2}$$

$$r = \frac{n_{con}}{n_{trt}}, \Delta = \mu_{trt} - \mu_{con}$$

Randomization and blinding

The randomization process was conducted by an independent investigator who did not participate in the treatment or data collection processes, using computer-generated randomization (mixed-size block randomization). The allocation was concealed by using nontransparent, sequentially numbered envelopes. Participants were allocated in a 1:1 ratio into either the HILT group or the rESWT group. The assessor was blinded to the treatment allocation, but the participants were not blinded due to the different nature of the intervention in each of the groups (Fig. 1).

Interventions

High-intensity laser therapy (HILT)

The HILT group received pulsed laser treatment using an HIRO 3 device, which employs a pulsed Nd: YAG laser therapy source with a wavelength of 1,064 nm, from ASA Arcugnano, Italy. The HILT protocol used in this study was modified from Yesil et al., with changes made to the session frequency. The number of sessions was reduced from 15 to 9 (3 sessions per week for three weeks) to improve feasibility and practicality. The device emits pulsed radiation at a wavelength of 1,064 nm with a peak power of 3 kW. The energy density ranges from 360 to 1,780 mJ/cm^2, with a short duration of 120 to 150 microseconds, a mean power of 10.5 W, a low frequency of 10 to 40 Hz, a duty cycle of approximately 0.1%, a probe diameter of 0.5 cm, and a spot size of 0.2 cm^2. A three-phase treatment regimen was administered on the plantar fascia area. The total energy used in one session was 1,281.1 joules. The laser fluency was adjusted to three different levels: 970 mJ/cm^2, 1,070 mJ/cm^2, and 1,170 mJ/cm^2, resulting in a total of 624 J in the initial phase. The second phase included exposure to fluences of 360 mJ/cm^2, 510 mJ/cm^2, 610 mJ/cm^2, and 360 mJ/cm^2, amounting to a total of 33.1 J. The third phase involved intentional manual scanning. 624 joules of energy were administered during this phase.[13]

Radial extracorporeal shock wave therapy

The rESWT protocol followed the Yinilmez study, consisting of one session per week for three weeks, totaling three sessions of rESWT using a Duolith® SD1 device from Storz Medical AG, Tägerwilen Switzerland. The treatment was administered with a transmitter (R15, 15 mm) delivering an energy flux density/penetration depth of 0.38 mJ/mm^2 up to a depth of 40 mm. The protocol contained an energy density of 2 bars with a frequency of 2,000 shocks per minute at 10 Hz. ESWT was administered in a circular motion, delivering 1,000 shocks at the plantar fascia insertion point and another 1,000 shocks along the fascia.[16]

Additional treatments

The following standard treatments were given to both groups: 1) patient education about self-care of acute pain and proper shoes that cushion and support heels and 2) plantar fascia stretching exercise. A brochure containing all exercise recommendations was given to all participants, and they were instructed to exercise at home twice daily. 3) Participants were allowed to use oral acetaminophen for pain relief; exercises and acetaminophen use were recorded in a log book.

Outcome measurements

The primary outcome measure was subjective pain intensity using a 10-cm horizontal Visual Analog Scale (VAS) three times each day: at the first step in the morning, during daily activities, and the maximal pain level of the day. The secondary outcome was foot function using the Thai version of Foot and Ankle Ability Measure (FAAM). The FAAM is a 29-item self-reported questionnaire that is divided into two subscales: a 21-item ADL subscale and an 8-item sport subscale. Each question is scored on a 5-point Likert scale (from 0 to 4), and each subscale score is calculated as a percent ranging from 0-100 (worst to best outcome). The reliability measurement revealed a high intra-class correlation coefficient of 0.8 and 0.77, respectively, between the test and retest. The internal consistency was strong (Cronbach alpha = 0.94 and 0.88, respectively).[17] All patients in both groups were assessed for VAS and FAAM at baseline (week 0), at 3 weeks, and 7 weeks.

Statistical analysis

Statistical analyses were performed using STATA version 17.1 (StataCorp®, Texus, USA), with a statistical significance threshold of P 0.05 (2-sided). Descriptive data are presented as mean and standard deviation. Baseline demographic data is presented as the mean and standard deviation for quantitative data and as a number and percentage for qualitative data. The corresponding data from the HILT and rESWT groups were compared using the t-test and the chi-squared test (or Fisher's exact test where appropriate). A multilevel mixed-effects linear regression (mixed-effects model method) was used to analyze the primary outcome with repeated measures after randomization. Six dropout participants were not included in the analysis. However, since the dropout rate was less than 20% of the calculated sample size, the analysis in this study was considered sufficient per protocol analysis.

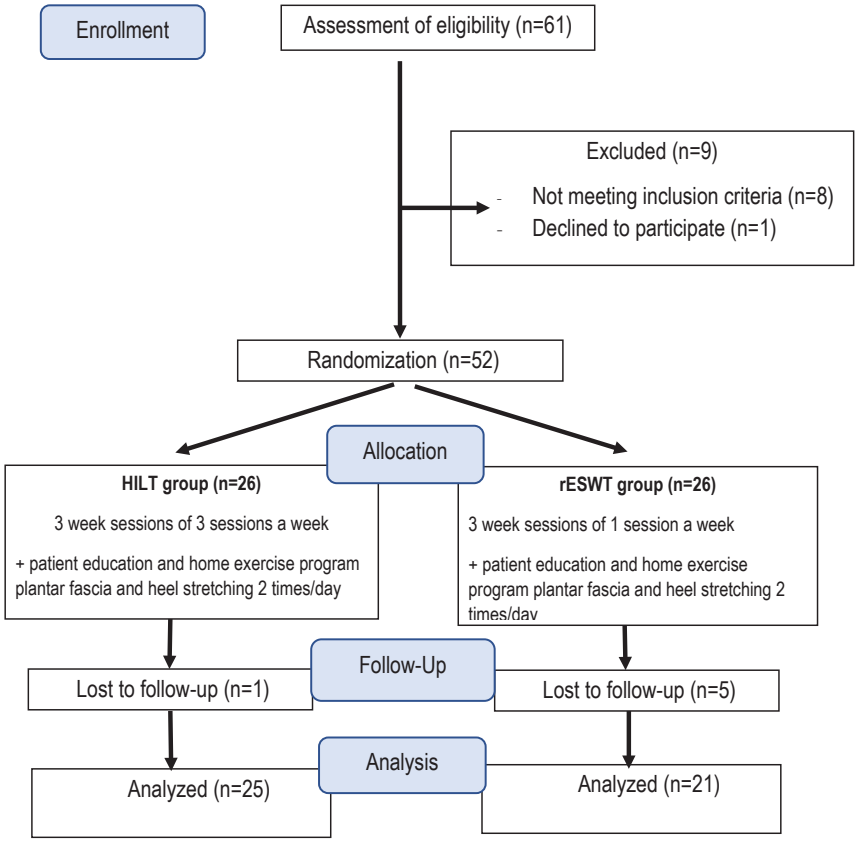

Figure 1. CONSORT flow chart of the participants. HILT, high intensity lower therapy; rESWT, extracorporeal shock wave therapy

Results

Fifty-two participants were enrolled and randomly assigned to either the HILT (n = 26) or the rESWT group (n = 26). Six participants did not complete the intervention: one in the HILT group and five in the rESWT group (Fig. 1). The reasons for the loss of follow-up were unrelated to post-therapy effects. There were two transportation problems, one COVID-19 infection, one ankle fracture, one case of myalgia, and one of post-vaccine fever. The data on the dropout participants was not included in the analysis. No side effects were reported in either the HILT or the rESWT groups. Both groups had similar demographic characteristics (Table 1). Both group's VAS and FAAM scores were not significantly different at baseline.

At the end of the study, there was no statistically significant difference in VAS and FAAM scores between the two groups at 3 and 7 weeks, except the ADL subgroup of FAAM at 3 weeks. The mean activities of daily living (ADL) scores of FAAM in the rESWT group were higher than in the HILT group in the third week (Table 2). The VAS of both groups revealed significant improvement at 3 and 7 weeks. The FAAM scores of the rESWT group revealed significant improvement at 3 and 7 weeks, while the FAAM scores of the HILT group showed significant improvement only at 7 weeks. (Table 3)

Discussion

Many recent studies have reported on the effects of HILT on musculoskeletal disorders, including PF. Still, there are as yet no recommended guidelines for treating PF.[19-21] A few studies have compared HILT to the standard treatments during chronic PF.[12,13,15] The present study evaluates the effectiveness of HILT compared with rESWT in chronic PF.

Table 1. Demographic and clinical characteristics of patients

Characteristics	HILT (n = 25)	ESWT (n = 21)	*p-value
Age (years)	51.2 (14.9)	47.5 (13.2	0.379
Sex, n (%)			
Male	11 (44.0)	4 (19.0)	0.072
Female	14 (56.0)	17 (81.0)	
Weight (Kg.)	65.2 (19.7)	65.4 (16.1)	0.970
Height (meter)	1.6 (0.1)	1.6 (0.1)	0.502
BMI* (kg/m^2)	26.3 (6.0)	25.1 (5.1)	0.465
Standing/walking time (hour)	5.6 (3.4)	6.4 (2.9)	0.376
Duration of pain (month)	11.0 (12.0)	8.0 (6.4)	0.325

Data are presented as mean (SD); BMI, Body mass index; *p < 0.05 indicates statistical significance

Table 2. VAS and FAAM at baseline, at the 3 weeks, and at the 7 week

Prarameters	HILT (N = 25)	ESWT (N = 21)	MD (95% CI)	*p-value
VAS score, first step				
Baseline	5.4 (2.3)	4.8 (2.3)	-0.60 (-1.91, 0.71)	0.367
At 3 weeks	3.0 (2.4)	2.5 (2.2)	-0.53 (-1.84, 0.78)	0.425
At 7 weeks	2.5 (2.4)	1.9 (2.1)	-0.52 (-1.84, 0.80)	0.437
VAS score, daily activities				
Baseline	5.9 (1.7)	4.9 (1.8)	-1.00 (-2.23, 0.23)	0.110
At 3 weeks	3.3 (2.2)	3.4 (2.4)	0.11 (-1.12, 1.33)	0.866
At 7 weeks	2.9 (2.6)	2.2 (2.1)	-0.65 (-1.89, 0.59)	0.303
VAS score, maximal pain				
Baseline	7.0 (1.9)	6.9 (2.0)	-0.09 (-1.49, 1.31)	0.897
At 3 weeks	4.1 (2.5)	4.3 (2.8)	0.25 (-1.15, 1.65)	0.723
At 7 weeks	3.6 (2.6)	3.5 (2.8)	-0.04 (-1.46, 1.39)	0.961
FAAM, Activities of daily living (ADL)				
Baseline	71.1 (18.4)	74.7 (12.3)	3.95 (-6.22, 14.12)	0.447
At 3 weeks	73.6 (16.0)	83.9 (15.3)	10.82 (0.82, 20.82)	0.034*
At 7 weeks	81.8 (21.3)	88.5 (11.1)	6.89 (-2.65, 16.43)	0.157
FAAM, Sport				
Baseline	72.5 (19.8)	76.6 (15.1)	3.95 (-5.68, 13.57)	0.422
At 3 weeks	80.0 (16.6)	85.6 (17.2)	5.79 (-3.96, 15.54)	0.244
At 7 weeks	85.6 (14.2)	87.9 (14.8)	2.48 (-7.06, 12.03)	0.610

Data are presented as mean (SD); *p < 0.05 indicates statistical significance

MD, Mean difference; CI, Confidence interval; VAS, visual analog scale; FAAM, foot and ankle ability measure

Table 3. VAS and FAAM by time period compared to baseline in the HILT and rESWT groups

Parameters	HILT		RESWT	
	MD (95% CI)	*p-value	MD (95% CI)	*p-value
VAS score, first step				
Baseline	0		0	
At 3 weeks	-2.37 (-3.47, -1.28)	<0.001*	-2.30 (-3.31, -1.30)	<0.001*
At 7 weeks	-2.99 (-4.11, -1.89)	<0.001*	-2.93 (-3.93, -1.93)	<0.001*
VAS score, daily activities				
Baseline	0		0	
At 3 weeks	-2.58 (-3.59, -1.57)	<0.001*	-1.47 (-2.36, -0.58)	0.001*
At 7 weeks	-3.02 (-4.04, -2.00)	<0.001*	-2.69 (-3.58, -1.80)	<0.001*
VAS score, maximal pain				
Baseline	0		0	
At 3 weeks	-2.95 (-4.01, -1.88)	<0.001*	-2.60 (-3.73, -1.47)	<0.001*
At 7 weeks	-3.53 (-4.62, -2.44)	<0.001*	-3.49 (-4.62, -2.36)	<0.001*
FAAM, ADL				
Baseline	0		0	
At 3 weeks	1.18 (-6.06, 8.41)	0.749	8.49 (1.46, 15.52)	0.018**
At 7 weeks	9.86 (3.03, 16.69)	0.005*	13.18 (6.15, 20.20)	<0.001*
FAAM, Sport				
Baseline	0		0	
At 3 weeks	7.39 (-0.29, 15.07)	0.059	9.22 (0.83, 17.62)	0.031**
At 7 weeks	12.87 (5.28, 20.45)	0.001*	11.41 (3.10, 19.73)	0.007**

MD, Mean difference; CI, Confidence interval; HILT, high-intensity laser therapy; rESWT, Radial Extracorporeal shock wave therapy

* < 0.001 indicates statistical significance

** $p < 0.05$ indicates statistical significance

There was no statistically significant difference between the two groups according to the VAS and FAAM with the exception of the ADL subgroup of FAAM in the third week, in which rESWT showed better results.

Regarding pain as the primary outcome of this study, the results are consistent with Ordahan et al. that HILT is effective in chronic PF.[14] Our study show a positive result at a longer follow-up of 7 weeks. Additionally, both groups were instructed to record additional treatments in a logbook, including exercise and oral acetaminophen. The as well as calf muscle and plantar fascia-specific stretching.[25] We found an average of 4.8 days per week of exercise in the HILT group and 4.5 days per week in the rESWT group. This result shows good exercise compliance that may affect positive outcomes in the seventh week, although the patients finished the treatment in the third week. As a result, This indicates that PF stretching exercises provide good benefits.[22] Moreover, 4 HILT group participants and none of the rESWT group used oral acetaminophen for pain relief, which could have affected HILT positive outcomes. These could be confounding factors for good potentially affecting outcomes. In a further study, HILT and rESWT without plantar stretching and oral acetaminophen should be investigated.

Regarding the foot function using FAAM, there was no significant difference found between the groups regarding foot function using FAAM except in the ADL subgroup which had a notable improvement after three weeks. rESWT assistance helped improve ADL, including standing, walking, home responsibilities, personal care, light to moderate work, heavy work, and recreational activities after three weeks. However, there was no significant improvement in sports activities.

Before the present study, two randomized studies evaluated the effectiveness of HILT in PF. However, the results of those studies were difficult to compare due to differences in method and measurement. First, Ordahan et al. reported that HILT was more effective than LLLT in improving pain and foot functions in the third week.[14] Nonetheless, most cases in that study were subacute PF with a mean duration of 8±1.5 weeks, and only immediate outcomes at the third week were measured. On the contrary, our study was performed on people with chronic PF with a longer measurement duration of seven weeks. Second, Yesil et al. found that both HILT plus exercise and placebo HILT plus exercise could improve pain and function at 4 and 12 weeks in the painful calcaneal spurs and PF population. Still, only HILT showed a significant improvement in dynamic pedographic measurement and had improvement significantly better than placebo in some foot function subscales.[13] However, in the Yesil et al. study, the number of PF cases could not be differentiated from those with calcaneal spurs. Moreover, patients at varying stages, ranging from acute to chronic, were included in that study. This population differs from our study which included only patients with chronic PF. All in all, regardless of disease duration, HILT tended to show positive outcomes on PF.

Regarding the treatment protocols, the current HILT protocols are heterogeneous.[1] At the time of the present study other studies had yet to investigate the effectiveness of varying intensity and frequency in HILT treatment. However, In this study, the HILT group had 9 sessions (3 sessions per week for 3 weeks), and the rESWT group had only 3 sessions (1 session per week for 3 weeks). The rESWT protocol once proved has previously been reported to be sufficient to provide a therapeutic effect.[23] Additionally, the different mechanisms of the two treatments were operationally equal in frequency for both groups. We used rESWT with an energy density of 2 bars with a frequency of 2,000 shocks per session, which does not affect post-treatment pain compared to unlike other studies which used more than 2,000 shocks.[24]

Although the 9-session HILT protocol might still cause some inconvenience for patients compared with the 1 session per week for three weeks rESWT protocol, HILT has some advantages not found with rESWT. One advantage of HILT is that it is not only non-invasive but also has photochemical and photothermic effects that can help stimulate tissue healing and reduce pain.[20,25] These mechanisms are comparable to those of rESWT. Furthermore, the anti-inflammatory effect of HILT helps reduce inflammation, suggesting that pain reduction may be faster in cases of acute inflammation. However, the results of our study do not show the differences. This finding any difference which could be due to the selection of chronic PF patients as the participants.

Recently, Thammajaree et al. studied the effects of rESWT versus HILT in individuals with PF and found no significant difference in VAS outcomes. Regarding foot function outcomes, a study by Thammajaree et al. found no statistically significant difference in foot function index (FFI) between the two groups. That finding differs from our study, in which rESWT showed better outcomes in the ADL subgroup of FAAM in the third week.[15] Although Thammajaree et al. and our study compare the same interventions in the PF population, some differences in the methodology may be a cause of the different results. First, Thammajaree et al. used different treatment protocols in both groups, e.g., a total of six sessions of rESWT for three weeks, while our study used once a week sessions for three weeks. Moreover, Thammajaree et al. assessed patients at the immediate post-treatment point of 3 weeks, while our study assessment was after the longer duration of 7 weeks. Second, the measurement tools for foot function assessments in the studies were different. FFI uses a different aspect of FAAM to evaluate foot function.[17] FFI contained includes measurement of pain, disability, and activity limitation. The validity and reliability of FFI can only be generalized to individuals with rheumatoid arthritis, unlike the Thai FAAM score, including the Activity of Daily Life (ADL) and Sports subscale, which are region-specific measures of changes in physical function specifically related to the foot and ankle and correlated with SF-36.[17] Lastly, the Thammajaree et al. included a population of PF of any duration. In contrast, our study included only those with chronic PF for whom other conservative treatments had failed. Despite these differences, it is evident that HILT and rESWT do not differ in terms of pain reduction in PF patients regardless of the time since onset. Minor differences in foot function results could be due to differences in treatment protocol and population selection.

Regarding the research design, the sample size formula used in this study is based on a non-inferiority clinical trial. According to the data collection, in the current study, there were six dropouts. Only 46 patients were analyzed, which is compatible with the per-protocol analysis. However, this small sample size problem can bias results towards non-inferiority trials and give rise to misleading results. Future studies should apply both per protocol and intention-to-treat analysis with prespecified imputation techniques to avoid bias from applying only per protocol analysis.[26]

Lastly, no adverse effects were reported in either group. However, according to other studies, rESWT may have side effects, such as pain during and after treatment, while no significant side effects were found with HILT.[27]

Study limitations

There are some limitations to this study. First, there was no control group. An additional sham group might have allowed discarding the placebo effect in this study. Second, the short follow-up period does not show the long-term effect of HILT on chronic PF. Third, more ultrasonographic findings are needed to evaluate the outcome.[28-30] Fourth, due to the differences between this study and the study we used to calculate our sample size, i.e., using non-active and active control intervention, the sample size of this study may not reflect the most appropriate effect sample size, which might be larger than that in this study. Further study may be needed to ensure an appropriate sample size for population inference using the results of this study as a reference.

Additionally, future research, including each modality's unit cost to determine each treatment's feasibility, would provide useful information for clinical practice.[31] Additionally, future research with focused ESWT could be valuable. Focused ESWT can result in more pain reduction and less pain after treatments than rESWT in chronic PF patients.[9]

Conclusions

In this study we compared the effect of HILT with rESWT for chronic PF. We found no statistically significant difference between the two groups. The results of our study suggest that among the 46 patients in the study, both treatments for chronic PF had the same pain reduction after three weeks and at a longer follow-up of seven weeks. Regarding foot

function, rESWT helps improve ADL after three weeks. Also, both treatments improve overall foot function at a longer follow-up of 7 weeks. Based on our findings, we recommend that clinicians select either HILT or rESWT to help reduce pain and improve foot function in patients with chronic PF.

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Original Article

Comparison of the Effectiveness of Telerehabilitation and Conventional Rehabilitation in Patients with Chronic Low Back Pain: A Randomized Controlled Trial

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ABSTRACT

Objectives: To compare the pain numeric rating scale (NRS) and Oswestry Disability Index (ODI) between telerehabilitation (TR) and conventional rehabilitation (CR) in patients with chronic low back pain

Study design: A randomized controlled trial

Setting: Department of Physical Medicine and Rehabilitation, King Taksin Memorial Hospital, Bangkok, Thailand

Subjects: Thirty-six participants with chronic low back pain

Methods: Participants were allocated by randomization into two groups. The conventional rehabilitation (CR) group (n = 18) was treated with a home exercise program demonstrated by a Bangkok Medical Association (BMA) specialist at the hospital, and the telerehabilitation (TR) group (n = 18) was treated with the same home exercise program by a BMA specialist via a video link. Participants in both groups were asked to do the exercises at home once a day for 8 weeks, with 10 repetitions of each exercise. NRS and ODI of both groups were rated prior to the exercise program and again at the end of the eight-week exercise program.

Results: Before beginning the exercises, the two groups had no statistically significant difference in either NRS (p = 1.00) or ODI (p = 0.97). After the 8-week exercise program, the NRS of the TR group was significantly lower than that of the CR group (p = 0.03) although the ODI was not significantly different between the two groups (p = 0.90). Group analysis found that NRS was significantly reduced by 2.06 in the CR group (p = 0.00) and 3.06 in the TR group (p = 0.00) and that ODI was significantly decreased by 12.26 in the CR group (p = 0.00) and by 12.13 in the TR group (p = 0.00) at the end of the study.

Conclusions: In treating chronic low back pain, telerehabilitation is not superior to conventional rehabilitation in reducing chronic pain, disability-related low back pain and is an option for individuals who can access the telerehabilitation service.

Keywords: conventional rehabilitation, chronic low back pain, exercise, telerehabilitation

ASEAN J Rehabil Med. 2024; 34(2): 56-62.

Introduction

Low back pain is localized below the costal margin and above the inferior gluteal folds, can occur either with or without sciatica.[1] Mechanical low back pain can be caused by overuse of back muscles by an individual with normal anatomical structure. It can also result from secondary injury or deformity. Common causes of mechanical back pain include muscle strain, herniated nucleus pulposus, osteoarthritis, and spinal stenosis.[2] Chronic low back pain is defined as pain persisting for three months or more.[1] It results in physical problems for individuals as well as socioeconomic problems for society in both developed and developing countries.[3] In addition to health problems, chronic low back pain also increases the prevalence of depression, anxiety, and sleep disturbance compared with healthy people.[1,3] The worldwide prevalence of low back pain has been reported to be around 18.3%.[4] Low back pain also limits activity, resulting in some low back pain patients becoming chronic low back pain patients. The prevalence of chronic low back pain is about 25.9%.[3] In developed countries, more than 70 percent of people have experienced low back pain during at least one period of their life.[1]

Available low back pain treatments include conservative and surgical treatment. Conservative treatment includes exercise, behavioral modification, psychological therapy, manual therapy, physical modalities, and pharmacological treatment such as analgesic drugs, non-steroidal anti-inflammatory drugs (NSAIDs), tramadol, muscle relaxants, and antidepressants.[5, 6] The American College of Physicians recommends in an evidence-based guideline that the first line of low back pain treatment is non-pharmacological conservative treatment. Physicians should recommend using non-invasive therapies before drugs or surgery. Although there are a variety of invasive treatments for chronic low back pain, invasive procedures are not the first line of treatment.[6] The most common cause of back pain is mechanical back pain, and the first-line treatment

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Received: January 12, 2024 Revised: February 18, 2024 Accepted: February 24, 2024

is exercise and education.[5] Exercise is one of the effective non-pharmacological conservative care treatments for low back pain because it has a lower potential for harm than other alternatives.[7] Self-managed home exercise programs are widely accepted and used by healthcare professionals in long-term rehabilitation therapy, defined as conventional rehabilitation.[4, 8]

Telerehabilitation is defined as a remote science technology rehabilitation service.[9] It allows for treatment of diseases by substituting telephone and video conferencing for the traditional face-to-face approach in the patient-rehabilitator interaction. Various types of therapy, such as exercise and motor retraining, can be delivered through telerehabilitation. Telerehabilitation can be helpful in chronic low back pain patients who are not eligible for surgery. It saves the patient the cost of traveling to the hospital, facilitates patient access to treatment, and can be done at home via video conference. To maximize effectiveness, Both the physician and the patient should have access to high-quality screens and high-speed internet.[10] Additionally, telerehabilitation motivates patients to exercise because the patient is already used to being at home.[11]

There have been many studies of telerehabilitation in musculoskeletal disorders, e.g., post-total knee arthroplasty, post-total hip arthropathy, low back pain, neck pain, temporomandibular joint disorders, and chronic musculoskeletal spinal conditions.[10-16] A systematic review of 15 studies found that both patients and rehabilitation professionals were satisfied that telerehabilitation is comparable to face-to-face physician consultation in treating musculoskeletal disorders.[13] However, recent evidence has provided inconsistent results regarding the efficacy of treatment of chronic low back pain via telerehabilitation.

Telerehabilitation is a relatively new technology. It helps with the supervision of patients in remote locations and supports physiatrists by replacing face-to-face with more physician-conservative rehabilitation.[10] Telerehabilitation shown to be helpful during the COVID-19 pandemic because it allowed for provision of physical therapy patient care without the patient coming to the hospital.[17] The present study aimed to compare the effectiveness of telerehabilitation and conventional rehabilitation in patients with chronic low back pain.

Methods

This randomized controlled trial was approved by the Bangkok Metropolitan Administration Human Research Ethics Committee (Approval number S016hc/66). The sample size was calculated based on a previous study using the n4Studies application to have a power of 0.8 and an alpha value of 0.05.

Participants

Patients diagnosed with chronic low back pain who visited athe Physical Medicine and Rehabilitation outpatient clinic at King Taksin Memorial Hospital between November 2023 and January 2024 were invited to join this study. After giving their informed consent, they were recruited into the study. The inclusion criteria were age between 25 to 59 years and having pain caused by muscle strain as determined by medical history and physical examination that had persisted for at least three months. The NRS of participants was mild (1-3) or moderate (4-6) prior to the start of treatment. Patients with any of the following were excluded from the study: a history of back or spine surgery, back trauma during the previous six months, a malignancy condition, communication disorder, pregnancy, orthopedic or neurological disorders, and having no internet or mobile communication. Randomization was done by computer with patients assigned to receive either telerehabilitation (TR) or conventional rehabilitation (CR) at a 1:1 ratio.

Procedure

The physiatrist assessor interviewed participants regarding their demographics and occupation, reviewed their medical records, identified the duration of pain, asked about their maximum pain intensity, and had the patients complete the Oswestry Disability Index Thai version (ODI). All participants were assessed twice, before the initial treatment and following the last treatment.

In this two-arm randomized study, at the first hospital visit all patients in both groups were prescribed the same home exercise program and the same assessor. The assessor was the physiatrist. The assessor taught the patients a home exercise program, after which the participants made an appointment with the assessor once a week for 8 weeks. The BMA Doctor application was used at the 2nd through the 8th follow-up visits in the TR group, and face-to-face interaction in the hospital was used at the 2nd through 8th follow-up visits in the CR group. All participants were given an appointment once a week, a total of 8 times over 8 weeks, with the same assessor. The home exercise program included lumbar region and lower extremity stretching exercises (lumbar extensor, psoas major, piriformis muscles and hamstring), strengthening exercises for abdominal muscles (transverse abdominis, abdominal external/internal oblique muscles), lumbar muscles (lumbar erector spina) as well as bridging, spinal mobility (cat-camel motion exercise), McKenzie's extension and Williams's flexion exercises. Participants were asked to do all the exercises at home once a day for 8 weeks, with 10 repetitions of each exercise.

The telerehabilitation (TR) group met with the assessor at the Department of Physical Medicine and Rehabilitation, King Taksin Memorial Hospital, only at the first visit during which they were taught the home exercise program and received guidance on using the "BMA Doctor" mobile application. This application was a project of the Bangkok Metropolitan Administration which allows patients access to medical services at 11 hospitals under the Bangkok Medical Service Department. Participants in the TR group downloaded the application. Participants

were required to have an updated Android or IOS mobile phone connection to the internet. After registration of the application, TR group participants pressed the "telemedicine" button on the screen to start a conversation with the assessor. This process was repeated at the 2nd through the 8th follow-up visits. All participants in the TR group received their appointments via the BMA Doctor application once a week for a total of 8 times. During the follow-up after the 8th week, the same assessor reviewed with each participant their experience with the home exercise program. The review process lasted about 15 minutes. The same form of access was used for all the follow-up periods for each participant. At the 8th and final visit, the assessor asked the patients about their maximum pain intensity and had them complete the Oswestry Disability Index Thai version (ODI).

The assessor met with members of the conventional rehabilitation (CR) group at the Department of Physical Medicine and Rehabilitation, King Taksin Memorial Hospital. The assessor taught the same home exercise program at the hospital. CR group participants were given an appointment at the hospital (face-to-face interaction) once a week for 8 weeks. During follow-up, the assessor asked the participants about and reviewed the home exercise program. At the 8th and final visit, the assessor asked the members of the CR group about their maximum pain intensity and had them complete the Oswestry Disability Index Thai version (ODI).

Outcome measures

The primary outcome was subjective pain intensity measured using a numeric rating scale (NRS) where 0 means no pain and 10 means most severe pain. The assessor asked participants to report their maximum pain at that moment. The secondary outcome was the Oswestry Disability Index score (range 0 to 100, with higher scores indicating more disability related to back pain).[18] The Oswestry Disability Index (version 1.0) Thai version was used in this study. That Index has demonstrated validity and reliability: the content validity of each item ranged from 0.6-1.0, and the Cronbach's alpha of all items was 0.8107.[19] If participants had ongoing pain during treatment, they were allowed to take acetaminophen 500 mg 1 tablet q 6 hours, but no other pain medications were allowed during the study, e.g., tramadol and oral NSAIDs.

Statistical analysis

Demographic data of participants in both groups were gathered, analyzed, and described. Quantitative data are shown as means and standard deviations. The qualitative data are shown as frequencies and percentages. IBM SPSS Statistics 26 was used for the statistical analysis. Mean differences of NRS and ODI values between groups were analyzed using an unpaired t-test for parametric data with statistical significance set at $p < 0.05$. Before and after treatment analysis within groups was done using the paired t-test for parametric data also with statistical significance set at $p < 0.05$.

In cases where participants were lost to follow-up or had only an initial assessment, the end-of-study data was imputed based on the beginning data. This method was used to avoid misleading results from intention-to-treat analysis.

Results

A total of 40 patients were initially screened, of whom 36 were enrolled. All 36 participants were allocated to groups of whom 30 completed the study, a dropout rate of 17 percent (Figure 3). All participants who completed the study were included in the statistical analysis and were analyzed according to their assigned group. Most participants in the study (61%) were female in both groups; the mean age was 39 (6.5) years, and the mean duration of pain was 10 (7.1) months. The most common occupation was office worker. (Table 1).

In the study, an intention-to-treat analysis was used. No statistically significant differences between the two groups in pain on the NRS before treatment was found (mean difference = 0.00, $p = 1.00$). At the end of the study, there were statistically significant differences in pain on the NRS between the two groups: the TR group had significantly lower pain on the

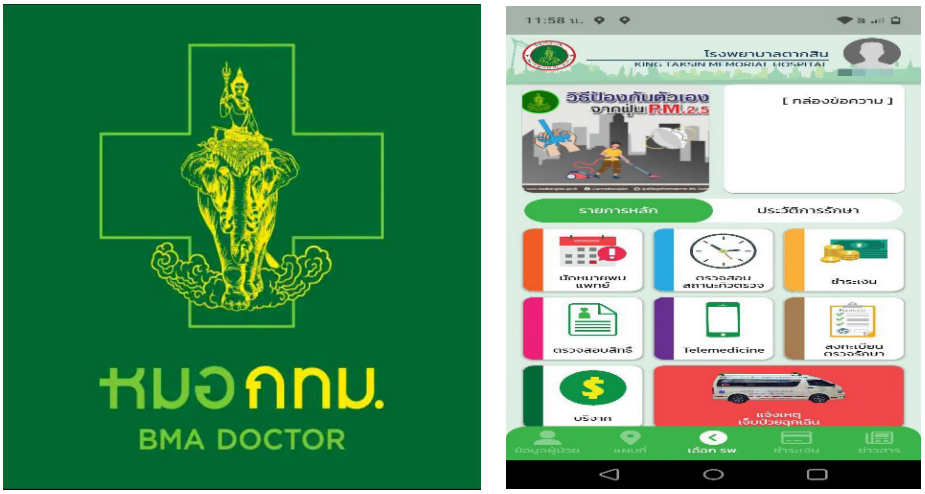

Figure 1. BMA Doctor application

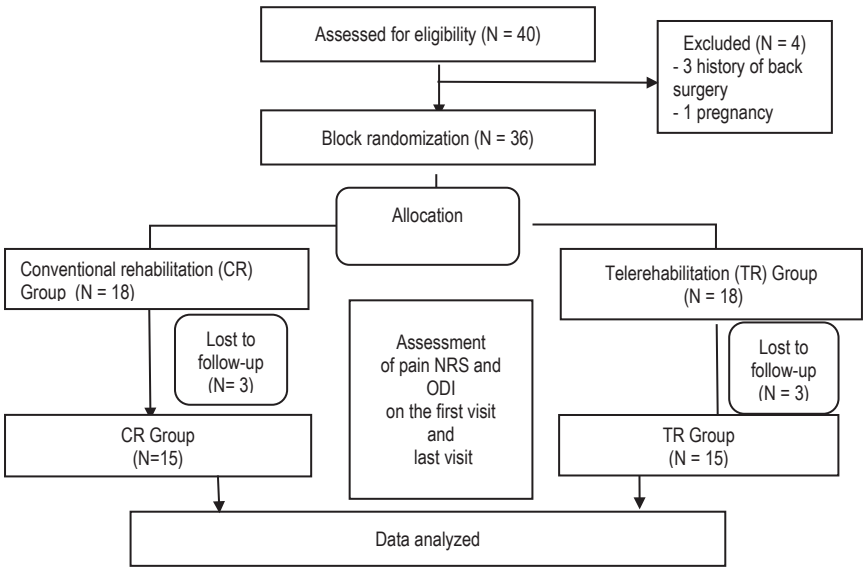

Figure 2. Schematic flow diagram of the study

Table 1. Demographic data of participants with chronic low back pain of the conventional rehabilitation (CR) and the telerehabilitation (TR) groups

	CR Group (n = 18)	TR Group (n = 18)
Age (years)[1]	39 (6.07)	39 (7.11)
Gender[2]		
Female	10 (56)	12 (67)
Male	8 (44)	6 (33)
Duration of pain (months)[1]	10 (7.61)	10 (6.78)
Occupation[2]		
Office worker	9 (50)	12 (67)
Healthcare worker	6 (33)	4 (22)
Laborer	2 (11)	2 (11)
Housewife	1 (6)	0 (0)

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

NRS than the CR group (mean difference = 1.00, p = 0.03). Within-group analysis found NRS was statistically significantly reduced in the CR group, 2.06 (p = 0.00) vs. 3.06 in the TR group (p = 0.00) (Table 2).

At the beginning of the study, there were no statistically significant differences in ODI between the groups (mean difference = 0.13, p = 0.97). After the 8-week therapy, ODI had significantly decreased in both the CR group, 12.26 (p = 0.00), and the TR group, 12.13 (p = 0.00). There were no statistically significant differences in ODI between the two groups at the end of the study (mean difference = 0.26, p = 0.90) (Table 2).

Three participants in the CR group reported taking acetaminophen as an add-on drug therapy to relieve pain; one participant in the TR group did so. No participants in either group had side effects from exercise, such as musculoskeletal injury, which is a common risk.[20]

Discussion

Low back pain is often associated with work loss and economic burden on society. General exercise is one of the non-invasive treatments for chronic lower back pain. It usually includes muscle strengthening and trunk stabilizing exercises. Twelve higher-quality trials showed a significant increase in pain relief with general exercise for chronic low back pain.[6,21] The home exercise program aims to improve the function of abdominals, back extensors, upper and lower limb muscles, and spine.[21] Telerehabilitation has been used with chronic low back pain patients. It is easy to use and convenient to access. Outcome, ease of access, quality,

Table 2. Comparison of outcome parameters between the conventional rehabilitation (CR) and the telerehabilitation (TR) groups

Parameters Mean (SD)	CR Group	TR Group	Mean difference	p-value
Pain numeric rating scale				
At the beginning of the study	5.53 (1.36)	5.53 (0.74)	0.00	1.00
At the end of the study	3.47 (1.41)	2.47 (0.83)	1.00	0.03*
Before and after p-value	0.00*	0.00*		
Oswestry Disability Index (percent)				
At the beginning of the study	29.73 (10.55)	29.86 (6.39)	-0.13	0.97
At the end of the study	17.47 (6.02)	17.73(5.85)	-0.26	0.90
Before and after p-value	0.00*	0.00*		

Between groups analysis using unpaired t-test, within-group analysis using paired t-test, *statistical significance level at p < .05

and lower cost are the main focus of telerehabilitation.[11] This technology initiative can enhance healthcare service in the "new normal" era after the COVID-19 pandemic.[22,23] Telerehabilitation is an exercise-based rehabilitation service which helps patients in remote locations to avoid close contact with physicians to reduce the spread of disease. This new normal medical service was designed to improve the quality of life for Thai people over the long term and to help create a more sustainable society.

This randomized controlled trial compared the effectiveness of telerehabilitation with conventional rehabilitation in patients with chronic low back pain. Most of the participants were female which is in line with a study by Alfalogy et al.[3] Although that study reported that 82.9% of patients with chronic low back pain were above 40 years, the present study found the mean age to be 39 (6.5) years.[3] Prior to the beginning of the eight-week treatment, there was no significant difference in the baseline pain NRS or ODI between the two groups. At the end of the study, there was a significant difference in pain NRS between the two groups, with the TR group having significantly lower pain NRS scores than the CR group. However, there was no significant difference in ODI between the two groups. These results suggest that both groups were able to reduce pain intensity. Although both the TR and CR groups showed an NRS pain reduction in this study, the difference in pain NRS reduction was not great, 3.47(1.41) and 2.47(0.83), respectively, and there was no clinical difference in pain intensity reduction. TR did not improve function on ODI more than CR in chronic low back pain patients. Participants in the TR group were able to communicate with the physician from remote areas. They did not have to spend time and money going to the hospital, which could be a source of added motivation and satisfaction with exercise. The CR group took slightly more acetaminophen than the TR group, but the difference was not statistically significant. That lack of difference may be because this study included only patients with mild and moderate degrees of pain at the initial treatment.

In the current study, after 8 weeks of therapy pain was significantly reduced in the CR group, which is in line with a study by Ozden et al.[4] Several studies have similarly reported on why CR can reduce pain.[4, 14, 22] For example, Villatoro-Luque et al.[22] reported that pain location only affected the level of pain during flexion and extension movements. In that study, the pain intensity when performing the knee extension test and kinesiophobia was reduced more in the telerehabilitation group than in the clinic group. The present study did not measure the pain intensity when participants performed the exercise movements.

In the present study, the TR group had greater pain reduction than the CR group, which is in line with an Ozden et al.[4] study. In contrast, other studies have reported no difference in pain reduction between a conventional group and a telerehabilitation group.[14] That difference may be due to the fact that this study and a study by Ozden et al. lasted 2 months, whereas the other studies had a longer duration, e.g., Cottrell et al.[14] measured pain-related disability, pain severity, and health-related quality of life at baseline, 3 months, 6 months, and 9 months. The Cottrell study showed no significant group-by-time interaction for either pain-related disability, pain severity, or health-related quality of life. Bailey et al.[5] conducted a longitudinal observational study which evaluated a 12-week digital care program that included 10,000 participants with chronic knee and back pain. That large, diverse, real-world population cohort study showed a longitudinal change in pain with a higher mean reduction rate in the first week, but a lower mean reduction rate at 2-5 weeks and 6-12 weeks. This result suggests that pain reduction rates can vary over time.

In the present study, the differences between the treatment groups in disability related to low back pain were measured by changes in ODI scores using the Oswestry Disability Index (version 1.0) Thai version. That index has been shown to have good internal consistency, with the content validity of each item ranging from 0.6-1.0, and a Cronbach's alpha of all items of 0.8107. In this study, there were no statistically significant differences in the baseline ODI between the two groups. At the end of the study, there was again no significant difference in ODI between the two groups. This result is in line with a study done by Cottrell et al.[14], whereas other studies have reported significant differences in ODI between the two groups at the end of the study.[4] The present study focused on mild to moderate degree pain, so only low baseline Oswestry Disability Index scores were detected.

In this study, NRS was significantly reduced (by 2.06 in the CR group and 3.06 in the TR group) at the end of the treatment period. ODI significantly decreased (by 12.26 in the CR group and 12.13 in the TR group) between preintervention and postintervention after the 8-week therapy, which is in line with a study by Ozden et al.[4] No statistically significant improvements in pain, function, quality of life, or kinesiophobia were found in either the CR group or the TR group. This study's positive results support using telerehabilitation as a treatment for chronic low back pain.

This study had some limitations. First, the study did not assess long-term outcomes, e.g., 3, 6, and 9 months. Second, the study did not monitor either patient satisfaction or quality of life. Third, the sample size was relatively small, and the BMA doctor application was Thai, which might limit the generalizability of the results. Fourth, this study used NRS for pain assessment. Although all participants were able to communicate well, NRS is subjective. Fifth, because of the study design the assessor in this study could not be blinded. Further study is needed to explore clinical outcomes during a long-term follow-up period.

Conclusions

Based on the findings of this study, telerehabilitation provides no additional benefits in terms of pain relief over conventional rehabilitation in patients with chronic low back pain although it does reduce inconvenience and travel expense for patients. BMA Doctor use of telerehabilitation positively affects clinical pain and disability outcomes. Telerehabilitation may be another option for treatment in patients with chronic low back pain. It should be considered for individuals who can access the service.

Disclosure

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

Acknowledgments

The author would like to sincerely thank the patients participating in this study and colleagues who provided recommendations on the writing of the manuscript.

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Original Article

Cross-Cultural Adaptation of the Fall Risk for Older People – A Community Setting (FROP-Com) Assessment Tool - Thai Version

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ABSTRACT

Objectives: The primary aim of this study was to translate and culturally adapt the Fall Risk for Older People – Community Setting (FROP-Com) assessment tool for older Thai people and to evaluate the instrument's internal consistency and reliability. The secondary goal was to identify contributing risk factors for falls in individuals assessed with the Thai-version FROP-Com tool.

Study design: Cross-sectional descriptive study

Setting: Faculty of Medicine, Vajira Hospital, Bangkok, Thailand

Subjects: Thai community-dwelling elders aged 60 years and over

Methods: This study utilized standard guidelines for the cross-cultural adaptation process, which consisted of (a) forward translation, (b) synthesis translation, (c) backward translation, (d) expert committee review, and (e) test of the pre-final version. Internal consistency was assessed using Cronbach's alpha coefficient. This study used intraclass correlation coefficients (ICC) with 95% confidence intervals to evaluate intra-rater and inter-rater reliability.

Results: The Thai FROP-Com assessment tool was successfully adapted for the Thai language. A total of 140 Thai community-dwelling participants aged 60 and older who met the inclusion criteria completed the study. Validation showed a good internal consistency of 0.96, while the intra-rater reliability was 0.92 and the Kappa coefficient was 0.89. The inter-rater reliability was 0.91 and the Kappa coefficient was 0.86.

Conclusions: The FROP-Com assessment tool displayed positive reliability and internal consistency for assessing risk factors among Thai older people. The tool was demonstrated to be valid and is now available for use with older members of the Thai population.

Keywords: Thai version, FROP-Com assessment tool, fall risk factors, Thai older people, cross-cultural adaptation

ASEAN J Rehabil Med. 2024; 34(2): 63-69.

Introduction

Globally, falls are the leading cause of death for seniors aged 60 years and over. According to the World Health Organization (WHO), the worldwide annual prevalence rate for falls among older persons varies from 28% to 35%.[1] In Southeast Asia, the prevalence of falls among individuals over 60 ranges from 10.4% to 53.6%.[2] In Thailand, elderly residents of urban and suburban neighborhoods had higher fall prevalence rates, ranging from 18.7% to 19.8%.[3,4] Among older Thai people (age ≥ 65), 11% of deaths were brought on by falls.[5] Thus, it is essential to look into and identify the risk factors that make older Thai individuals more likely to fall.

Age, gender, general health information, housing situation, and fall history have all been recognized as potential fall risk factors, both intrinsic and extrinsic, in older persons. In 2007, the WHO recommended classifying these risk factors into four categories: biological, behavioral, environmental, and socioeconomic. Many tools for assessing fall risk factors have been developed for older people in community settings. Thai-FRAT is a community-based screening tool that takes about five minutes to complete. It can be used by non-healthcare professionals and has 97% specificity when a person ticks four out of the five questions.[6]

The Physiological Profile Assessment (PPA) developed by Stephen Lord takes 45 minutes to administer. The PPA involves a series of simple tests of vision, peripheral sensation, muscle force, reaction time, and postural sway, but omits assessments of medication, medical conditions, or home hazards. A computer program using data from the PPA can be employed to assess an individual's performance with a normative database so that deficits can be targeted for intervention.[7] The Falls Risk for Older People in the Community (FROP-Com) assessment tool is a clinical assessment tool invented to evaluate multifactorial fall risks. It can be used in time-limited situations, requiring only 5-10 minutes to classify those at high risk of falls who require more detailed assessment and

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Received: December 9, 2023 Revised: February 26, 2024 Accepted: March 16, 2024

management. The FROP-Com assessment tool includes 26 questions with either ordinal (0-3) or dichotomous scoring that address 13 risk factors: (1) history of falls, (2) number of medications, (3) number of medical conditions, (4) sensory deficit, (5) foot problems/inappropriate footwear, (6) cognitive status, (7) bladder control problems, (8) nutritional status, (9) environment, (10) functional behavior, (11) physical function, (12) balance, and (13) gait/physical activity. A score of 0-20 indicates mild to moderate fall risk, and 21-60 suggests high fall risk. The tool has a high intraclass correlation coefficient (ICC) for intra-rater reliability of 0.93 (95% CI 0.84-0.97) and a strong inter-rater reliability of 0.81 (95% CI 0.59-0.92). In a previous study, the sensitivity and specificity of FROP-Com were determined to be 71.3% (95% CI: 64.4-78.3) and 56.1% (95% CI: 48.9-63.4), respectively.[8] This tool is simple to use, accurate, and dependable. The entire FROP-Com tool, along with its scoring standards, additional assessments, and interventions, are available at https://www.nari.net.au/frop-com. The primary aim of the present study was to translate the FROP-Com assessment tool developed by Russell et al.[8] in 2009 to create a Thai version using standard guidelines for the cross-cultural adaptation process. The secondary goal was to identify contributing risk factors for falls in individuals assessed by the Thai-version FROP-Com tool.

A Thai-translated fall risk assessment version of the original tool is necessary to overcome the language barrier. The present study validated the Thai FROP-Com translation of the FROP-Com assessment instrument for thorough falls risk assessment developed by Russell et al. in 2009.[8]

Methods

Study design

This cross-sectional descriptive study consisted of two phases: cross-cultural adaptation followed by investigation of the psychometric properties of the Thai-version FROP-Com assessment tool.

The study was approved by the Faculty of Medicine Vajira Hospital, Navamindradhiraj University Institutional Review Board (COA.No.105/2018). The authors received permission to translate the FROP-Com from Dr. Frances Batchelor, Acting Director Health Promotion, MARC Program Manager, National Ageing Research Institute Ltd., PO Box 2127, Royal Melbourne Hospital, Victoria 3050, Australia via e-mail f.batchelor@nari.unimelb.edu.au. The guidelines used in the translation and the details of each step are described in Beaton et al.[9]

Participants

A total of 140 Thai community dwellers who met the following inclusion criteria were recruited: having or not having a history of falls within the past 12 months, being able to walk outdoors either with or without gait aids, and understanding Thai verbal instructions. The data were collected at the Department of Rehabilitation Medicine, Faculty of Medicine, Vajira Hospital.

The sample size was calculated using the formula for translating questionnaires.[10] The minimum sample size required was 95 individuals. However, we recruited a larger sample of older people to determine the fall risk factors associated with fall status without adjusting for other factors (p = 0.05), a total of 140.

Intervention

In the present study, five steps of cross-cultural adaption were conducted: (a) forward translation, (b) synthesis translation, (c) backward translation, (d) expert committee review, and (e) preliminary version testing.

Step 1. Forward translation. The FROP-Com assessment tool Russell M. et al. proposed in 2009 was translated into Thai FROP-Com. Two translators translated the original English version to Thai by matching Thai words with the same meaning to ensure the equivalence of the concept of each fall risk factor in both languages. The forward translation versions were completed by the Center for Translation and Language Services Research Institute for Languages and Cultures of Asia (RILCA), Mahidol University Salaya, Nakhon Pathom 73170, Thailand.

Step 2. Synthesis translation. The two translators and a recording observer synthesized the first and second translations, producing one common translation from the original FROP-Com assessment tool and the versions of the first and second translators. A detailed report on the process was prepared and the issues addressed and resolved in this step were documented.

Step 3. Back or reverse translation. Two bilingual translators converted every sentence from the Thai translation back to English. They chose English words that had the same meaning as the Thai version while being ignorant of the original English version.

Step 4. Expert committee. The two forward and two back translated versions were reviewed by an expert committee including four experts, a geriatric physical therapist, an orthopedic physical therapist, a family medicine doctor, and a language specialist, to create the final translated version. The committee also considered all of the suggestions made by the translators and research teams after which the Thai FROP-Com translation was finally finished.

Step 5. Preliminary version testing. This step was conducted to ascertain the level of acceptance among the intended audience and to validate the Thai-translated version. It was evaluated with the assistance of ten older adults (aged 60 to 80), both with and without a history of falls. This procedure was followed to evaluate the overall translation accuracy and the acceptance of each of the fall risk factors. The evaluation included the question, “Did you understand all the words?” and responses to “Please rate the scale of acceptable meaning in fall risk factors.” Acceptability of meaning was measured on a 5-point Likert scale (range: unacceptable meaning to acceptable meaning). The final question asked the participants to rate

Step 1.	Forward translation	Two translators translated the original English version into Thai using Thai words with the same meaning. The forward translated versions were completed by the Center for Translation and Language Services Research Institute for Languages and Cultures of Asia (RILCA), Mahidol University Salaya, Nakhon Pathom 73170, Thailand.
Step 2.	Synthesis translation	The two translators and a recording observer synthesized the two translations of the first and second translators. One common translation version was produced from the original FROP-Com assessment tool and the versions of the first and second translators. Details of the process and the issues addressed and resolved in this step were documented.
Step 3.	Back translation	Two bilingual translators converted each sentence from the Thai translation back into English. They chose English words that had a similar or the same meaning as the Thai version while being totally ignorant of the original English version.
Step 4.	Expert committee	A committee of four experts (a geriatric physical therapist, an orthopedic physical therapist, a family medicine doctor, and a language specialist) reviewed the two forward and two back translation versions for the final translated version. They also considered all of the suggestions from the translators and research teams in completing the Thai FROP-Com.
Step 5.	Preliminary version testing	This step was used to ascertain the level of acceptance and to validate the Thai translation among the intended audience. The evaluation was done by ten older adults (60 to 80 years old), both with and without a history of falls. This procedure was done to evaluate the overall translation and the acceptance of each fall risk factor. The questions were "Did you understand all the words?" and "Please rate acceptability of the meaning of the fall risk factors". The five levels of acceptability of meaning (Likert scale) ranged from unacceptable to acceptable (scale 1 to 5). The final part of the questionnaire asked the participants to rate the acceptability of the translation overall.

Figure 1. The five steps in the cross-cultural adaption of the Thai FROP-Com assessment tool

the overall acceptability of the translation as a percentage.

To test the reliability and consistency of the Thai-version FROP-Com tool, two physiotherapists assessed the participants with it. They completed all the baseline evaluations and repeated the assessment with the same participants in the next two weeks.

Outcome measurements

The intra-rater and inter-rater reliability of the Thai FROP-Com assessment tool were the primary outcome measurements of this study. Two physiotherapists independently reviewed all of the baseline evaluations of each of the 10 participants for inter-rater reliability. After two weeks, they then visited the participants again and repeated all of the Thai FROP-Com assessment tool items.

Statistical methods

Demographic information was examined with descriptive statistics analysis. Content analysis was used to compile the qualitative information and comments from steps 1 through 5 of the cross-cultural adaptation.[11]

The percentage of agreement for each item was used to evaluate the level of agreement for each translation. The level of agreement in the final Thai translation version used in the pilot study was assessed using rater agreement or Fleiss' Kappa agreement. The Kappa values were interpreted as follows: less than 0.40 indicating fair agreement, 0.41-0.60 for moderate agreement, 0.61-0.80 for substantial agreement, and 0.81-1.00 for excellent agreement. Rater agreement and the percentage of subjects rating the meaning acceptable (scale >3) were calculated[11,12] Rating of acceptability ranged from unacceptable to acceptable: 1 = unacceptable, 2 = slightly unacceptable, 3 = neutral, 4 = slightly acceptable, and 5 = acceptable.

Intraclass Correlation Coefficient (ICC) was used to determine the intra-rater and inter-rater reliability. The first and the second numbers represent the model and the number of the rater, respectively. ICC (3,1) was employed for two-way mixed effects, consistency, and single rater/measurement to determine the intra-rater reliability while ICC (2,1) was applied for two-way random effects, absolute agreement, and single rater/measurement to evaluate inter-rater reliability. Finally, content validity was assessed by the 10 participants in the pre-testing phase of the Thai FROP-Com assessment tool.

The sensitivity, specificity, and cutoff score of the Thai-version FROP-Com tool were also defined by measuring the area under the curve (AUC) of the receiver operating characteristic (ROC) curve.

The secondary goal of this study was to use univariate logistic regression analysis to identify the factors associated

Table 1. Demographic characteristics of the study participants

	Non-Fallers[a] (N = 77)	Fallers[b] (N = 63)	Total (N = 140)
Age group N (%)			
80-89 years	20 (25.97%)	16 (25.40%)	36 (25.72%)
70-79 years	30 (38.96%)	22 (34.92%)	52 (37.14%)
60-69 years	27 (35.07%)	25 (39.68%)	52 (37.14%)
Gender N (%)			
Female	53 (68.83%)	42 (66.67%)	95 (67.86%)
Male	24 (31.17%)	21 (33.33%)	45 (32.14%)
Thai FROP-Com Score[c]	19.51 (5.2)	25.5 (3.6)	24.19 (4.14)
BMI (kg/m^2) N (%)			
Obese (BMI ≥ 25)	11 (14.28%)	9 (14.28%)	20 (14.28%)
Overweight (23.0 ≤ BMI < 25.0)	26 (33.77%)	18 (28.57%)	44 (31.42%)
Normal (18.5 ≤ BMI < 23.0)	29 (37.67%)	22 (34.93%)	51 (36.45%)
Lean (BMI < 18.5)	11 (14.28%)	14 (22.22%)	25 (17.85%)
Living alone N (%)			
Yes	27 (35.06%)	10 (15.87%)	37 (26.43%)
No	50 (64.94%)	53 (84.13%)	103 (73.57%)

[a]Participants who had no history of falling in the past 12 months; [b]participants who had one or more falls in the past 12 months; [c]mean (SD)

FROP-Com, The Falls Risk for Older People in the Community; BMI, body mass index

with the occurrence of one or more falls over the previous 12 months. Fallers were participants who were rated 1-3 on previous falls within 12 months in the assessment tool without adjustment for other factors. Odds ratios of the Thai FROP-Com risk factors were used to judge the strength of association among variables (p-value < 0.05). All data were analyzed using IBM SPSS Statistics for Windows, version 19.0. (Armonk, NY, USA).

Results

The FROP-Com has been successfully translated into a Thai version. A total of 140 Thai community members who satisfied the inclusion requirements, including age at least 60 years, participated in a cross-sectional study. Participants were stratified by age into three groups, 60-69, 70-79, and 80-89 years, with the proportion of each group shown in Table 1. Most (67.86%) were female; 17.85% of the subjects had a low body mass index (BMI) of less than 18.5 kg/m^2, while 14.28% were considered to be obese (BMI ≥ 25 kg/m^2). Only 26.43% lived alone, with most staying with family members or caregivers.

The 140 Thai FROP-Com scores were used to calculate the relationship between the sensitivity and specificity obtained from fallers (n = 63) and non-fallers (n = 77) (Table 2).

Good internal consistency (0.96) was demonstrated via validation, with ICC (3, 1) intra-rater reliability of 0.92, 95% confidence interval (95% CI) = 0.89 to 0.95, and a Kappa coefficient of 0.89. The inter-rater reliability measured by ICC (2, 1) was 0.91; 95% CI = 0.87 to 0.95 with the Kappa coefficient of 0.86. The specificity was 97.0%, and the sensitivity was 95.3%. A Thai FROP-Com cutoff score ≥ 25.0 was defined to distinguish between participants with and without a history of falling in the past 12 months.

Table 2. Sensitivity and specificity of the Thai FROP-Com scores

Thai FROP-Com score	Sensitivity	1 - Specificity	Specificity
8	0.000	0.000	1.000
9	0.007	0.000	1.000
10	0.012	0.000	1.000
11	0.031	0.000	1.000
12	0.047	0.000	1.000
13	0.055	0.000	1.000
14	0.076	0.000	1.000
15	0.105	0.000	1.000
16	0.173	0.000	1.000
17	0.408	0.000	1.000
18	0.539	0.000	1.000
19	0.765	0.000	1.000
20	0.875	0.000	1.000
21	0.910	0.000	1.000
22	0.922	0.000	1.000
23	0.945	0.020	0.980
24	0.953	0.030	0.970
25	0.953	0.030	0.970
26	0.970	0.119	0.881
27	0.978	0.189	0.811
28	1.000	0.564	0.436
29	1.000	0.758	0.242
30	1.000	1.000	0.000

FROP-Com, The Falls Risk for Older People in the Community

The mean Thai FROP-Com score for all participants was 24.19 (SD±4.14). For the subjects who completed the Thai FROP-Com assessments tool, the risk factors with the highest proportion classified as high risk (3 on the 0-3 point scale items or 1 on the 0-1 scale items) were the number of medical conditions (57.6%), vision deficit (45.4%), inappropriate footwear (43.3%), incontinence (34.3%), nocturia (43.1%), and

foot problems (30.9%). However, only 9% were rated as having severe balance problems when walking and turning, and 13% were rated at least minimally unsteady when walking and turning based on observation.

Twenty-two items from the Thai FROP-Com assessment tool which were designed to be calculated as in the original FROP-Com assessment tool were included to determine the factors most strongly associated with fall status without adjustment for other factors ($p < 0.05$). Thirty percent of the participants assessed by the Thai FROP-Com assessment tool were rated as having mild falls risk (scores ≤ 10, n = 42), while 42.85% were evaluated as having moderate falls risk (scores 11-24, n = 60), and 27.15% were classified as having high falls risk (scores ≥ 25, n = 38). Eight risk factors differentiated fallers from non-fallers: multiple falls history in the past 12 months, higher number of medical conditions, the presence of visual deficit, foot problems, inappropriate footwear, bladder control problems (either incontinence or nocturia) unsteadiness when walking and turning/risk of losing balance, and low physical activity level. Odds ratios of Thai FROP-Com risk factors are shown in Table 3.

Discussion

The translation and validation process was conducted following recommendations for cross-cultural adaptation. The assessment tool was effectively cross-culturally adapted, and demonstrated the feasibility for senior Thai people. The translated Thai FROP-Com assessment tool has 28 key headings. The Thai FROP-Com's expert members determined that the meaning of words remained unchanged from their original form. Finally, simple and unambiguous Thai vocabulary was substituted to increase the content validity of the Thai-translation version. Items related to fall risk from the Thai FROP-Com evaluation were analyzed as shown in Table 3.

The ICC of inter-rater reliability was greater than the original version of 0.81 (95% CI 0.59-0.92). Similarly, intra-rater reliability was higher than the original FROP-Com assessment tool of 0.93 (95% CI 0.84-0.97). The psychometric features of the Thai FROP-Com assessment tool demonstrated strong internal consistency, reliability, and validity. The cutoff score of ≥ 25 was determined by measuring the area under the curve (AUC) of the receiver operating characteristic (ROC) curve.

A previous study reported that the FROP-Com cutoff score of ≥ 19 had been used to discriminate high levels of fall risk in people with Alzheimer's disease.[13] Another study showed a significant correlation between the FROP-Com score and the Functional Gait Assessment score in stroke patients.[14] A study that evaluated the ability of the FROP-Com tool to predict falls and fall injuries for community-dwelling older people presenting to the emergency department after falling suggested an optimal cutoff score of ≥ 15 to indicate

Table 3. Odds ratios of Thai FROP-Com risk factors

Falls risk factor	OR	95% CI	*P*-value
Number of falls in the past 12 months	2.52	1.94-3.28	<0.001*
Number of medical conditions	2.09	1.67-2.89	<0.001*
Number of sedative medications	1.62	1.05-2.37	0.678
Number of falls risk medications	1.58	0.88-1.66	0.569
Vision deficit	1.69	1.29-1.95	<0.001*
Somatosensory deficit	1.37	0.33-5.75	0.269
Foot problem	1.57	1.45-2.68	<0.001*
Inappropriate footwear	1.37	0.33-5.75	<0.001*
Cognitive impairment	1.11	0.56-2.21	0.368
Incontinence	2.16	1.12-5.01	<0.001*
Decreased food intake	0.48	0.13-1.99	0.481
Weight loss	1.26	0.59-2.72	0.552
Alcohol intake	0.46	0.29-2.72	0.268
Home environment appears unsafe	0.48	0.19-1.42	0.191
Self-awareness in ADLs performance	0.34	0.37-1.81	0.743
Impaired balance (from observation)	2.67	1.59-5.46	<0.001*
Assistance required to perform personal ADLs	2.06	0.89-2.52	0.388
Assistance required to perform domestic ADLs	1.96	0.69-2.92	0.758
Low level of physical activity	2.08	1.32-3.16	<0.001*
Inability to walk safely in the house	1.16	0.49-2.41	0.948
Inability to walk safely in the community	0.91	0.72-1.69	0.412
Injury from falls in the past 12 months	0.76	0.57-2.42	0.688

*Statistically significant ($p < 0.05$)

OR, odd ratio; CI, confidence interval; FROP-Com, The Falls Risk for Older People in the Community; ADLs activities of daily living

Details of each fall risk factor are available in the appendix

a high fall risk with a sensitivity of 70.8% to help identify individual risk factors and provide the fall prevention intervention guidance.[15]

Thai FROP-Com was designed to be comprehensive, i.e., able to identify all existing risk factors, with higher scores being indicative of higher falls risk. For the subjects who completed the Thai FROP-Com assessments tool, the risk factors found to indicate high risk were the following: number of medical conditions, vision deficit, inappropriate footwear, incontinence, nocturia, and foot problems. Approximately 10% of the participants were rated as having either unsteadiness or severe balance problems with level walking and turning.

The secondary goal of the study is to identify contributing risk factors for falls in individuals that need to be addressed. Our study identified eight risk factors considered to be associated with a high risk for falls as follows: a history of multiple falls in the past 12 months, a higher number of medical conditions, the presence of vision deficit, foot problems, inappropriate footwear, bladder control problems (either incontinence or nocturia), unsteadiness when walking and turning/risk of losing balance, and low physical activity level. The number of current medications was classified on a 4-point scale, i.e., 0 = no medications, 1 = 1-2 medications, 2 = 3 medications, and 4 = 4 or more medications. Additionally, certain medications that are considered to increase the risk of falls were categorized on a 4-point scale based on the number of prescription medications. Polypharmacy and fall-predisposing drug use failed to predict falls in our study. This might be explained by the fact that most of the participants took 1-3 prescription medications and only a few participants used medications that have been recognized as affecting the balance.

Since entering a private home was occasionally seen as intrusive, accessing and evaluating the home environment was frequently difficult. It was not possible to view the situation inside residences for this study. As evaluating the homes of older Thai people in community settings can be unacceptable to them, alternative approaches, include asking the participants to self-report home safety issues using pictures of potentially unsafe situations. Despite the insignificant odds ratio regarding the inability to walk safely in the community, footpath surfaces in community-dwelling settings are often uneven, and there are frequently extra risks outside the house, e.g., rough walkways and roads, which should be taken into consideration.

Although the Thai FROP-Com was advantageous to identify falls status, the primary aim of the assessment was to identify contributing risk factors for falls in individuals rather than identifying fall risk factors that need to be addressed. The variables most frequently assessed as high risk using the Thai FROP-Com in this study offer suggestions for actions that could be useful in preventing falls in older Thai people.

Limitations of this study include that the Thai FROP-Com assessment tool was not validated for other samples, e.g., populations with risk factor profiles for hip fractures, renal failures, and severe osteoporosis. That is a necessary next step in the development of more specific assessment tools for these particular populations. The sensitivity and pecificity reported here might not be extrapolated to other groups of community-dwelling older people. Nevertheless, this study provides preliminary guidance for identifying fall risk factors which could aid decision-making regarding falls reduction efforts for older Thai people.

The information in this study could help researchers and clinicians such as physicians, nurses, physical therapists, and health care professionals[13-15] utilize this new tool which is both practical and easy to use. This tool could also contribute to future research and to improvements in clinical practices by providing data which could be used in the development of fall prevention programs. The most pertinent risk variables to focus on in a fall intervention program for Thai senior citizens appear to be medication review, vision review, home safety adjustments, and exercises to increase balance, strength, and mobility. The next step is to identify and implement effective preventive measures which are both culturally suitable and acceptable to the target population.

Conclusions

The Thai-translated FROP-Com demonstrated validity, high reliability and internal consistency in assessing risk factors for falls and is available for use with older population in Thailand.

Conflict of Interest

The authors declare no competing interests.

Acknowledgments

The study data was collected from older people who lived in the Dusit District of Bangkok, Thailand. The authors would like to thank all participants in that community. We would also like to thank the National Ageing Research Institute (NARI), Melbourne, Australia, for permission to use FROP-Com for translation and data collection. The Faculty of Medicine, Vajira Hospital, Navamindradhiraj University supported this research. The funder had no role in the study's design, collection, analysis, data interpretation, or manuscript writing.

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Original Article

Ultrasonography Lower Extremity Nerve Cross-Sectional Area Reference Values Including Demographic and Electrophysiological Relationships in Healthy Thai Adults

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ABSTRACT

Objectives: To establish the average values of cross-sectional area (CSA) in the sural, fibular, and tibial nerves by ultrasonography and to investigate correlations with demographic data and nerve conduction studies (NCS)

Study design: A cross-sectional study

Setting: Lerdsin Hospital, Bangkok, Thailand

Subjects: Healthy Thai adults aged 19-80 years

Methods: Ninety participants were recruited and their CSA was measured at seven sites within the three nerves of the lower extremities. The NCS was performed and the mean was calculated for the values at each site. Demographic data or NCS parameters were identified as correlations with the CSA.

Results: The mean and standard deviation values of the CSA (mm^2) were: (1) sural: 2.4 (0.5), (2) fibular nerve - ankle 1.6 (0.5), fibular neck (FN) 8.3 (1.5), fibular head (FH) 9.5 (1.7), popliteal fossa (PF) 12.5 (1.5), (3) tibial nerve - ankle 11.5 (2.5), PF 16.4 (2.9), (4) the FH/PF and FH/FN ratios were 1.1 (0.2), and 1.2 (0.2). The CSAs of the sural ($p = 0.048$), fibular at FN ($p = 0.025$), fibular at PF ($p = 0.043$), and tibial at PF ($p = 0.043$) nerves were significantly greater in male than those in female. The CSA was statistically correlated with age, weight, and body mass index in the sural nerve, several sites of the fibular nerve, and the tibial nerve at the ankle. Height was associated with the CSA of the tibial nerve at the ankle ($r = 0.209$, $p = 0.048$). The CSA of the tibial nerve at PF was statistically significantly correlated with the proximal amplitude of the tibial motor NCS ($r = -0.233$, $p = 0.027$).

Conclusions: Establishing nerve CSA particular to the Thai population may offer normative values and differentiate aberrant neural structures. Some demographic characteristics and NCS can have an impact on the CSA.

Keywords: cross-sectional area, ultrasonography, peripheral nerves, electrodiagnosis

ASEAN J Rehabil Med. 2024; 34(2): 70-78.

Introduction

High-resolution ultrasonography can help to diagnose peripheral neurological disorders. It can locate nerve lesions and reveal nerve morphology.[1, 2] The benefits of using ultrasound imaging are that it is non-invasive, has dynamic capability, is affordable, and does not expose individuals to radiation. The nerve's cross-sectional area (CSA) is the most studied metric for diagnosing nerve disorders. That value is obtained by placing the probe perpendicular to the nerve. The CSA increases when the nerve is inflamed or compressed[2, 3] and decreases when the nerve fibers are lost, e.g., when there is motor neuron disease.[4] Previous studies have indicated that the CSA of the nerve is associated with race, sex, height, weight, and body mass index (BMI)[5-8], but is not related to the site on the body.[9] One study that investigated the upper extremities found that the ulnar nerve's CSA was affected by multiethnicity, even though the study group was predominantly Asian.[10] However, there have been few investigations of the CSA of the nerves of the lower extremities because the muscles, blood vessels, and nerves are deeper and more complex. Thus, the CSA in the lower extremities is more challenging to measure than in the upper extremities.[11] Seok et al.[12] reported that the CSA of the sciatic, fibular, and tibial nerves in the Korean population is lower than in the Caucasian population. However, the electrodiagnosis was not tested to exclude peripheral neuropathy in their study. Fisse et al.[13] conducted a systematic review of the CSA of the nerves of the lower limbs, with the majority of the subjects from Europe and North America and a minority from Asia. They concluded that the CSA of the fibular and sural nerves are not different in different populations.

According to a recent systematic review and meta-analysis, no statistically significant changes were seen in the tibial nerve's CSA at the ankle and popliteal fossa (PF) across different geographical regions.[8] However, there was a discrepancy in the tibial nerve regarding the level of the PF, which could be attributed to the testing approach.[13] The findings and conclusions of prior studies have been varied and not consistent with each other.

A nerve conduction study (NCS) is a physiological nerve test to diagnose peripheral nervous system issues. Use of NCS combined with ultrasonography is becoming increasingly

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Received: September 8, 2023 Revised: November 9, 2023 Accepted: December 1, 2023

widespread, improving differential diagnostic accuracy. Ultrasonography helps to identify peripheral nerve diseases, e.g., soft tissue edema, in individuals with NCS limitations.[14] However, few studies have investigated the relationship between the CSA and NCS parameters, which may potentially be beneficial for adjunctive diagnosis. According to one previous study, an increase in the CSA of the ulnar nerve at the wrist results in statistically significantly prolonged distal motor latency.[5.] This association has not been investigated in the nerves of the lower extremities.

The purpose of this study was to establish normal reference values of the CSA of the sural, the fibular, and the tibial nerves in a healthy Thai population and to investigate the potential relationship between the CSA and demographic data, including sex, age, weight, height, and BMI and the NCS parameters. Each of these measures can provide the clinician with diverse diagnostic tools for assessing pathological changes in peripheral nerve conditions.

Methods

Study design

This study was a prospective cross-sectional study and was approved by The Ethics Committee at Lerdsin Hospital. The certification number is LH651010. The Thai Clinical Trials Registry number is TCTR20220204003.

The study was conducted at Lerdsin Hospital from May 2022 to May 2023. Prior to assessment, signed informed consent was obtained from the participants. The inclusion criteria were Thai ethnicity, good health, and age between 19 and 80. Participants who had relevant neuromuscular symptoms, including numbness, neuropathic pain or weakness, a history of peripheral polyneuropathy, neuromuscular diseases, degenerative spinal stenosis, intervertebral disc disease, other medical conditions that affect peripheral nerves (dia betic mellitus, chronic renal failure, liver disease, thyroid disease, immunocompromised, autoimmune disease, alcoholism), were pregnant, had a history of internal fixation in the legs, used a pacemaker or had abnormal NCS by screening were excluded.

Following a study by Seok[12], the sample size was calculated using an 'infinite population mean formula'. The mean CSA and standard deviation (SD) of the sural, fibular, and tibial nerves were calculated for each site. We used an error (d) of 7% and an alpha value of 0.05 to calculate values with the maximum sample size (tibial nerve) used in the study. The sample size was 78 participants. With an estimated potential dropout rate of 10%, 90 participants were included. We divided the participants into three groups by age (19-30, 31-50, and 51-80) following the previous studies and due to the fact that the NCS parameters change as the age increases.[5, 15] Each age group included an equal number of men and women.

Intervention

A brief history of the patients was taken and clinical examinations were performed. Age, sex, height, weight, and BMI were determined. Before the ultrasonography examination, all participants were screened for NCS to rule out peripheral polyneuropathy using a reference from the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) 2020.[16]

NCS

The tibial, fibular, ulnar, and sural nerves were tested bilaterally by a physiatrist using a Nicolet Synergy equipment (Natus Medical Inc., San Carlos, California, USA). Participants lay on a bed in the supine and lateral decubitus positions. Skin temperature was maintained at 32-34 degrees Celsius.

Compound motor action potential (CMAP) NCS

- Tibial motor study: the recording electrodes were placed on the abductor hallucis (AH) muscle. The stimulation sites were at the posterior medial malleolus 8 cm from the AH muscle and the PF.

- Fibular motor study: the recording electrodes were placed on the extensor digitorum brevis (EDB) muscle. The stimulation sites were at the anterior ankle 8 cm from the EDB muscle and posteroinferior to the fibular head (FH).

- Ulnar motor study: the recording electrodes were placed on the abductor digiti minimi (ADM) muscle. The stimulation sites were at the volar wrist 8 cm from the ADM muscle and the olecranon fossa.

Sensory nerve action potential (SNAP) NCS

- Sural sensory study: the stimulation site was at the lateral calf 14 cm from the electrode at the lateral malleolus.

- Ulnar sensory study: the stimulation site at the volar wrist was lateral to the flexor carpi ulnaris tendon 8 cm from the ring electrode on the little finger.

Ultrasonography

All individuals were tested using a multifrequency linear transducer 4-18 MHz (Konica Minolta, SONIMAGE® HS1, Tokyo, Japan) in B mode. The ultrasound examination was performed by a physician with six years of musculoskeletal ultrasound experience. Using ultrasonography, each nerve was detected, the transducer angle adjusted until perpendicular to the nerve to obtain the images with the smallest CSA. The color Doppler test was used to check the vascular component. The distance between the skin and the target location determined focus and depth. The CSA was measured at each location using the elliptical function to trace inside the nerve's hyperechoic border. Each location, including the body's left and right sides, was examined three times. Inter-rater reliability was evaluated one week after the first visit by a physician with one year of experience in neuromuscular ultrasonography who was blinded to the previous outcomes. Thirty participants were chosen at random for this measurement. Before beginning data collection, both investigators received specialized training specific to this study.

Sural Nerve. With the participant in a lateral decubitus position, the CSA was measured at 14 cm from the lateral malleolus, which runs lateral to the small saphenous vein (Figure 1).

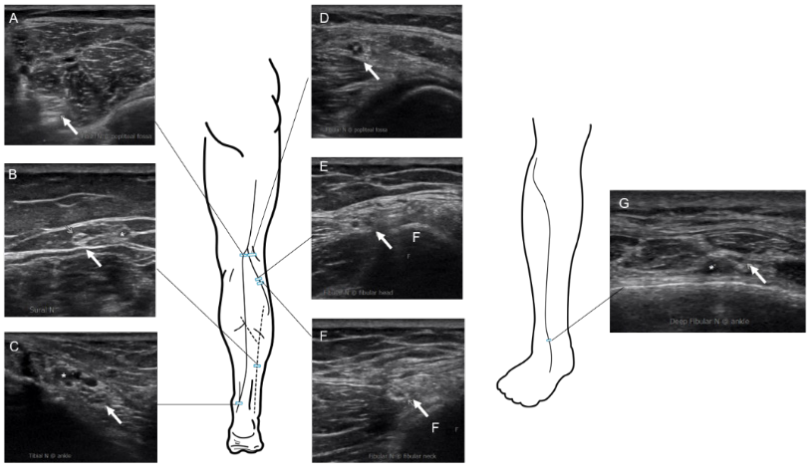

Figure 1. Sites of nerve ultrasonography to determine the cross-sectional area (CSA). (A) tibial nerve at popliteal fossa, (B) sural nerve, (C) tibial nerve at the ankle, (D) fibular nerve at the popliteal fossa, (E) fibular nerve at the fibular head, (F) fibular nerve at the fibular neck, (G) fibular nerve at the ankle. Arrows are the CSA of the nerve. The vessels are marked with an asterisk (*).

Fibular Nerve. With the participant in a lateral decubitus position, the first measurement was done at the PF, where the fibular nerve is lateral to the short head of the biceps femoris tendon and just superior to the lateral tibial condyle. The second was made at the FH. The third was obtained at the fibular neck (FN) before bifurcation into the deep fibular and superficial fibular nerves. The participant was then shifted to a supine position and the last measurement was made at the anterior ankle lateral to the dorsal pedis artery (Figure 1).

Tibial Nerve. Participants lay down in a prone position. Following the path of the sciatic nerve, the tibial nerve is located posterior to the popliteal vein. The initial measurement was taken at the PF. The second measurement was obtained at the medial ankle (Figure 1).

These sites were chosen based on various criteria, including anatomical landmarks, clinically significant points, and proximity to the point of NCS stimulation.

Outcome measurements

The CSA of each nerve in each of the selected locations was recorded. The FH/PF fibular nerve CSA ratio was calculated by dividing the FH fibular nerve CSA by the PF fibular nerve CSA. By dividing the fibular nerve CSA at the FH by the fibular nerve CSA at the FN, the FH/FN fibular nerve CSA ratio was obtained. The NCS were measured, including the distal and proximal CMAP latency, amplitude, and fibular and tibial nerve area. The latency and amplitude of the sural SNAP were also noted.

Statistical methods

Statistical analysis was performed using the PASW Statistics version 18.0 program. (SPSS Inc., Chicaco, IL, USA). Continuous data is presented as mean and standard deviation (SD). Categorical data is presented as frequencies and percentages. The mean ± 2SD was used to calculate the reference ranges of the nerve CSAs, the FH/PF, and the FH/FN ratios of the fibular nerve. The unpaired t-test was used for comparison between the sexes. The paired t-test was used for side-by-side comparison. The one-way ANOVA test was used to compare the mean CSA among age groups. The correlations between the CSA at each site of each nerve and demographic factors (age, weight, height, BMI) or NCS parameters were evaluated using Pearson's correlation coefficient (r). Intraclass correlation coefficient (ICC) was used to measure the inter-rater reliability of ultrasonographic testing. An ICC of 0.61-0.80 was regarded as a good agreement, and an ICC greater than 0.80 was considered excellent.[17] A *p*-value of < 0.05 was considered statistically significant.

Results

This study included a total of 90 participants. The CSA of bilateral fibular nerves at the FN and right tibial nerve at the PF could not be accurately measured in one male participant due to the vascular mixing in the nerve fascicle, so the study included 89 participants. Of the 89 participants, 14 were male and in the 31-50 age group (Figure 2). The mean age, weight, height, and BMI of the participants were 41.4±14.5 years, 64.1±13.8 kg, 163.2±8.5 cm, and 24.5±4.3 kg/m^2, respectively (Table 1). The inter-rater reliability was good to very good as indicated by the ICC, ranging from 0.80 to 0.98.

Comparison of demographic data and side-to-side

Statistically significant differences between sexes were found in the sural nerve (p = 0.048), the fibular nerve at the FN (p = 0.025), the fibular nerve at the PF (p = 0.043), and the tibial nerve at the PF (p = 0.043). The CSA of male participants was larger than that of female participants. The CSA of the fibular nerve at the FN (p = 0.022), the FH (p < 0.001), and the PF (p = 0.040) were significant different among age groups. The CSA of the 51-80 age group was greater than that of the others. There was no statistically significant difference in the CSA between the left and right sides at all measurement sites (Table 2).

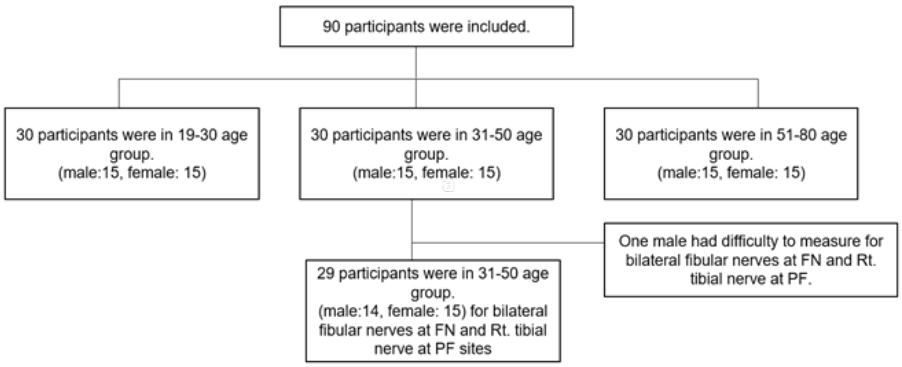

Figure 2. Flow chart of participants: FN, fibular neck; PF, popliteal fossa

Table 1. Demographic data of participants

Items	All[1] (n = 90)	Men[1] (n = 45)	Women[1] (n = 45)
Age (year)	41.4 (14.5) [19-72]	40.6 (14.4) [19-72]	42.2 (14.8) [23-70]
Weight (kg)	64.1 (13.8) [42-100]	69.4 (12.5) [45-100]	58.9 (13.1) [42-90]
Height (cm)	163.2 (8.5) [144-189]	169.2 (6.4) [157-189]	157.3 (5.8) [144-168]
BMI (kg/m^2)	25.0 (4.3) [15.2-34.1]	24.2 (4.1) [15.2-33.9]	23.7 (4.5) [17.5-34.1]

[1]Mean (SD) [range]; n, number; SD, standard deviation; kg, kilogram; cm, centimeter; BMI, body mass index; m^2, square meters

Table 2. Ultrasonography cross-sectional area (mm^2) of lower limb peripheral nerves in healthy participants

Nerve site	n	All[1]	Min, max	Ref range (2SD)	Side[1,a]			Sex[1,b]			Age group[1,c]			
					Left	Right	*p*-value	Male	Female	*p*-value	19-30	31-50	51-80	*p*-value
Sural nerve	180	2.4 (0.5)	1.0,4.2	1.3,3.4	2.4 (0.6)	2.3 (0.6)	0.714	2.5 (0.5)	2.2 (0.5)	0.048*	2.3 (0.5)	2.3 (0.4)	2.5 (0.6)	0.134
Fibular nerve														
Ankle	180	1.6 (0.5)	1.0,3.0	0.6,2.6	1.6 (0.6)	1.6 (0.5)	0.685	1.6 (0.5)	1.7 (0.5)	0.089	1.6 (0.5)	1.6 (0.5)	1.7 (0.5)	0.688
FN	178	8.3 (1.5)	4.0,12.3	5.2,11.4	8.4 (1.8)	8.2 (1.6)	0.404	8.7 (1.6)	8.0 (1.4)	0.025*	7.9 (1.1)	8.1 (1.4)	8.9 (1.8)	0.022*
FH	180	9.5 (1.7)	6.5,14.0	6.1,12.9	9.5 (2.0)	9.5 (1.8)	0.834	9.7 (1.8)	9.2 (1.6)	0.162	8.9 (1.4)	9.0 (1.3)	10.6 (1.9)	<0.001*
PF	180	12.5 (1.8)	9.2,16.7	8.9,16.1	8.5 (1.6)	8.6 (1.6)	0.184	12.9 (1.5)	12.1 (2.0)	0.043*	12.2 (1.6)	12.1 (1.6)	13.2 (2.0)	0.040*
FH/PF	180	1.1 (0.2)	0.8,1.6	0.8,1.4	1.1 (0.2)	1.1 (0.2)	0.149	1.1 (0.2)	1.1 (0.1)	0.387	1.2 (0.1)	1.2 (0.1)	1.2 (0.2)	0.077
FH/FN	178	1.2 (0.2)	0.9,2.4	0.8,1.6	1.2 (0.3)	1.2 (0.2)	0.629	1.1 (0.1)	1.2 (0.3)	0.207	1.1 (0.1)	1.2 (0.2)	1.2 (0.3)	0.139
Tibial nerve														
Ankle	180	11.5 (2.5)	7.0,20.5	6.6,16.4	11.6 (2.5)	11.4 (2.5)	0.226	11.9 (2.6)	11.1 (2.3)	0.159	11.4 (2.6)	10.9 (2.0)	12.2 (2.5)	0.098
PF	179	16.4 (2.9)	10.5,22.0	10.6,22.2	16.3 (2.9)	16.5 (3.0)	0.328	17.0 (2.6)	15.8 (3.1)	0.043*	15.8 (2.8)	16.3 (2.7)	17.1 (3.1)	0.230

[1]Mean (SD) [range], [a]Paired t-test, [b]Unpaired t-test, [c]One-way ANOVA test, *statistically significant; mm^2; square millimeter; SD, standard deviation; n, number; Min, minimum; Max, maximum; Ref, reference; FN, fibular neck; FH, fibular head; PF, popliteal fossa

The CSA measurements.

The normal CSA values of each nerve, the FH/PF ratio, and the FH/FN ratio of the fibular nerve in all participants are shown in Table 2.

Correlation of nerve cross-sectional area with demographics

Age, weight, and BMI showed a significant positive correlation with the CSA in the following nerves: the sural, the fibular at the FN, FH, PF, and the tibial at the ankle. There was also a significant association between age and the FH/FN ratio of the fibular nerve. Height was associated with the CSA of the tibial nerve at the ankle (Table 3) (Figures 3, 4).

Correlation of nerve cross-sectional area with NCS

The CSA of the tibial nerve at the PF correlated significantly with the proximal amplitude of the tibial motor NCS (r = -0.233, *p* = 0.027). The CSA of the tibial nerve at the PF rises as the proximal tibial amplitude motor NCS decreases (Table 4).

Discussion

This study was the first in Thailand to establish normal lower extremity nerve CSA reference values. We presented the CSA of seven sites of three common nerves. When just the mean values were compared in each nerve at each site (sural nerve, fibular nerve; ankle, FN, FH, PF, tibial nerve; ankle, PF), our findings were consistent with reported

Table 3. Correlation of cross-sectional area (mm^2) with age, weight, height, and body mass index

Nerve sites	Age[a]		Weight[a]		Height[a]		BMI[a]	
	r	*p*- value	r	*p*- value	r	*p*- value	r	*p*- value
Sural nerve	0.253	0.016*	0.540	<0.001*	0.167	0.116	0.554	<0.001*
Fibular nerve								
Ankle	0.176	0.098	0.026	0.805	-0.107	0.315	0.289	0.317
FN	0.282	0.007*	0.344	<0.001*	0.100	0.351	0.359	<0.001*
FH	0.453	<0.001*	0.293	0.005*	0.069	0.519	0.317	0.002*
PF	0.249	0.018*	0.250	0.017*	0.112	0.294	0.233	0.028*
FH/PF	0.178	0.093	-0.030	0.780	-0.066	0.539	0.002	0.984
FH/FN	0.245	0.020*	-0.130	0.224	-0.064	0.554	-0.116	0.277
Tibial nerve								
Ankle	0.237	0.024*	0.365	<0.001*	0.209	0.048*	0.311	0.004*
PF	0.185	0.082	0.144	0.176	0.073	0.496	0.127	0.232

[a]Pearson's correlation coefficient (r); * statistically significant; mm^2, square millimeter; BMI, body mass index; FN, fibular neck; FH, fibular head; PF, popliteal fossa

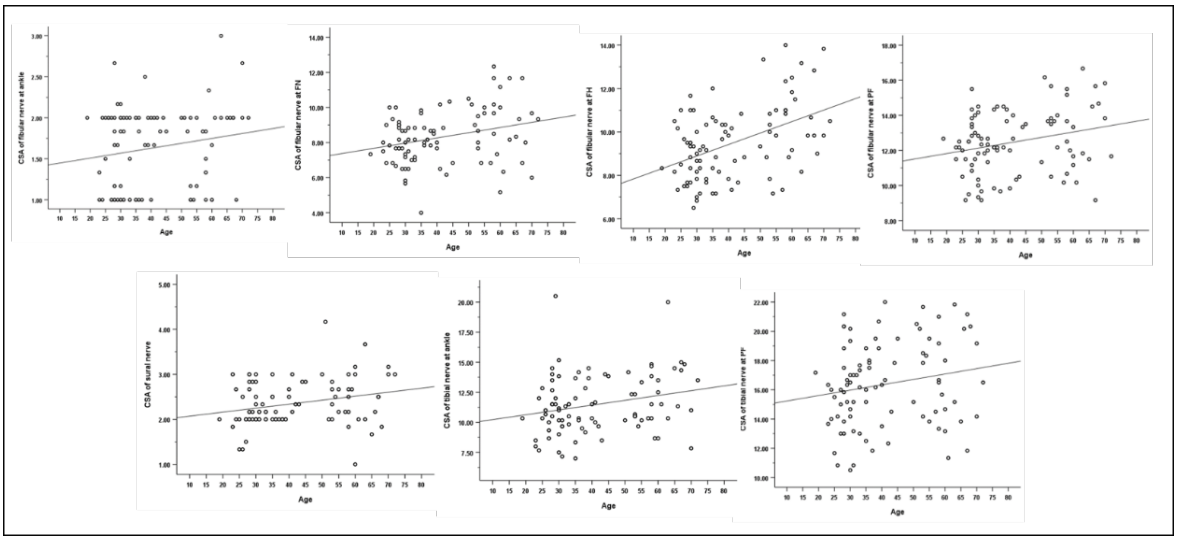

Figure 3. Correlation of cross-sectional area (mm^2) with age at each site of the lower limbs' nerves; CSA, cross-sectional area; FN, fibular neck; FH, fibular head; PF, popliteal fossa

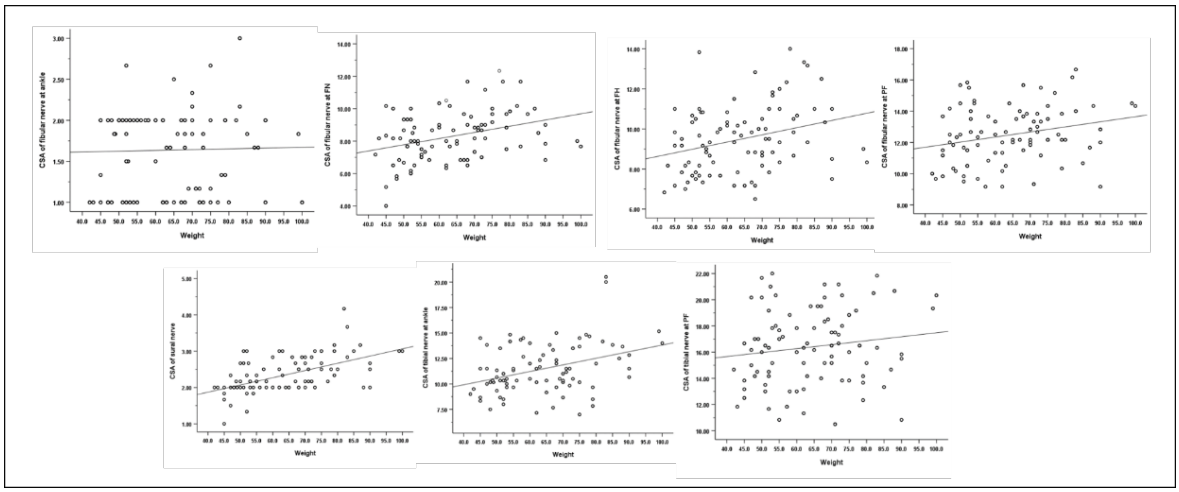

Figure 4. Correlation of the cross-sectional area (mm^2) with weight at each site of the lower limbs' nerves; CSA, cross-sectional area; FN, fibular neck; FH, fibular head; PF, popliteal fossa

Table 4. Correlation of cross-sectional area (mm^2) with nerve conduction study

Deep fibular motor study	CSA of the fibular nerve at ankle[a]		Deep fibular motor study	CSA of fibular nerve at FN[a]	
	r	*p*- value		r	*p*- value
Distal latency	-0.090	0.407	Proximal latency	-0.025	0.813
Distal amplitude	0.123	0.258	Proximal amplitude	-0.039	0.716
Distal area	0.088	0.420	Proximal area	-0.059	0.583
Tibial motor study	CSA of tibial nerve at ankle[a]		Tibial motor study	CSA of tibial nerve at PF[a]	
	r	*p*- value		R	*p*- value
Distal latency	0.044	0.680	Proximal latency	0.183	0.084
Distal amplitude	-0.148	0.163	Proximal amplitude	-0.233	0.027*
Distal area	-0.146	0.169	Proximal area	-0.150	0.160

[a]Pearson's correlation coefficient (r); *statistically significant; mm^2, square millimeters; NCS, nerve conduction study; CSA, cross-sectional area; FN, fibular neck; PF, popliteal fossa

Table 5. Comparison of demographic data with the previous studies

Study	Ethnicity	Age[1]	Sex (M:F)	Weight[1]	Height[1]	BMI[1]
Present study	Thai	41.4 (14.5)	45:45	64.1 (13.8)	163.2 (8.5)	24.9 (4.3)
Tan[10]	Malaysian	40.0 (14.4)	38:46	64.7 (14.3)	160 (10.1)	24.2 (4.8)
Hsieh[21]	Taiwanese	42.1 (14.0)	30:36	63.6 (11.3)	163.2 (8.1)	23.9 (3.3)
Seok[12]	Korean	43.9 (14.4)	44:50	62.8 (12.2)	165.2 (9.0)	22.9 (3.1)
Bae[18]	Korean	46.3 (14.2)	51:56	64.4 (11.4)	165 (8.7)	23.3 (2.7)
Bedewi[7]	Asian	38.3 (12.1)	N/A	77.1 (18.4)	161.5 (9.8)	29.3 (6.6)
Qrimli[19]	Canadian	44.1 (18.4)	30:70	N/A	N/A	25.3 (5.3)
Kerasnoudis[20]	German	53.5 (14.8)	45:30	N/A	175 (9.0)	77.9 (10.7)
Grimm[22]	German	51.2 (18.2)	55:45	74.5 (24.1)	174.5 (11.4)	N/A
Boehm[23]	European	N/A	26:30	N/A	N/A	N/A
Cartwright[24]	American	45.9	22:38	74.5	168	26.5
Lothet[6]	American	N/A	N/A	N/A	N/A	N/A

[1]Mean (SD); M, male; F, female; BMI, body mass index; N/A, not applicable

Table 6. Comparison with cross-sectional area (mm^2) of the lower extremities' nerves in the previous studies

Study	Ethnicity	Sural nerve[1]	Fibular nerve[1]				Tibial nerve[1]	
			Ankle	FN	FH	PF	Ankle	PF
Present study	Thai	2.3 (0.5)	1.5 (0.5)	8.3 (1.5)	9.5 (1.7)	12.5 (1.8)	11.5 (2.5)	16.4 (2.9)
Tan[10]	Malaysian	1.5 (0.6)	N/A	N/A	8.9 (2.0)	7.5 (1.8)	10.1 (2.0)	11.8 (2.2)
Hsieh[21]	Taiwanese	2.3 (0.7)	N/A	N/A	N/A	12.1 (2.2)	8.5 (2.2)	20.8 (4.8)
Seok[12]	Korean	2.6 (0.6) (D)	N/A	N/A	9.2 (2.9)	10.4 (2.7)	12.1 (3.1)	24.4 (4.4)
Bae[18]	Korean	3.3 (1.0) (D)	2.1 (1.0)	N/A	12.5 (3.5)	11.4 (3.7)	15.6 (3.8)	24.7 (6.1)
Bedewi[7]	Asian	3.5 (1.4)	N/A	N/A	8.9 (3.2)	9.7 (4.1)	12.7 (4.5)	19.1 (6.9)
Qrimli[19]	Canadian	2.1 (1.0)	N/A	N/A	11.1 (3.9)	11.7 (3.8)	12.7 (3.4)	N/A
Kerasnoudis[20]	German	1.8 (0.6)	N/A	N/A	7.1 (2.3)	8.6 (1.8)	6.4 (1.5)	8.4 (2.7)
Grimm[22]	German	2.2 (0.6)	N/A	N/A	N/A	8.4 (1.6)	10.2 (2.0)	23.2 (4.9)
Boehm[23]	European	1.8 (0.6) (P)	N/A	8.9 (2.0)	N/A	N/A	9.6 (2.2)	N/A
Cartwright[24]	American	5.3 (1.8) (D)	N/A	N/A	11.2 (3.3)	11.7 (4.6)	13.3 (4.3)	35.3 (10.3)
Lothet[6]	American	3.8 (1.4)	N/A	N/A	12.4 (3.3)	N/A	12.3 (3.5)	N/A

[1]Mean (SD); mm^2, square millimeter; D, distal; P, proximal FN, fibular neck; FH, fibular head; PF, popliteal fossa; N/A, not applicable

values in most of the previous studies, although some findings were different. Our results and those of prior studies are summarized in Tables 5 and 6. Despite a finding that Asians did not differ in age, weight, height, and BMI, the CSAs at the same location varied. Bae et al.[18] In that study, reported CSAs were greater than those in the present study at multiple locations. In Qrimli's study in Canada, the CSA at several locations appears comparable to our findings[19], but specific CSA sites investigated in a study in Germany were smaller than ours.[20] This finding suggests that ethnicity may have an impact on CSA values.

The CSA of the fibular nerve at the FH has shown variation across many investigations (7.1-12.5 mm^2). This variation may be due to differences in ultrasound measurement methods. The common fibular nerve curves around the fibular neck, close to the bone. It goes from posterolateral to anterolateral beneath the fibular neck before splitting into its branches.[25] The fibular nerve assumes an average angle of 28.2±7.3 degrees relative to the longitudinal axis of the fibula bone in Thais, but this angle varies across populations.[26] Positioning the ultrasound probe in the short axis perpendicular to the nerve for the smallest CSA measurement was not easy. It was also challenging to determine the CSA of the tibial nerve at the PF. There have been measurement discrepancies in many previous studies ranging from 8.4 to 35.3 mm^2. The standard deviation has also showed a wide variation in different studies. The frequency of the ultrasound may affect the trace of the inner border of the nerve site due to the deep structure and poor visualization.

The CSA values of the sural nerve, fibular nerve (FN, FH), and tibial nerve (PF) were significantly higher in males. This finding is similar to a previous study.[20] The explanation for the difference might be that on average men have a higher weight, height, and BMI than women which might influence the CSA of nerves. The side-to-side difference was not statistically significant, a finding comparable to several studies.[7, 10, 12, 21] Based on this observation, the side-to-side difference might be used as an internal control, e.g., detecting nerve disease in extremely thin or obese individuals or patients of different ethnicities with a unilateral lesion. We discovered that the CSA of nerves at numerous sites (sural nerve, fibular nerve at FN and FH, and PF tibial nerve at the ankle) had a statistically significant positive association with advanced age. These results correspond with previous studies.[10, 12, 19, 21, 24] Research findings on the morphometric effects of aging on the tibial nerves in mice may explain this. Aging affects the diverse elements of the tibial nerve differently. In mice, outfolded myelin loops with irregular shapes, macrophages, and mast cells increase significantly with advanced age in the endoneurium, resulting in the CSA becoming larger.[27]

Statistically significant differences in the CSA and weight were seen in the sural, fibular (FN, FH, PF), and tibial (ankle) nerves. However, our investigation found only the CSA of the tibial nerve at the ankle to be correlated with height, a finding which differs from previous research.[10, 12, 22-24] The CSA should be used primarily in tall and obese people. The intra-nerve variability (calculated as maximal CSA/minimal CSA) and the inter-nerve CSA variability have recently been determined, allowing quantification of heterogeneous nerve involvement in immune-mediated neuropathies.[28] The fibular nerve ratio has also been calculated using specific landmarks, including the FH and the PF. These novel measurements are less affected by height and weight.

Our investigation found that as the CSA increases, there is a corresponding drop in the proximal amplitude in the tibial motor NCS. Similar results were found in a prior study conducted in an general population.[5] Studies of focal neuropathy have shown that the CSA is enlarged when neuropathy is more severe. Motor NCS amplitude is usually significantly reduced.[2] Furthermore, the amplitude of the tibial CMAP and the CSA of the tibial nerve exhibit a negative correlation in patients with diabetic polyneuropathy,[29] a finding notable for its parallels with nerve pathology.

Moreover, the histology of the tibial nerve shows a greater CSA as the nerve fascicle increases.[30] However, the amplitude of the CMAP, which indicates the number of motor nerve fibers that responded to stimulus and which could transmit impulses to the recorded muscle, decreased. This finding seems to imply that the morphology of a nerve may not always reflect its physiological characteristics.

Inter-rater reliability in our study ranged from good to very good. The findings of this study are consistent with an earlier report[9], indicating that high-resolution ultrasonography may be used as a reliable method for measuring nerve CSA in the lower extremities. However, technical expertise, knowledge of anatomical landmarks, and development of study protocols are necessary to accurate ultrasound examinations.

Currently, there has been an increasing amount of research focused on using ultrasonography to diagnose focal neuropathy and polyneuropathy. The common fibular nerve is the most common form of compressive neuropathy of the lower limbs. Previous research has found that cut-off values of the CSA at the FH and a ratio of the FH/PF higher than 11.7 mm^2 and 1.1, respectively, indicate high sensitivity and specificity.[2, 31] Likewise, the CSA of the tibial nerve at the ankle which identifies posterior tarsal tunnel syndrome is more than 15 mm^2.[2] However, our research found that the upper normal limit of the fibular CSA at the FH was 12.9 mm^2, and that of the tibial CSA at the ankle was 16.4 mm^2. The normal CSA values in healthy individuals were discovered to be slightly higher than the in patients with diseases. Telleman et al.[32] presented an overview of a scoring system for assessing the pattern of nerve abnormality in hereditary and acquired polyneuropathies. With that system, the degree of nerve CSA enlargement in the upper and lower limbs at each landmark can be used to differentiate peripheral neuropathy diagnoses. Thus, the CSA reference values are essential.

The optimal CSA cut-off values in the lower limb nerves for diagnosing diabetic polyneuropathy were 11.6 mm^2 of the fibular nerve at the FH and 4.2 mm^2 of the sural nerve.[29] The present CSA findings may serve as reference values in investigations or can be utilized as supplementary evidence when electrodiagnosis is limited. Additionally, when subgroup analysis was conducted, significant differences in nerve CSAs were observed between sexes and among age groups. Consequently, normal CSA values should be determined with consideration given to subject characteristics. However, when the CSA values are outside the normal range, it is essential to utilize clinical and physical examinations as well as

additional investigations to identify possible diseases. A potential approach for further research would be to investigate the accuracy of specific cut-off values for each condition.

A limitation of this study was that we used the ellipsoid function to measure the CSA of nerves; some nerves were not round or oval which could have resulted in a measurement error. It may be more accurate to trace inside the nerve if it is difficult to visualize the deep structure of the popliteal fossa. Thus, the use of ultra-high-frequency ultrasound will be necessary. In clinical and electrophysiologic studies, the normal nerve CSA should be compared to the CSA of patients with peripheral nerve disorders. In addition, in future research repeat reliability of the same rater should be obtained to help ensure the accuracy of the results.

Conclusions

Our study was a large-scale prospective study that used ultrasonography to assess the CSA of several nerves in the lower limbs of a healthy Thai population. The CSA of the several nerve locations differed by sex and age. A statistically significant correlation was observed between the values of CSA and demographic characteristics including age, weight, and BMI, as well as electrodiagnostic parameters. Specifically, an increase in nerve CSA was shown to be associated with a reduction in amplitude. This study's results might serve as standard reference values for the Thai population to differentiate nerve diseases.

Disclosure

The authors have no conflicts of interest to report.

Acknowledgments

The authors would like to thank Woratee Dacharux, MD., for the manuscript advisory, Julaporn Pooliam, MSc., for the statistical analysis, and the Lerdsin Hospital Ethics Committee at Lerdsin Hospital, Bangkok, for their support of this research.

Funding

This research received funding from Lerdsin Hospital.

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Original Article

Factors Related to Quality of Life in Patients with Carpal Tunnel Syndrome: A Cross-Sectional Study

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ABSTRACT

Objectives: To determine the association between the quality of life (QoL) of patients diagnosed with carpal tunnel syndrome (CTS) by electrodiagnostic study (EDX) and CTS severity, as well as to identify other associated factors

Study design: Cross-sectional study

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

Subjects: A total of 140 CTS participants diagnosed by EDX including patients aged 18 or over, who were able to communicate in Thai, were fully conscious, and were willing to participate in this research.

Methods: Participants were recruited and asked to complete the questionnaire about demographic and clinical characteristics related to CTS, the Boston questionnaire (Thai version), the Thai version of the Hospital Anxiety and Depression Scale (Thai HADS), and the EQ-5D-5L questionnaire. The data from questionnaires and the EDX results were collected and analyzed.

Results: Utility scores of the EQ-5D-5L questionnaire were correlated with Boston functional severity score (FSS) (r = -0.603, $p < 0.001$), Boston symptom severity score (SSS) (r = -0.546, $p < 0.001$), and anxiety (p=0.004). The electrophysiological severity had no association with patients' QoL ($r_s = 0.079$, $p = 0.354$). Health visual analog scale (VAS) scores were correlated with anxiety, Boston functional severity score, and leisure activity. Other factors studied, e.g., age and income, were not associated with the patient's QoL.

Conclusions: CTS patients' QoL is correlated with the subjective symptom severity, functional severity, anxiety, and the inability to participate in leisure activities, but not electrophysiologic severity.

Keywords: carpal tunnel syndrome, quality of life, electrodiagnosis, anxiety

ASEAN J Rehabil Med. 2024; 34(2): 79-84.

Introduction

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy.[1] The prevalence varies from 3.8-16%[2,3] and is more common among women.[4] However, there has been no report on the prevalence of CTS in the general Thai population, only that of Thais in certain occupations, such as employees at the Royal Irrigation Hospital (62%)[5], and workers of the stone sculpture industry (13%).[6] CTS is caused by the entrapment of the carpal tunnel's median nerve, leading to demyelination and nerve ischemia.[7] Its symptoms include numbness, pain, and/or dysesthesia along the median-innervated hand area. In severe cases, weakness and atrophy of median-innervated muscles can be manifested. These symptoms usually occur in the patient's dominant hand and often get worse at night or while doing activities involving the wrist for an extended period.[3,7] One consequence of CTS is difficulties in performing activities of daily living (ADLs).[8] This may cause patients to quit or switch jobs, resulting in financial problems for them and their families.[9,10] Moreover, CTS has been reported to cause anxiety and depression, which invertedly affect how the patients perceive the severity of their symptoms.[11]

Suspected CTS patients are usually referred for electrodiagnostic studies (EDX) to confirm the diagnosis and to assess the electrophysiological severity. Based on our observations, the higher the severity of CTS, the more burden they feel. In addition, patients with CTS have been reported to have a worse quality of life (QoL) than those without CTS.[12] The study in the United Kingdom (UK) reported that the CTS patients' QoL is inversely associated with its symptom severity.[13] However, the association between electrophysiological severity and QoL has not been established. As the standards for socio-economic status and QoL for the UK and Thai populations are different[14,15], the UK study cannot be applied to future CTS management for the Thai population. The objective of this study is to determine the association between CTS patients' QoL and the severity of CTS. Additionally, we aim to identify other factors that may be associated with QoL. We hypothesized that higher symptom severity scores or more severe CTS according to electrophysiological severity would be correlated with lower utility and health VAS scores.

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Received: June 6, 2023 Revised: September 16, 2023 Accepted: December 20, 2023

Methods

Study design

This study is a cross-sectional study. It has been approved by the Siriraj institution review board (No. 569/2564 (IRB1)).

Participants

Patients diagnosed with CTS by EDX at the Department of Rehabilitation Medicine, Faculty of Medicine Siriraj Hospital were recruited according to the following criteria: being at least 18 years of age, able to understand and communicate in the Thai language, fully conscious and willing to participate in this research and able to provide written informed consent. Patients with a history of prior injections or surgery of the wrist, a history of wrist fracture, and a known history of other neurological disorders with symptoms involving the wrist and hand, e.g., polyneuropathy, proximal median or ulnar neuropathy, plexopathy, mononeuritis multiplex, cervical radiculopathy, and females who were pregnant or within 12 months postpartum, were excluded from this study. Sample size calculation was based on a study by Ulbrichtová R. et al.[16] using Spearman rank correlation ($\alpha = 0.05$, power = 0.8) and was equal to 140 participants. Demographic data (sex, age, BMI, comorbidity (e.g., hypertension, diabetes mellitus, dyslipidemia, spondylosis, rheumatologic diseases), dominant hands, health insurance plan, educational level, occupation, characteristics of work and leisure, income) and clinical data (duration and side of symptoms, consequences of symptoms toward work/leisure) were collected using questionnaires.

Outcome measurements

Three following questionnaires were used in this study.

• QoL data was collected using EQ-5D-5L questionnaires. The first part of the questionnaire was the EQ-5D descriptive system, with scores ranging from 1 to 5 of five health dimensions, which were then converted into utility scores using the "Thai 5L Calculator" program containing the score conversion formula based on a study by Pattanaphesaj J. of population-based preference scores of the Thai version EQ-5D-5L.[17] The other part was the health visual analog scale (VAS), in which patients rated their health on a scale of 0 to 100, with 100 being the best health they can imagine and 0 being the worst health they can imagine. The current EQ-5D-5L questionnaire was developed to provide greater discriminatory power and increased reliability for index score (kappa coefficient = 0.44-0.77) compared to the older EQ-5D-3L questionnaire and has shown reasonable convergent validity.[17]

• The subjective severity (symptom severity score) and the functional status score of CTS were obtained using the Thai version of the Boston questionnaire. This questionnaire consists of two sections: the 11-item symptom severity score (SSS) and the 8-item functional status score (FSS). Each item is scored on a range of 1 to 5. The higher the score, the more severe the patient feels. The Thai version of the Boston questionnaire provides reliable measurement with a Cronbach's alpha coefficient of 0.89 and 0.91 for SSS and FSS, respectively.[18]

• Anxiety and depression were measured using the Thai version of the Hospital Anxiety and Depression Scale (Thai HADS). It is divided into two subscales: an anxiety subscale and a depression subscale. Each subscale has seven items with scores ranging from 0 to 3. Summing up the scores in each subscale, a total score of at least 11 indicates that the patient may present abnormality in each psychiatric condition. The sensitivities of the anxiety and depression subscales are 100% and 85.71%, respectively, and the specificities are 86.0% and 91.3%, respectively. Thai HADS also shows good reliability (kappa coefficient = 0.67 for anxiety, and = 0.73 for depression) and validity (Cronbach's alpha coefficient = 0.8551 for anxiety, and = 0.8259 for depression) for both subscales.[19]

According to EDX, the CTS severity grading scheme developed by Stevens JC[20] was used to stratify electrophysiological severity into three groups: (1) mild CTS, prolonged distal sensory latency with or without sensory nerve action potential (SNAP) amplitude reduction; (2) moderate CTS, abnormal median sensory latency as noted for mild CTS, and prolonged median motor distal latency; and (3) severe CTS, prolonged median sensory and motor distal latency with SNAP either absent or at low amplitude or absent motor response.

Statistical methods

All the data was analyzed using the IBM SPSS statistics program version 28. The data is presented as mean and standard deviation (SD) for quantitative data and number with percentage for qualitative data. The correlation analysis was done using the Pearson correlation coefficient for jointly normally distributed data and the Spearman rank correlation coefficient for nonnormally distributed continuous data. We also compare the differences between two independent groups of quantitative data using an independent t-test and the differences among more than two groups using analysis of variance (ANOVA). Further multiple stepwise linear regression was done to iteratively examine the statistical significance of each independent variable and to eliminate confounding variables. The p-value < 0.05 indicates statistical significance.

Results

The 140 CTS patients recruited into this study met all the eligibility criteria. Tables 1, 2 and 3 show participants' characteristics and QoL.

The electrophysiological severity of CTS was found to have no association with the health VAS score ($r_s = -0.007$, $p = 0.933$) or utility score ($r_s = 0.079$, $p = 0.354$) of EQ-5D-5L. On the contrary, the subjective measures of CTS severity obtained from the Thai version of the Boston questionnaire

showed a significant inverse correlation with the utility score (r = -0.546, $p < 0.001$) and health VAS score (r = -0.222, $p = 0.008$) of EQ-5D-5L (Table 4).

Functional severity scores obtained from the Thai version of the Boston questionnaire were also found to be significantly inversely correlated with the utility scores (r = -0.603, $p < 0.001$) and health VAS scores (r = -0.276, $p = 0.001$) of EQ-5D-5L. In terms of QoL, lower health VAS scores were significantly correlated with the absence of leisure activities ($p = 0.011$), presence of anxiety ($p = 0.001$), presence of depression ($p = 0.012$), and having at least one comorbidity ($p = 0.015$). Lower utility scores of QoL were significantly correlated with being affected by CTS ($p = 0.002$) and anxiety ($p = 0.004$).

Table 1. Demographic data of participants

Characteristics	
Age (years)[1]	58.9 (10.5)
BMI (kg/m^2)[1]	25.3 (4.4)
Sex: Female[2]	118 (84.3)
With comorbidity[2]	102 (72.9)
Have routine work[2]	122 (87.1)
Have leisure[2]	120 (85.7)
Participants' income (baht/month)[2]	
≤50,000	129 (92.1)
>50,000	11 (7.9)

[1]Mean (SD), [2]number (%)
BMI, body mass index

Table 2. Clinical characteristics of participants

Characteristics	
Right handed[1]	122 (87.1)
Side of symptoms[1]	
Right	34 (24.3)
Left	29 (20.7)
Both	77 (55.0)
Worse side (patients with symptoms presented on both hands)[1]	
Right	47 (61.0)
Left	30 (39.0)
Duration of symptoms[1]	
≤6 months	68 (48.6)
>6 months	72 (51.4)
Dominant hand affected[1]	116 (82.9)
Being affected by CTS[1]	92 (65.7)
EDX grading[1]	
Mild degree	34 (24.3)
Moderate degree	43 (30.7)
Severe degree	63 (45.0)
Boston Symptom Severity Score[2]	25.5 (6.5)
Boston Functional Severity Score[2]	13.0 (4.3)
Thai HADS[1]	
Anxiety (score ≥11)	8 (5.7)
Depression (score ≥11)	5 (3.6)

[1]Number (%), [2]Mean (SD)
HADS, Hospital Anxiety and Depression Scale; EDX, electrodiagnosis; CTS, carpal tunnel syndrome

Table 3. Quality of life of participants based on EQ-5D-5L

EQ-5D-5L	Mean (SD)
Utility score	0.850 (0.149)
Mild degree	0.867 (0.105)
Moderate degree	0.845 (0.152)
Severe degree	0.845 (0.167)
Health VAS	75.4 (15.0)
Mild degree	75.3 (12.0)
Moderate degree	74.1 (16.0)
Severe degree	76.3 (16.0)

VAS, visual analog scale

Multiple stepwise linear regression analyses were done. Table 5 shows that factors contributing to lower utility scores were Boston FSS, Boston SSS, and anxiety. In addition, factors related to lower health VAS scores were Boston FSS, anxiety, and having leisure activities.

Further analysis revealed that subjective severity (Boston questionnaire) was not associated with electrophysiologic severity ($p = 0.059$). Other factors (sex, age, BMI, level of education, health care scheme, characteristics of routine work, income of patients, debts and savings, dominant hands, dominant hand involvement, and duration of CTS) were not associated with the patient's QoL.

Discussion

The patients' QoL was inversely correlated with self-reported symptom severity of CTS. Patients with higher utility scores had better QoL, while those with higher Boston SSS had more severe CTS. The utility score reflects the health states of patients where they reported whether they had problems in each specific dimension while health VAS score reflects how the patients perceive their current health. This implies that patients may report to have problems in their lives leading to a lower utility score and, as a result, a diminished QoL. They might, however, perceive their health more positively than its actual condition. This could explain the correlation obtained by regression analysis between Boston SSS and the utility scores but not with the health VAS scores.

The patients's QoL was not correlated with the electrophysiologic severity measured by EDX which is consistent with previous studies.[13,21] In other words, the electrophysiologic severity does not reflect the symptoms and perspectives of patients toward the syndrome. This finding may be due to the fact that the decreased hand function in CTS patients can be compensated for by other normal muscles innervated by other nerves. The severity of self-reported symptoms is beneficial for evaluating the patient's QoL. It is essential to provide standard treatment according to EDX severity. However, healthcare providers should also provide treatments that aim to relieve patients' symptoms and concerns despite the low degree of severity.

Anxiety contributed to a lower QoL compared to patients with no anxiety. According to previous studies[13,22], treating

Table 4. Association between quality of life and demographic data, and clinical characteristics

	EQ-5D: Utility score	*p-value	EQ-5D: Health VAS	*p-value
Boston Symptom Severity Score#	r=-0.546	<0.001*	r=-0.222	0.008*
Boston Functional Severity Score#	r=-0.603	<0.001*	r=-0.276	0.001*
EDX grading$	r_s=-0.079	0.354	r_s=-0.007	0.933
Age#	r=-0.088	0.303	r=-0.077	0.366
BMI#	r=0.046	0.588	r=-0.003	0.697
Side of symptoms@		0.394		0.505
Right	0.848 (0.120)		77.9 (15.1)	
Left	0.883 (0.107)		75.2 (14.1)	
Both	0.839 (0.172)		74.3 (15.3)	
Duration of symptoms@		0.906		0.763
< 3 months	0.856 (0.147)		74.2 (17.5)	
3-6 months	0.838 (0.142)		74.2 (14.8)	
6-12 months	0.868 (0.107)		78.2 (12.2)	
>12 months	0.848 (0.169)		75.9 (14.4)	
Dominant hand†		0.691		0.537
Right	0.848 (0.151)		75.7 (14.5)	
Left	0.863 (0.133)		73.3 (18.6)	
Dominant hand affected†		0.220		0.989
Yes	0.843 (0.154)		75.4 (15.1)	
No	0.884 (0.118)		75.4 (14.9)	
Consequences of symptoms to work/leisure†		0.002*		0.345
Affected	0.826 (0.162)		74.5 (15.4)	
Not affected	0.898 (0.107)		77.0 (14.2)	
Thai HADS Anxiety†		0.004*		0.001*
No anxiety (score <11)	0.859 (0.143)		76.4 (14.5)	
Anxiety (score ≥11)	0.705 (0.178)		58.2 (13.6)	
Thai HADS Depression†		0.085		0.012*
No depression (score <11)	0.854 (0.145)		76.0 (14.8)	
Depression (score ≥11)	0.738 (0.216)		59.0 (21.3)	
Sex†		0.342		0.935
Male	0.878 (0.127)		75.1 (15.1)	
Female	0.845 (0.153)		75.4 (15.0)	
Comorbidity†		0.127		0.015*
Yes	0.839 (0.155)		73.5 (15.0)	
No	0.882 (0.126)		80.4 (13.9)	
Have routine work†		0.408		0.072
Yes	0.854 (0.147)		76.3 (15.1)	
No	0.823 (0.164)		69.4 (13.4)	
Have leisure/hobbies†		0.989		0.011*
Yes	0.850 (0.147)		76.7 (14.5)	
No	0.851 (0.165)		67.5 (15.7)	

#Pearson correlation coefficient (r), $Spearman rank correlation coefficient (r_s), †independent t-test, @analysis of variance (ANOVA), *$p < 0.05$ indicates statistical significance

VAS, visual analog scale; BMI, body mass index; HADS, Hospital Anxiety and Depression Scale; EDX, electrodiagnosis

anxiety results in a better life quality for patients. Holistic care, including the psychosocial approach, should not be disregarded since recognition of anxiety and the ability to handle these conditions can help patients to achieve a higher QoL.

According to our results, leisure activities contributed to a higher QoL in CTS patients. The enhancement of patients' overall mental health and well-being through leisure activities is clear and supported by evidence.[23] Leisure activities allow patients to relax or escape from a stressful life. Some activities may help build social relationships and psychological support by engaging in group activities leading to a better QoL. Nevertheless, some activities require hand skills, and patients who engage in such activities for an extended period could possibly aggravate CTS. Our study did not collect data on specific types of activities that patients were involved in; we suggest that these data should be collected in future research.

The mean QoL from EQ-5D-5L in this study is relatively high, implying that CTS does not impact much of patients' overall QoL as CTS only involves hands and the symptoms are not correlated with the electrophysiologic severity as mentioned above. However, exploring the details of each

Table 5. Multiple stepwise linear regression analyses

Variable	Model		Unstandardized coefficients[#]	*p*-value
Utility score for QoL	1	(Constant)	1.132 (0.003)	<0.001*
		Boston FSS	-0.021 (0.002)	<0.001*
	2	(Constant)	1.234 (0.041)	<0.001*
		Boston FSS	-0.015 (0.003)	<0.001*
		Boston SSS	-0.007 (0.002)	<0.001*
	3	(Constant)	1.226 (0.040)	<0.001*
		Boston FSS	-0.015 (0.003)	<0.001*
		Boston SSS	-0.007 (0.002)	<0.001*
		Anxiety (score ≥11)	-0.109 (0.041)	0.008*
VAS for health	1	(Constant)	76.4 (1.3)	<0.001*
		Anxiety (score ≥11)	-18.3 (5.3)	0.001*
	2	(Constant)	88.4 (3.9)	<0.001*
		Anxiety (score ≥11)	-17.1 (5.1)	0.001*
		Boston FSS	-0.9 (0.3)	0.001*
	3	(Constant)	81.9 (4.6)	<0.001*
		Anxiety (score ≥11)	-14.9 (5.1)	0.004*
		Boston FSS	-1.0 (0.3)	<0.001*
		Leisure	8.7 (3.4)	0.011*

[#]Estimated coefficient (SD), *$p < 0.05$ indicates statistical significance

VAS, visual analog scale; FSS, functional severity score; SSS, symptom severity score

dimension reveals that patients reported higher scores (more problems) in pain/discomfort, anxiety/depression, and usual activities dimensions than in mobility and self-care dimensions. Despite the lower impact on QoL, patients still perceive a worsened QoL in specific dimensions, and holistic care in these dimensions remains essential.

This study evaluated the QoL using the EQ-5D-5L questionnaire, which requires patients to report their subjective feelings. The Boston questionnaire has similar properties, which might explain the close correlation between the results from these two questionnaires but not the correlation between the QoL and EDX. Additionally, the number of patients with anxiety and/or depression was small (7%) yet a significant correlation with the QoL was found, indicating that answers to the EQ-5D-5L questionnaire were probably influenced by the psychological condition of patients. Objective measures, e.g., hand grip strength, should be included as measures of hand function or severity stratification in future studies.

Although some dimensions in the EQ-5D-5L questionnaire, including pain/discomfort and usual activities dimensions, resemble those in the Boston questionnaire, the mobility dimension of the EQ-5D-5L questionnaire does not reflect the physical impairment caused by CTS. Nevertheless, up to now, there are no CTS-specific measures of life quality. The EQ-5D-5L questionnaire is also concise, simple, and less time-consuming, suitable for patients of advanced ages. Based on all the properties discussed above, the EQ-5D-5L questionnaire has shown itself to be a proper measure in this study.

A strength of this study is the comprehensive data collection, which includes a considerable number of factors that could potentially contribute to the patient's QoL. This strength allows us to analyze the correlation among those factors and confidently report the results of analyses. A limitation of this study is that some of the questionnaires used are not disease-specific and subjective, i.e., based on the patients' feelings, which means that other unexpected factors may affect their feelings on the day they complete the questionnaire. In addition, the patients recruited in this study mainly lived in Bangkok and surrounding areas, so they may not accurately reflect CTS patients in other areas of Thailand. We recommended recruiting patients from regional hospitals in similar studies in the future to more accurately represent the entire population.

Conclusions

CTS patients' QoL is correlated with the subjective symptom severity, functional severity, anxiety, and the inability to participate in leisure activities, but not the electrophysiologic severity obtained by EDX.

Disclosure

The authors declare no conflicts of interest.

Acknowledgment

We would like to thank all the participants in this study, Mr. Suthipol Udompunturak for the statistic consultation, and all medical personnel in the electrodiagnosis clinic for their help. The Faculty of Medicine Siriraj Hospital, Mahidol University, funded this study.

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Original Article

Facilitators and Barriers to Cardiac Rehabilitation Uptake Among Patients with Coronary Artery Disease in Thailand: A Qualitative Study

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ABSTRACT

Objectives: This study explored factors affecting cardiac rehabilitation (CR) uptake among patients with coronary artery disease (CAD) in Thailand.

Study design: An exploratory qualitative design

Setting: Data collection was conducted at two CR centers, one in an urban hospital and one in a remote hospital.

Subjects: CR healthcare providers (HPs) and patients with CAD who had been referred for CR by medical staff during their in-patient stay.

Methods: An exploratory qualitative research design using semi-structured interviews of 20 patients and 22 HPs was employed. Data were collected from June 2018 to July 2019. Transcribed interview data were analyzed thematically.

Results: The common themes identified by patients and HPs that contributed to uptake of CR included culture and religion, as well as social, logistical, and educational themes. Knowledge of CR and its benefits also facilitated attendance. Both groups recognized commitments to family and work as barriers to CR. Both groups also perceived that they had misconceptions about CR exercise programs and inaccurate communication regarding CR as barriers to CR attendance. Importantly, high respect for doctors as well as Buddhist beliefs and practices were cultural factors mentioned by patients as important enablers of CR. Notably, this is the first study in Thailand to identify feeling safe attending CR as being a major enabling factor for CR uptake.

Conclusions: Religious and cultural factors impact the uptake of CR among patients with CAD in Thailand. Creation of culturally-based CR programs should be considered a priority, as should identifying potential approaches to successful delivery of CR in rural areas of the country.

Keywords: cardiovascular disease, rehabilitation, qualitative study, facilitators, barriers, attendance

ASEAN J Rehabil Med. 2024; 34(2): 85-94.

Introduction

Coronary artery disease (CAD), also known as coronary heart disease (CHD), is mainly caused by atherosclerosis of coronary arteries which occurs due to an inflammatory process of the coronary arterial wall.[1] CAD is the leading cause of death worldwide and is rising.[2] In 2022, the global annual mortality from CAD was approximately 8.95 million,[2] with almost half of the deaths from all cardiovascular diseases (CVD).[2]

Even though mortality from CAD in developed countries has declined in recent years because of an emphasis on primary prevention and the enhancements in the diagnosis and treatment of CAD, a similar reduction has not been observed in developing countries.[3] In Thailand, according to World Health Organization (WHO) data published in 2020, CAD deaths reached 51,305 cases, accounting for 11.53% of total deaths and ranking the country 165th globally for CAD-related mortality.[4] CAD represents the highest disease burden for Thais,[5] impacting patients' quality of life, the national budget, and the healthcare system.[5]

Currently, standardized approaches for preventing and treating CAD include pharmacological therapy and coronary revascularization.[6] Primary prevention, defined as prevention of the first occurrence of CAD, includes assessing and managing cardiovascular risk factors, e.g., weight management, healthy eating, regular exercise, and not smoking.[7] Secondary prevention, an essential part of contemporary care of patients with CVD, is designed to prevent the recurrence of cardiovascular events as well as complications of CVD. This prevention involves medical care, modification of behavioral risk factors, psychosocial care, education, and support for self-management, all of which can be delivered in various settings.[8]

Cardiac rehabilitation (CR) is recommended worldwide in evidence-based clinical guidelines as a secondary prevention strategy for patients with CAD.[9] CR is the sum of all activities

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Received: December 5, 2023 Revised: March 27, 2024 Accepted: March 28, 2024

which can favorably influence the underlying causes of the disease, as well as the provision of the best possible physical, mental, and social conditions, so that patients may, by their own efforts, preserve or, if lost, resume as much as possible their usual place in the life of the community.[10] There is substantial evidence supporting the effectiveness of CR, including restoration and maintenance of the heart's physical functioning, a considerable reduction in morbidity and mortality from cardiac causes, and improved psychosocial well-being and quality of life.[11]

Despite its known benefits, CR uptake could be better around the globe: current rates of attendance at CR programs internationally are suboptimal.[12] Many factors can contribute to CR uptake and adherence, including demographics, psychological and medical conditions, access to programs, and sociocultural factors.[12, 13] In Thailand, the CR uptake rate needs to be improved. It has been estimated that only approximately 18.3% of eligible patients attend CR programs.[14] Currently, there is a lack of understanding of the reasons for this poor rate of patient CR program uptake. This study explored factors affecting CR uptake among patients with CAD in Thailand, a nation where cultural and religious beliefs strongly influence many people's lives and health.

Methods

Design

An exploratory qualitative design using semi-structured interviews was employed to investigate patients with CAD regarding their decision whether or not to attend an outpatient CR program. Data collected from patients and HPs were used to gain a deeper understanding of factors that impact patients' decision to attend CR.

Settings and participants

The study was conducted in two Thai CR outpatient centers, one urban and one rural. Convenience sampling was used to identify patients to be invited to attend phase two, the early outpatient phase of CR. A second sample consisted of medical staff whose duties included referring patients to CR from an inpatient setting. Details of participants from both hospitals are shown in Table 1.

Ethical considerations

The study protocol, which conforms to the Helsinki Declaration, was approved by the Human Research Ethics Committees of University of Queensland (approval #2017001672), the urban hospital (#MURA2018/339), and the rural hospital (#HE621143). All participants gave written informed consent to participate in the study.

Data collection

The researchers developed a qualitative semi-structured interview guide following Kaillio's five phases of development (2016).[15] The first phase included evaluation of the appropriateness of the semi-structured interview research questions. A semi-structured interview was considered a suitably rigorous method for answering the research questions in this study. The interviews involved seeking people's perspectives, experiences, and opinions as factors which could potentially affect

Table 1. Characteristics of participants of both hospitals (n = 42)

Interviewee characteristics Patients with CAD (n=20) HPs (n=22)	Urban center number (%)	Rural hospital number (%)
Patients with CAD	10 (50.0)	10 (50.0)
Age		
< 60 years	2 (20.0)	3 (30.0)
≥ 60 years	8 (80.0)	7 (70.0)
Gender		
Male	7 (70.0)	3 (30.0)
Female	3 (30.0)	7 (70.0)
Procedures/condition		
Post CABG	5 (50.0)	6 (60)
Heart failure developed from CAD	2 (20.0)	1 (10)
ACS/MI	3 (30.0)	3 (30)
HPs	12 (54.5)	10 (45.5)
Cardiac surgeon	3 (25.0)	3 (30.0)
Cardiologist	4 (33.3)	3 (30.0)
CR physician	2 (16.7)	1 (10.0)
Physiotherapist	1 (8.3)	1 (10.0)
CR nurse	2 (16.7)	2 (20.0)
Work experience in CR		
< 10 years	2 (16.7)	2 (20.0)
≥ 10 years	10 (83.3)	8 (80.0)

CAD (coronary artery disease); CR (cardiac rehabilitation); HP (healthcare provider).
CABG (coronary artery bypass grafting); ACS (acute coronary syndrome); MI (myocardial infarction)

CR uptake. In the second phase, a predetermined framework for the interview guide was created based on a comprehensive literature review of factors contributing to CR uptake among patients with CAD both in Thailand and worldwide. Based on that review, factors identified were classified as either enablers or barriers. As some factors did not fit clearly into one of those two categories, a third category, "other factors," was used to include those factors as well as any newly identified factors that could potentially contribute to CR uptake among patients with CAD in the Thai context. In the third phase, the researchers formulated two levels of guide questions: main theme questions and follow-up questions. The guide questions were categorized as either main theme questions (which factors contribute to CR uptake?) or as follow-up questions (which enabling and preventive factors or reduce CR uptake?). In the fourth phase, the guide questions were pilot-tested with two Thai Ph.D. students to confirm the coverage and relevance of the preliminary guide's content, to identify any questions requiring reformulation and to test the implementation of the guide. Testing of the interview guide confirmed that no change to the interview questions was required. The fifth and final phase involved the researchers confirming the completeness of the semi-structured interview guides.

The completed guide was then translated into Thai and pilot-tested with two Thais to check the clarity of the questions. Face-to-face interviews in the Thai language were conducted. Interviews with both patients and HPs lasted from 20 to 90 minutes and were conducted between June 2018 and July 2019. The following interview questions were used: (a) "What factors have enabled you/patients with CAD to attend a CR program?"; (b) "What factors have prevented you/patients with CAD from attending a CR program?"; and (c) "What other factors have contributed to your/patients with CAD uptake of CR?". Both hospitals provided the interviewer with a private room in the hospital to interview each participant.

Data analysis

Interview transcripts were analyzed using a deductive thematic approach.[16] All authors independently read the English transcripts of the responses to develop initial codes and themes, which were then discussed to refine the analysis, reach a consensus, and finalize the extracted themes.

Results

Five general themes were identified from the patients' perspective. The themes were the influence of Thai culture on CR uptake, patients' knowledge and understanding of CR and its benefits, patients' feelings and attitudes towards CR and its benefits, and patients' ability to access or attend CR. There were also seven themes identified from the perspective of HPs. These themes included the current situation of CR and the Thai healthcare system; strong support from patients' family members; patients' knowledge and understanding of CR and its benefits; patients' health literacy regarding CR and its benefits; patients' educational level; patients' feelings and attitudes towards CR and its benefits; patients' ability to access or attend CR; and communication issues. Themes identified from the perspective of both patients and HPs from both hospitals have been combined and are presented as intrinsic and extrinsic factors (facilitators and barriers) to CR uptake (Table 2). Facilitators and barriers to CR uptake with illustrative quotes are provided in the text below.

Table 2. Themes and corresponding sub-themes from the perspective of patient and HPs of both hospitals

Major themes/subthemes	Urban center		Rural hospital	
	Patient	HP	Patient	HP
Facilitators of CR uptake				
Intrinsic facilitators				
• Respect for doctors	✓	-	✓	-
• Patients' feeling safe attending CR	✓	✓	✓	✓
• Buddhist beliefs and practices relevant to patients' health	-	-	✓	-
Extrinsic facilitators				
• Family support	✓	✓	✓	✓
• Communication between/among patients and HPs	✓	✓	✓	✓
Barriers to CR uptake				
Intrinsic barriers				
• Patients' knowledge and understanding of CR and its benefits	✓	✓	✓	✓
• Patients' educational levels	-	✓	-	✓
• Patients' health literacy	-	✓	-	✓
• Patients' feeling that their daily activities provide sufficient exercise	✓	✓	✓	✓
Extrinsic barriers				
Patients' ability to access or attend CR				
• Family and work responsibilities	✓	✓	✓	✓
• Transport/distance	✓	✓	✓	✓
• CR-related costs and the economy	✓	✓	✓	✓
• Access to CR services (CR setting/staff)	-	✓	✓	✓

CR (cardiac rehabilitation); HP (healthcare provider)

1. Facilitators of CR uptake

Participants described intrinsic and extrinsic facilitators of CR uptake. Intrinsic facilitators from patients' and HPs' views were similar at both hospitals regarding patients feeling safe attending CR. However, only patients highlighted that they highly valued their doctors' opinions and recommendations. Notably, only rural patients described the intrinsic facilitators of Buddhist beliefs and practices as being relevant to patients' health.

1.1 Intrinsic facilitators of uptake of CR

1.1.1 Patients' feeling safe attending CR: Patients from both hospitals highlighted that they preferred exercising at the hospital, believing that the hospital CR settings were safer than at fitness centers.

"When I came here to join rehab, I felt safe and relaxed. If anything happened to me or my heart, the doctors and nurses could save my life, or else I would be sent to the emergency room quickly." (P6, urban hospital)

Patient safety was also a perspective noted by HPs from both hospitals.

"Some patients told me they came to attend CR here because they felt their heart condition and life would be safe. This was because they were closely monitored by qualified CR staff at an advanced CR facility." (HP2, urban hospital)

1.1.2 Respect for doctors: All patients highlighted that they had the greatest respect for their doctors, trusting that their advice would benefit their heart health and well-being. Consequently, when their doctors invited them to attend CR, they would do their best to do so.

"What did the doctor advise? I would do that thing. I did not dare to disobey the doctor's order." (P4, rural hospital)

However, when their doctors did not support their attending CR, even though they would like to do so, they would accept that advice.

"When the doctor suggested to me that I could exercise anywhere, even though I wanted to join rehab at the hospital, I would accept that doctor's advice." (P7, urban hospital)

1.1.3 Buddhist beliefs and practices relevant to patients' health: Although all participants were Buddhists, only rural patients identified that their beliefs and practices as Buddhists impacted their health. For example, two older rural male patients (aged over 60) discussed the importance of Buddhist doctrine as articulated by monks, relating that it calmed and helped them attend CR at the hospital.

"When I was diagnosed with heart disease, as I am Buddhist, I accepted this heart disease. Sometimes, I listened to Dhamma or Buddhist doctrine from monks. I joined rehab because that may make my heart better." (P5, rural hospital)

1.2 Extrinsic facilitators to uptake of CR

Extrinsic facilitators from both patients' and HPs' perspectives and across both settings were similar and included family support, good communication about CR between and among patients and HPs, and the national healthcare system.

1.2.1 Family support: Both patients and HPs felt that family support positively impacted patients' decision to attend CR. All patients noted strong physical, emotional, and/or financial support from their spouse, partner, or children.

"When I come here to join rehab, my wife usually accompanies me. However, if my wife is busy, my daughter takes me to the hospital and takes care of me while attending CR. My wife and my children are supportive and helpful." (P8, urban hospital)

Rural patients specifically noted that the support from extended family structures in remote villages encouraged them to attend CR. On occasion, patients highlighted that they felt uncomfortable and not supported if their family members were unable to accompany them to CR.

"I came here to join rehab alone. My wife and my daughter were working during weekdays. Sometimes I was quite upset when I did not have anyone to accompany me." (P9, rural hospital)

HPs also highlighted the strong support patients received from family. Additionally, the HPs from the rural hospital emphasized that strong physical, emotional, and financial support was required for patients who were elderly and living in remote villages.

"These elderly patients must have caregivers or relatives accompany them when they attend CR at the hospital. If they came here twice or three times a week, their caregivers had to take leave from their jobs often. That may be the major problem for both patients and their caregivers." (HP7, rural hospital)

1.2.2 Communication about CR

Communication between patients and HPs: Patients and HPs from both hospitals mentioned the need for good communication when CR staff encouraged patients to join a CR program.

"When I joined a rehab here, the rehab doctors and other staff gave me useful advice. They had excellent communication with patients. They treated me as a family member, and I felt they loved me. This reaction made me love myself and want to join rehab here." (P8, rural hospital)

Communication between patients was also noted as being necessary. Patients who joined a CR group session highlighted that they were able to share their feelings, experiences, and feelings of well-being, which encouraged them to continue attending a CR program.

"When I joined rehab here, I did exercises with other patients as a group. This activity was enjoyable and better than doing exercises alone. We could talk, share knowledge and our heart conditions, and live together. I got to know others who joined rehab, and we gave our phone numbers to each other." (P7, rural hospital)

Communication between HPs and HPs

Physicians, CR nurses, and physiotherapists from both settings indicated that having good communication between HPs improved CR uptake among patients with CAD.

"I discussed with the CR team about referring patients to CR after I set up a new surgery program 20 years ago. I needed this type of rehabilitation for my patients. I and other cardiac surgeons usually referred patients to CR because of the good collaboration with the cardiac rehab." (HP9, urban hospital)

2. Barriers to CR uptake.

Participants described intrinsic and extrinsic barriers to CR uptake. Intrinsic barriers from the view of patients and HPs from both hospitals were similar, and included patients' knowledge and understanding of CR and its benefits and whether patients felt their daily activities provided sufficient exercise. However, only HPs viewed patients' educational level and health literacy as affecting CR uptake.

2.1 Intrinsic barriers

2.1.1 Patients' knowledge and understanding of CR and its benefits: Generally, younger patients with higher educational levels mentioned knowing about CR.

"Yes, I think it (CR) was useful. Rehab gave me a faster recovery and knowledge of what I should do. What behavior could I modify in my everyday life? What should I refrain from eating? What foods should I eat? What foods are helpful to my heart? (P4, urban hospital)

However, some elderly patients with fewer years of education and lower family incomes highlighted that they did not know anything about CR.

"I did not know about rehab, and I had no idea what a rehab program was." (P6, urban hospital)

2.1.2 Patients' health literacy: HPs recognized that patients' knowledge and understanding of CR and its benefits affected their uptake of CR. They highlighted the importance of patients' health literacy, which was noted to be low among elderly, poor, and low-educated patients.

"I think patients' health literacy related to CR is very poor in Thailand." (HP1, rural hospital)

2.1.3 Patients' educational levels: HPs highlighted that eligible patients with CAD who never attended CR generally did not know about CR or the availability of CR at hospitals.

"The majority of Thai patients with heart problems or CAD did not have sufficient knowledge about what CR is and its benefits. Many patients also did not know whether CR was available in the hospitals." (HP3, urban hospital)

"Some patients and their caregivers did not understand about CR and its benefits as a result of their low educational levels." (HP7, urban hospital)

2.1.4 Patients feeling that their daily activities provide sufficient exercise (adequacy of home exercise)

Some patients felt that their daily activities provided sufficient exercise; this view discouraged them from attending CR. HPs mirrored this view.

"Patients believed that they could do any exercises at their home on their own, and that some of their household activities were tougher than attending CR here." (HP7, urban hospital)

In particular, patients from rural hospitals who were farmers highlighted that their farming activities provided enough exercise to address their condition; therefore, they did not need additional exercise as part of CR.

"I do many household activities and spend much energy with my farming work such as planting rice. That is similar to joining rehab or doing exercises at the hospital." (P7, rural hospital)

2.1.5 Patients' health: The severity of patients' heart disease and comorbidities, e.g., diabetes and hypertension, affected attendance at CR sessions. Some patients reported additional hospital admission due to the severity of their heart disease prevented CR attendance.

"I could not join rehab two times. The first time, I was admitted for bacterial sepsis. The second time, I was diagnosed with occlusion of heart blood vessels. This was the second occurrence of occlusions, so I received a balloon (angioplasty)." (P1, rural hospital)

This perspective was also recognized by HPs.

"Some patients were readmitted to hospitals for health and heart problems. In particular, many patients with CAD have comorbidities such as diabetes or hypertension. Because of that, these patients could not attend CR." (HP3, urban hospital)

2.2 Extrinsic barriers

Extrinsic barriers to CR attendance noted by patients and HPs alike included family and work commitments, transport-related factors, and the costs of attending CR. However, urban and rural HPs both also indicated that the small number of CR facilities and the limited CR staff were the key barriers to CR uptake among patients with CAD in Thailand.

2.2.1 Family and work commitments finances

Work commitments: Employed patients as well as HPs mentioned that sometimes CR sessions were canceled due to conflicts with patients' work schedules. They both noted that CR sessions were not available on weekends or after working hours on weekdays.

"I had to manage my working time properly as I held a high position at my office." (P2, rural hospital)

"Sometimes, some patients could not attend CR due to their work responsibilities." (HP3, rural hospital)

Farming commitments, such as rice planting or harvesting, affected CR attendance for some rural patients.

"This month until July, is the season of planting rice for us. It will be raining during these three months. I had to plant rice during these months. Sometimes, I could not come to join a rehab here." (P9, rural hospital)

This barrier was reinforced by HP comments, which highlighted that farming activities such as planting rice are an integral part of people's work.

"Many patients were farmers, and few attended CR during the rice planting and harvesting seasons. Importantly,

their agriculture relied on rain and the seasons. Therefore, it was difficult to make appointments for them to come to attend CR at this hospital during those times." (HP2, rural hospital)

Family responsibilities: In general, more women than men highlighted that they could not attend some CR sessions because of family responsibilities.

"Sometimes, I could not come to join rehab in the morning as I had to cook for my family members and do other household activities for them as well." (P3, urban hospital)

HPs from both hospitals also mentioned that family responsibilities could be a barrier.

2.2.2 Transport-related factors: Distance from patients' homes to the CR location, transportation difficulties, the availability of parking, and traffic congestion were mentioned as key concerns by patients and HPs from both hospitals, although congestion and parking were noted more frequently by urban hospital patients.

"When I came here to join rehab, I spent almost three or four hours on the road during rush hour. As this hospital is surrounded by many public offices such as the National Cancer Institute, Faculty of Science and Pharmacy, etc., the traffic jam was a serious situation here." (P5, urban hospital)

For rural patients living a long distance from the CR setting, other transportation problems were the most serious difficulties that prevented them from attending CR.

"From Laos (Savannakhet) to here is approximately 240 kilometers. My daughter and I drove from my hometown. It took approximately four hours for one trip. Sometimes, I had to spend one night at a hotel near the hospital before attending a rehab program." (P2, rural hospital)

Rural HPs also recognized the issue of distance.

"Some patients who did not have their own cars and who lived a distance from this hospital had difficulty with transportation from their homes to here. I think it was tough and time-consuming for them." (HP5, rural hospital)

2.2.3 CR-related costs and the economics of attending CR: Patients and HPs both viewed CR-related costs as impacting patients' decision to attend CR. Although patients who were fully covered by health insurance did not pay for the CR sessions, they still had to pay for CR-related costs such as travel, accommodations, and food. These costs directly affected their CR attendance. This was especially true for people with low incomes, patients with financial problems, and those who lived far from the CR location.

"Although my health insurance fully covered CR, I had to pay for other things such as petrol, accommodations, and food. Sometimes I had to pay my neighbors to accompany me to each CR session. Together, these cost me approximately 2,000–3,000 baht for each visit. It was a lot for me." (P6, urban hospital)

HPs reinforced how CR-related costs such as travel, accommodation, and food affected patients who were poor, aging, or living far from CR settings.

"Some patients were living in villages far from the hospital. When they came to attend CR, they had to pay for their accommodations, petrol, and food. Some patients paid their caregivers to accompany them." (HP6, rural hospital)

2.2.4 Access to CR services: HPs from both hospitals mentioned that there were only a few CR locations in Thailand, and most of these were located in Bangkok and some tertiary hospitals in the rural provinces. In one instance, a single rural CR facility served more than 20 provinces. A national shortage of CR staff and the cost were important concerns.

"Some CR hospital-based settings were closed as a result of a variety of problems e.g., resources, management, and funding as well as patients' concerns, etc." (HP2, urban hospital)

Patients designated as high-risk had to wait for the CR physician to be available before attending CR. The shortage of CR staff seemed to be a more serious concern for the rural hospital than for the urban hospital.

"There is a shortage of CR physicians nationwide. . . . . In Thailand, approximately 30 CR physicians have been trained. Few CR physicians have been interested in studying rehabilitation fields, especially CR." (HP2, urban hospital)

2.2.5 Communication related to CR

Communication between patients and HPs: Patients and HPs from both hospitals mentioned that a lack of communication related to CR between HPs and patients contributed to poor CR uptake.

"If patients knew that this program was available and would be useful for them, I believed many would join the programs. Some physicians who treated patients did not inform them about CR and its benefits." (HP2, urban hospital)

Communication among HPs: HPs from both hospitals emphasized that communication differed between physicians, and that a lack of communication resulted in some patients not being referred to CR.

"Sometimes, I would have liked to refer my patients to rehab, but I did not know who to talk to. This could be because of the small number of CR staff" (HP6, urban hospital)

Discussion

Facilitating factors and barriers to CR uptake from the perspective of patients and HPs across different settings were explored in the current study. Consistent with other international studies, the present study found that solid support from family members played a crucial role in encouraging patients with CAD to attend CR.[12,17,18] These supports were physical, mental, and spiritual.[13] Spouses in particular played a crucial role in promoting attendance and often attended sessions with their partner. This finding is consistent with an earlier study that found family support was the most substantial factor affecting patients' decision to attend CR in Thailand.[19]

The finding that physician support and recommendations are strong facilitators of CR attendance is in accord with international studies.[12, 20] Those studies reported that physicians were viewed as authoritative, knowledgeable people who rarely made mistakes and whose recommendations should be followed. While respect for doctors is universal, it is even more vital in some Asian cultures[21], as was evident in the current study. Culturally, these relationships could be based on the principle of "hierarchical order," which is characterized by a formalized superordinate–subordinate relationship or as a "respect pattern".[22] First, they could be based on status inequalities, e.g., age, wealth and power, knowledge, and religious or government roles. Second, they could be based on the assumption that these individuals deserve respect.[22]

In Thai society, cultural and social values based on interpretations of Buddhism have been fundamentally embedded in the Thai way of life, and behavior plays an important role in the caring relationship between husbands and wives.[23] These results are consistent with studies showing that Buddhism can affect the psychosocial well-being of individuals. In particular, elderly rural patients followed Buddhist doctrine associated with health when they were diagnosed with heart disease. They listened to Buddhist doctrine from monks which is linked to Buddhist beliefs regarding "karma" (actions) and "merits" (positive karma). This belief may have encouraged them to attend CR.

For some patients, this belief in karma is manifested in believing that their CAD resulted from their "karma." In other words, they were responsible for wrong actions in their past lives, and, as a consequence, they are now suffering in this present life, including developing CAD. Seeing their disease in this way can make these patients more relaxed or "sabai jai," helping them to accept treatment plans related to their CAD, including attending CR.

In line with other studies, our study demonstrated that attendance at CR was facilitated by patients feeling safe about attending the hospital.[12] If any subsequent cardiac events occurred, such as chest pain during exercise, HPs were available to assist or care for these patients. Notably, this study is the first in Thailand to identify that feeling safe attending CR is a major enabling factor for CR uptake.

This study also found that there are numerous barriers to CR participation. Consistent with the findings of several international studies, patients with a higher education level were more likely to attend CR.[13] At the rural hospital, CR non-attendees generally had fewer years of education than attendees at the urban hospital, reflecting the considerable 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 populations in rural areas to access, understand, and appraise health information, including information about CR.

In line with other international studies, health literacy among patients with CAD was related to increased knowledge gained from cardiac education through a CR program.[24] People with adequate health literacy were more likely to engage in physical activity and have better physical and mental health status.[25] A lack of knowledge regarding CR was the most common reason for not participating in a CR program.[26] Urban and rural HPs reinforced this view when they mentioned that patients' health literacy may affect their uptake of CR, particularly patients who are elderly, poor, and/or who have fewer years of education. However, these findings are contrary to one study that reported no association between health literacy and CR uptake.[27]

The association between health literacy and low education level among patients with CAD has previously been observed.[27] However, educational attainment should not be used as a definitive indicator of health literacy, as even among individuals with high educational attainment, there are still those with limited health literacy.[28]

In this study, patients' knowledge and understanding of CR and its benefits affected the uptake of CR. Consistent with the findings of some international studies, there was an association between patients' knowledge of CR and CR uptake.[12,17,20] This study suggests that CR attendees, especially younger CR attendees with higher educational levels, had practical knowledge of CR and its benefits. Despite this knowledge, 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.

In Thailand, availability of CR programs is limited. Throughout the northeast of Thailand, for example, only one CR facility currently provides a CR program which serves 22 Thai provinces areas as well as patients from the nearby countries of Laos, Cambodia, and Vietnam. Most rural non-attendees of CR lived more than 100 kilometers from the nearest CR program. The finding that the distance from patients' homes to the CR setting was a critical barrier preventing them from attending CR is in accord with other international studies undertaken in Europe, Japan, and Indonesia, where the distance to a CR facility was a common barrier to attendance, especially in rural areas.[13, 29, 30]

Additionally, in accord with other studies, our study demonstrated that transport difficulties, including heavy traffic and lack of parking, were associated with low CR uptake.[12, 20] In Thailand's remote areas of the northeast, the transportation system needs to be better developed. Many road networks need to be improved, some patients do not own cars, and public transport is minimal. However, transport is not a problem only for rural people, but is also a barrier for urban people[12] where traffic congestion is common, particularly in Bangkok[31], and parking is problematical.

Consistent with some international studies, our study found that women's decisions to attend CR are influenced by their family obligations.[21, 32] This could be explained culturally based on Buddhist beliefs that women and wives play essential roles in performing household duties and as caretakers

supporting other family members. Thai women live in a patriarchal social structure where they have prime responsibility for providing family care.[33]

The results of the present study are consistent with international studies which have found that some employed individuals do not attend CR due to their work responsibilities.[12] What is novel about this current research is the identification of specific work demands in rural areas. At the rural hospital, 63% of CR non-attendees were farmers, which could explain why they did not attend CR during the rice planting and harvesting periods. Many rural Thai people are heavily dependent on agriculture as their main source of income.[34]

Consistent with international studies[12, 30], this study suggests that the costs associated with CR influence CR uptake, while the Thai healthcare system was seen as an enabler of CR uptake. Public healthcare fully covers the cost of CR sessions, and the Universal Health Coverage Scheme covers 78% of the Thai population. However, patients were still responsible for indirect costs related to CR attendance, including food, transportation, parking, and accommodations. Although patients in both urban and rural areas had similar CR costs, transport and accommodations costs would usually be higher for those traveling from rural areas.

The results of this study also align with other studies that have reported patients interpreting CR as an exercise-only program.[20] This study has shown that some patients considered exercising in daily life activities is comparable to attending CR. The rural HPs and patients also reported that rural patients considered that their regular farming work and agricultural activities provided sufficient exercise. These views, which negatively impact CR attendance, are consistent with the findings of other studies.[20, 35]

International studies have also reported that poor communication and poor quality of information about CR have resulted in low CR uptake.[36] This study also found that ineffective communication between patients and HPs as well as among HPs was a barrier to CR uptake. Patients in rural areas, who tended to be elderly, have lower educational levels and have poor health literacy experienced communication difficulties. Interestingly, this study also found that not being contacted by the rehabilitation program staff resulted in poor CR uptake among patients with CAD at the rural hospital.

These results highlight specific implications for the successful delivery of CR in Thailand. These include improved access, better communication, and consideration of alternative methods of CR such as home-based CR programs, eHealth CR, and cardiac-tele rehabilitation, which should be considered as they could reduce CR cost, distance, and transportation barriers, e.g., implementing a smartphone CR home-based program which had been tested through a randomized control trial (RCT) as a way to increase CR use and improve patients' quality-of-life outcomes.[37]

Study limitations

This study has some limitations. First, as this study was only conducted in two CR settings in Thailand, the results may fail to reflect other significant national and international perspectives. Second, although the 42 interviewed participants came from diverse cultural and ethnic backgrounds, their experiences may not be representative of all patients with CAD and CR HPs in Thailand. Third, the study participants consisted mainly of Thai males, hence, the findings might not adequately reflect women's experience. Finally, most participants were elderly, had comorbidities, and had to follow up with many physicians, which may have introduced recall bias.

Conclusions

Family support, respect for doctors, a safe CR environment, plus spiritual beliefs and practices as Buddhists were found to be pivotal factors in encouraging patients to attend CR in Thailand. More specifically, CR uptake among patients with CAD in this study was in part shaped by the uniqueness of cultural and Buddhist beliefs, practices, and interpretations.

Patients' age, rural location, educational level, medical health provider communication, plus patient health literacy and knowledge of CR were found to be the main factors affecting CR uptake. Although these factors are similar to those in other countries, there were some local differences in the Thai context.

What is evident from the study is the need to create culturally-based CR with easily accessible programs and to identify practical methods to successfully deliver CR to remote populations in Thailand. Potential responses could include involving community leaders and other authorities, family members, as well as Village Health Volunteers (VHVs) in the empowerment of elder patients working on farms or in remote villages to participate in a CR hospital-based program or to use a CR home-based program. Potential approaches include: 1) initiating community engagement activities to raise awareness about the importance of CR, e.g., conducting community workshops or awareness sessions to educate community leaders, authorities, family members, and VHSs about the benefits of CR; 2) collaborating with local authorities to gain support for implementing CR programs in the community; 3) increasing family involvement, e.g., emphasizing the role of family members in supporting the participation of older patients and farmers in CR, conducting family-focused awareness programs to educate individuals about the significance of CR in improving cardiovascular health outcomes; 4) providing training for VHVs, e.g., training VHVs to act as CR advocates and educators in the community and providing VHVs with resources and information about CR to disseminate among community members; 5) consider cultural sensibilities and nuances and tailor CR programs to align with the community's cultural beliefs and practices. Incorporate

traditional or culturally relevant activities into the CR program to enhance acceptance; 6) design flexible CR programs that can be adapted to the unique needs and schedules of older patients and those working on farms, including considering offering home-based CR programs for those who face challenges in traveling to hospital settings.

Disclosure

The authors have no conflicts of interest to disclose.

Acknowledgments

The first author was a recipient of a scholarship from the Thai government and the University of Queensland. Special thanks should be given to Dr. Benja Songsangrit and Mr. Montri Yasud, research coordinators at Queen Sirikrit Heart Center of the Northeast of Thailand. Many thanks also to Miss Phermsuk Ua-Aree and Mrs. Kanokkarn Kobkitsumongkol, CR nurses and research coordinators at Ramathibodi Hospital, Mahidol University.

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