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Content

Notes from the Editor-in-Chief

In recent months, our committed team of editors and reviewers has been diligently curating a selection of articles that offer valuable insights and advancements across various fields. It is delightful to welcome readers to the third issue of the ASEAN Rehab Med Journal for 2024.

The first article of this issue, authored by Poonnark W, presents a significant research finding. Their randomized, double-blinded, controlled trial revealed that capsule-preserving hydrodilatation with a corticosteroid, in conjunction with physical therapy and a home exercise program, is more effective than intra-articular corticosteroid injection for treating subacute adhesive capsulitis. This treatment improved the range of motion, reduced pain, and restored shoulder function, providing valuable insights for our readers.

The second article, conducted by Jutakeo J and her colleague, reported their preliminary study of a non-randomized trial about dharma creative art therapy and suggested that it could reduce stress and improve mental health but does not affect anxiety, depression, and quality of life among cancer patients during chemotherapy.

The third article, Ngamwongsanguan P. conducted a quasi-experimental pilot study of 'SensibleSTEP' end-effector type robotic gait training on gait and balance abilities in older individuals after hip fracture surgery and found that the training could improve gait and balance abilities in older individuals undergoing hip fracture surgery after eight training sessions.

Next is a retrospective observational cohort design by Phitukjinda N. She concluded that the combination of pre-surgery ejection fraction, length of stay, metabolic equivalences pre-discharge, duration of exercise at two weeks, duration of exercise at six weeks, and the distance to 6-minute walk test at three months could serve as a prediction of the good functional status among post-cardiac surgery patients at six months after discharge.

Next, Triloga N and her colleague evaluated the reliability and validity of the Thai version of the modified Frenchay Activities Index (mFAI) questionnaire for stroke patients. They found that the Thai mFAI had good content validity, fair construct validity, excellent test-retest reliability, and excellent internal consistency. Then, they suggested that Thai-mFai is suitable for evaluating how well active stroke patients can perform daily activities.

Finally, Anukul R, and his colleague compared the sit-to-stand test with the 6-minute walk test in cardiac rehabilitation patients who have undergone coronary artery bypass graft (CABG) surgery and found that there is a moderately significant correlation was demonstrated between the sit-to-stand test and the 6-minute walk test in post-CABG patients and concluded that the sit-to-stand test should be considered an alternative submaximal exercise test in outpatient cardiac rehabilitation services.

Once again, we extend our heartfelt gratitude to all our authors and reviewers. Your continued support and dedication to our journal are invaluable. Your contributions allow us to foster a vibrant and dynamic scholarly community that thrives on collaboration, innovation, and excellence.

As we move forward, we want to warmly welcome all researchers, scholars, and experts considering submitting their work to the ASEAN Journal of Rehabilitation Medicine. We are always looking for new and exciting research that pushes the boundaries of knowledge and contributes to the advancement of our field.

Warm regards,

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

Original Article

The Efficacy of Ultrasound-Guided Capsule-Preserving Hydrodilatation with Corticosteroid Versus Conventional Corticosteroid Injection in Shoulder Adhesive Capsulitis: A Randomized, Double-Blinded, Controlled Trial

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ABSTRACT

Objectives: To compare the outcomes of treating subacute adhesive capsulitis (AC) using capsule-preserving hydrodilatation with corticosteroid (CPHC) versus intra-articular corticosteroid injection (IACI)

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

Setting: Chaophrayayommarat Hospital, Suphanburi, Thailand

Subjects: Fifty-two participants with AC and shoulder pain who had a numeric rating scale (NRS) of at least four after having received physical therapy for at least one month.

Methods: Eligible patients were randomly allocated either to the study group treated with CPHC or to the control group treated with IACI. The CPHC group (n=26) received a mixture of 4 mL of triamcinolone (10 mg/mL), 6 mL of 1% lidocaine, and 10 mL of normal saline, whereas the IACI group (n=26) received a mixture of 4 mL of triamcinolone (10 mg/mL) and 1 mL of 1% lidocaine. Following that, all participants underwent physical therapy at the hospital and a participated in a home exercise program. The primary outcome was shoulder passive range of motion (PROM). Secondary outcomes were subjective numeric rating scale (NRS), the Shoulder Pain and Disability Index (SPADI), and the Oxford Shoulder Score (OSS). Assessments were conducted at baseline and at 1- and 6-weeks post-treatment.

Results: At one week post-treatment, all outcomes were significantly different from baseline in both groups. The SPADI-disability and SPADI-total scores were significantly different between groups. At six weeks, all outcomes showed a strongly significant improvement in both groups and significant differences between groups except the internal rotation.

Conclusions: Capsule-preserving hydrodilatation with corticosteroid combined with physical therapy and a home exercise program demonstrated superior efficacy to intra-articular corticosteroid injection combined with the same physical therapy and a home exercise program for treating subacute adhesive capsulitis, resulting in improved ROM, reduced pain, and restored shoulder function

Keywords: adhesive capsulitis, capsule-preserving hydrodilatation, corticosteroid, ultrasound-guided, range of motion

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Introduction

Adhesive capsulitis (AC), also known as frozen shoulder, is a disorder presenting with a spontaneous onset of pain along with restricted active and passive shoulder movement. It is caused by inflammatory glenohumeral and subacromial synovium, coracohumeral ligament hypertrophy, and progressive fibrosis of the glenohumeral capsule.[1,2] The shoulder stiffness and pain usually significantly limit activities of daily living and lower quality of life.

Conservative therapy for adhesive capsulitis includes oral analgesic medication and physical therapy followed by an intra-articular corticosteroid injection (IACI), capsular hydrodilatation, arthrographic capsulotomy, and manipulation under anesthesia (MUA). Despite the amount of research on this topic, results appear inconclusive regarding the effectiveness of such treatment modalities.[3]

Hydrodilatation, which involves injection of fluid and corticosteroid into the shoulder capsule, also known as arthrographic distension, is aimed at stretching the contracted capsule and reducing inflammation.[4] To avoid discomfort and maximize the effectiveness of the treatment, it is necessary that the needle is inserted properly into the shoulder capsule. Two randomized controlled trials have reported that ultrasound-guided capsular hydrodilatation has similar effects as fluoroscopy for the treatment of AC but with less radiation exposure and greater cost-effectiveness.[5,6] However, hydrodilatation has several disadvantages, e.g., complaints of excruciating pain, time-consuming procedures, and complex preparations.[4] Hydrodilatation can distend the joint capsule until it ruptures, however, most rupture sites are located at the subscapularis bursa or the biceps sheath, not at the

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thickened capsule where the actual pathology is located.[4] Therefore, hydrodilatation with maximum volume and preservation of the capsule has a superior effect compared with the rupturing method.[4] Hydrodilatation has been demonstrated to be more effective than physiotherapy and to be as effective as MUA.[7] In review articles, physical therapy following hydrodilatation or IACI provided improvement of ROM and reduction of pain.[8,9] However, several studies have shown that without physical therapy the effectiveness of IACI is similar to hydrodilatation.[3,4,10] For that reason, determining the impact of concomitant physical therapy on the efficacy of hydrodilatation was problematic.

In a Cochrane review by Buchbinder et al. (2008), hydrodilatation with corticosteroid and saline provided short-term benefits in pain relief when compared with a placebo.[11] According to one 2018 systematic review, hydrodilatation was as effective as IACI in shoulder function improvement and pain reduction and yielded better external rotation improvement in the medium term (4-24 weeks),[12] while Saltychev et al. reviewed the efficacy of hydrodilatation based on 12 trials and concluded that hydrodilatation has only a small, clinically insignificant effect when treating AC.[13] However, there were differences in the methods utilized to expand the glenohumeral capsule in each of the research studies e.g., whether the capsule was preserved or ruptured, differences in injectate volumes and consistencies, approaches and guiding methods, the number of repeated injections, the duration and severity of the diseases, whether the study included physical therapy and/or a home exercise program or not, and the varied amounts of volume in the comparison groups, such as participants who received intra-articular injections of 10 mL, most likely had some dilatation.

According to a retrospective review of treating AC, hydrodilatation with an injected volume of 20 mL followed by physical therapy and home-based exercise provides significantly increased shoulder ROM and reduced pain.[14] However, there have been no studies of randomized trials reporting on the most effective therapy for AC patients. The present study aimed to compare the effect of CPHC versus IACI when combined with physical therapy and a home exercise program using the objective indices of shoulder functioning as well as improvement in self-reported outcomes.

Methods

Study design

The hospital ethics committee approved this randomized controlled trial with both the patient and assessor blinded. The trail was registered with the Thai Clinical Trials Registry [Registry number TCTR20210217005]. It was conducted from December 2020 to December 2023 at the rehabilitation outpatient clinic, Chaophrayayommarat Hospital. All enrolled subjects provided written informed consent prior to participation.

Participants

Study participants were adults (age ≥ 18 years) with a diagnosis of primary unilateral AC, limited shoulder PROM (more than 30 degrees restriction) in at least two directions[3] including external rotation, duration of symptoms less than 12 months (to minimize the possibility of interference with the natural recovery of shoulder ROM), subjective numeric rating scale (NRS) of shoulder pain scores of at least 4 out of 10, and no improvement after receiving at least one month of physical therapy.[14] Exclusion criteria were (1) a history of steroid injection or shoulder surgery at the affected shoulder prior to enrollment, (2) partial or full-thickness tear of the rotator cuff and/or other significant shoulder pathologies such as labral tears, significant osteoarthritis, or shoulder instability on ultrasonography or magnetic resonance imaging (MRI), (3) secondary AC (secondary to other causes including fracture, inflammatory, infectious arthritis or hemiplegia), (4) bleeding disorder, and (5) allergy to corticosteroid or lidocaine.

The sample size calculation was based on a study by Park et al. that showed capsular distension was more effective in passive external rotation improvement than IACI[15], in which the primary outcome was determined using the external rotation of the shoulder passive ROM at six weeks after the IACI with a mean (SD) of 44.5 (7.7) in the control group. The estimated clinical improvement increased by 15% in the CPHC group. Results were calculated for the sample size to compare two independent means. For an alpha level of 0.05, a power of 80% (β = 0.2), and an estimated drop-out rate of 10%, the target sample size was 52 participants (26 participants per group).

sample size formula: $$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 \left[\sigma_1^2 + \frac{\sigma_2^2}{r}\right]}{\Delta^2}$$

$$r = \frac{n2}{n1}, \Delta = \mu 1 - \mu 2$$

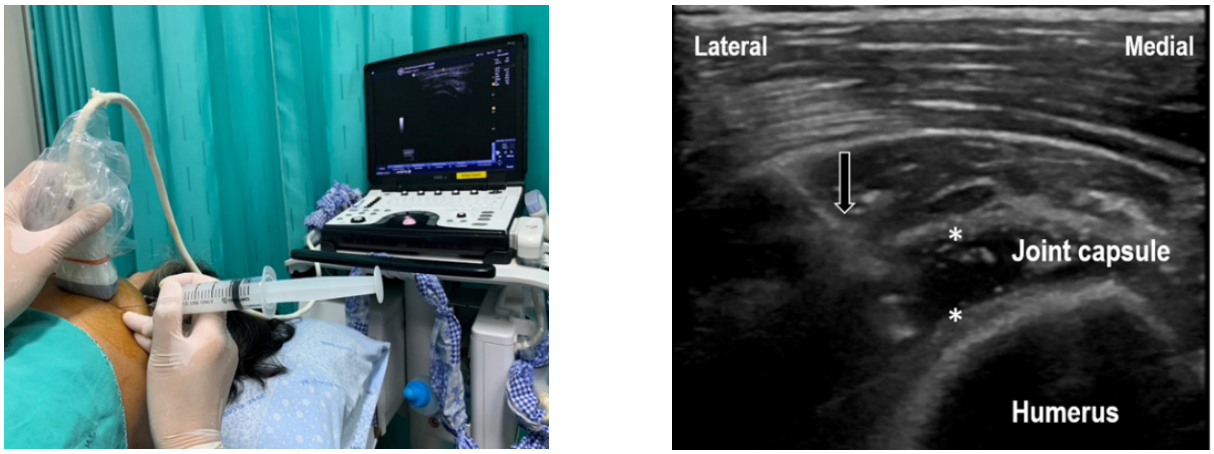
Randomization

Participants were randomly assigned to either the CPHC or IACI group using computer-generated block randomizations (block size 2). All assignments were concealed in sequentially numbered. Both the patients and the assessors were blinded to the treatment allocation.

Intervention

The investigator performed a musculoskeletal ultrasound to screen for partial or full-thickness tears of the rotator cuff to exclude participants with shoulder pathologies. After the inclusion and exclusion screening, written informed consent was obtained from the participants. The shoulder PROM was assessed and recorded.

All injections were performed under ultrasound guidance by a single certified physiatrist with more than five years of experience in ultrasound-guided injections using a 4 to 13 MHz linear array transducer. An aseptic technique was used following skin cleansing (Figure 1).



A B

Figure 1. Ultrasound-guided capsule-preserving hydrodilatation with corticosteroid. (A) approach and aseptic technique, (B) sonographic view of capsular distension during the injection (black arrows: needles; white asterisks: capsular distension).

All patients were in a lateral decubitus position with the shoulder and elbow semi-flexed, resting on a pillow for comfort, and the procedure was administered to the glenohumeral joint via the posterior approach, which is often used because it allows good needle and target visualization[16] and prevents the patient from seeing the size of syringe used.[3] Local anesthesia at the site of the injection was performed with 2 mL of 1% lidocaine. Then a 22-gauge, 1.5-inch-long needle was inserted parallel to the ultrasound probe until the needle tip entered the glenohumeral joint.[17] For the IACI group, a mixture of 4 mL of 10 mg/mL triamcinolone and 1 mL of 1% lidocaine was slowly introduced into the shoulder joint.[17] For the CPHC group, a 20 mL fluid mixture was injected composed of 4 mL of 10 mg/mL triamcinolone, 6 mL of 1% lidocaine, and 10 mL of normal saline. The capsular distension was monitored in real-time as a hypoechoic volume within the glenohumeral joint.

The participants were scheduled to return to the outpatient clinic for the first follow-up assessment one week after the injection and the start of an intensive rehabilitation program, including physical therapy at the hospital and a home exercise program. All participants received hospital-based physical therapy 2-3 times per week, consisting of shortwave diathermy for 15 minutes[18] and hot packs for 20 minutes, followed by manual shoulder mobilization for 10 minutes, therapeutic shoulder exercises for 15 minutes, and a cold pack for 15 minutes. The physiotherapist could end the therapy when the participant had a numeric rating scale (NRS) for pain of less than two and ROM was nearly average.

All participants received picture leaflets describing the home exercise program, which included active ROM, table-lean passive stretching, and cane-stretch exercises. They were advised to perform the exercises at least 10 minutes per session for a minimum of two sessions per day.

Whenever the participants attended a physical therapy program at the hospital, they were reminded and encouraged to continue their workouts at home. In addition, they were allowed to take the prescribed acetaminophen (500 mg) 1-2 tablets every 8 hours with a maximum of 6 tablets per day to control pain. No other analgesic drugs or pain therapy was permitted. The participants were allowed to contact the physiatrist who performed the injection if they thought that their symptoms had become worse.

Participants recorded their exercise sessions, medication use, physical therapy sessions, and any adverse effects or complications in a logbook every day.

At 6 weeks after injection, the assessors re-assessed all participants' shoulder PROM and subjective pain NRS, and their diaries were reviewed.

At the end of the trial, patients who had no significant improvement (NRS remaining at least four and shoulder passive ROM restricted by more than 30 degrees in at least two directions) were re-assessed by the physiatrist and continuation of physical therapy and performing an intervention such as CPHC was considered. Capsule-preserving hydrodilatation with corticosteroids could be considered when after continuing physical therapy for at least a month, if the NRS remained at least four and the shoulder passive ROM continued to be restricted by more than 30 degrees in at least two directions.

Outcome measurements

Passive shoulder ROM was the primary outcome measure. It was determined using a goniometer by one of the two well-trained physiotherapists who had high interrater reliability (Prior to this study, their intraclass correlation coefficient in all directions was more than 0.98). They were blinded to the patient's treatment. Flexion and abduction ROM were measured in a supine position, whereas external and internal rotation ROM was recorded in 90-degree abduction of the shoulder and 90-degree flexion of the elbow. If the observed abduction was less than 90 degrees, the maximum possible abduction was determined before measuring the external and internal rotation. To avoid bias, the assessor reported ROM values on separate sheets each time.

Shoulder pain and limited function or disability were assessed using two self-reported questionnaires, the shoulder pain and disability index (SPADI) and the Oxford shoulder score (OSS). Both were translated into Thai; the Thai SPADI has been reported to have excellent internal consistency and moderate to high construct validity[19], and the OSS-TH has demonstrated acceptable validity and reliability.[20]

The Thai SPADI questionnaire consisted of 13 items: 5 items for the pain domain and 8 items for the disability domain.[19] Each item is rated using NRS (0 for no pain or no difficulty to 10 for the worst pain/difficulty imaginable). The means of the pain and the disability domains are averaged to produce a total score ranging from 0 (best) to 100 (worst). The minimal clinically significant difference (MCID) for the SPADI total is between 8 and 13.[21]

The OSS-TH questionnaire consists of 12 questions to assess pain and daily function difficulty using a five-point Likert scale. A higher OSS score indicates more severe pain or greater movement difficulty.[20] The MCID for OSS has been reported to be between 5 and 6.[22,23]

In terms of NRS, patients were asked to rate the severity of their average degree of pain in the affected shoulder during motion in the last week on a scale ranging from 0 (no pain) to 10 (worst pain imaginable). Because AC is characterized by mobility restriction, pain during motion is a more sensitive measure for determining the disease's progression.[24]

At each follow-up visit, the physiatrist reviewed the participant's logbook to assess home exercise compliance, adverse effects, and complications.

Statistical methods

The data were processed using Stata Statistical Software version 14 (Stata Corp LLC, College Station, Texas, USA). The demographic data for both groups are shown as mean and standard deviation (SD) or median (25^{th}, 75^{th} percentiles) for continuous data and a percentage (%) for categorical data. The Kolmogorov-Smirnov test was used to determine data normality. When the data were normally distributed, the unpaired t-test was performed to compare the mean values of the two groups. For data lacking a normal distribution, the Mann-Whitney U-test was employed. The Chi-square test or Fisher's exact test were used to compare categorical variables between the two groups. Mixed models were used to compare the effect of treatment over time on quantitative outcomes using the mean difference from baseline. Model selection was based on the Bayesian Information Criterion. Residual plots were used to comprehensively test assumptions for mixed models, e.g., error term normality. A comparison of the predicted outcomes between the two treatments at each time point was also performed. The intention-to-treat concept was followed. In the case of missing data due to a loss of follow-up, the last observation carried forward approach was used. For individuals lost to follow-up, the last observations were defined as the last observations prior to dropout. *P*-values < 0.05 were considered statistically significant.

Results

Sixty-eight patients were evaluated for eligibility, with 52 accepted into the trial. Twenty-six patients were randomly allocated to the CPHC group and 26 to the IACI (control) group. A schematic flow chart of the participants, reasons for exclusion, and follow-up throughout the study is shown in Figure 2. Six participants did not complete the intervention: three in the CPHC group and three in the IACI group. The reasons for the loss of follow-up were unrelated to post-therapy effects: there were two COVID-19 infections and one trans-

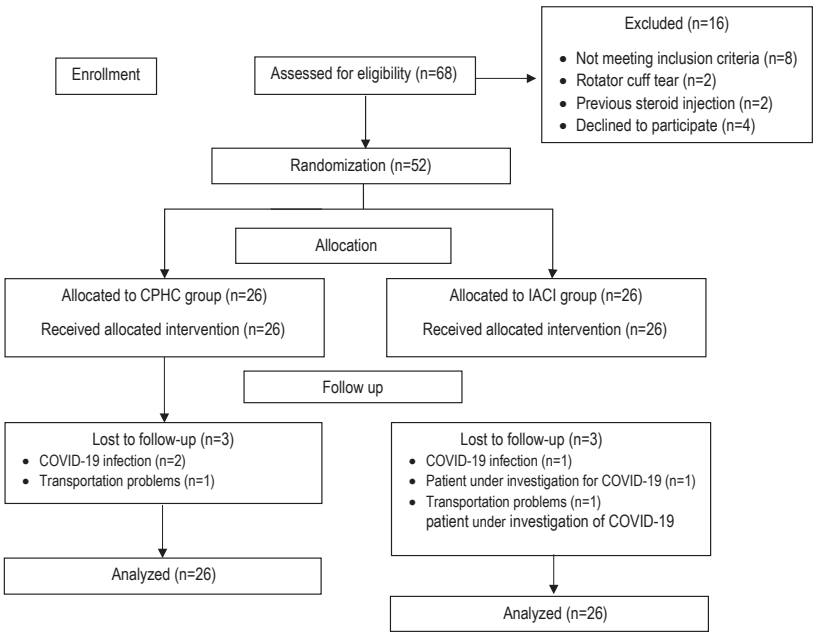


Figure 2. Consort diagram shows the progression of participants through the study's phases
CPHC, capsule-preserving hydrodilatation with corticosteroid; IACI, intra-articular corticosteroid injection

portation problem in the CPHC group, one COVID-19 infection, one patient under investigation for COVID-19, and one transportation problem in the IACI group.

There were no significant between-group differences in demographic data, pre-treatment or baseline variables. However, there were significant differences in the SPADI and NRS at baseline (Table 1).

Table 2 shows that both capsule-preserving hydrodilatation with corticosteroid (CPHC) and intra-articular corticosteroid injection (IACI) increased shoulder passive ROM in all directions at both one week and six weeks after intervention with statistically significant differences from baseline. In the comparison between groups, there was a statistically significant difference between the groups in increased ROM in all directions with the exception of internal rotation at six weeks but not at one week post-intervention. The CPHC group demonstrated a statistically significant mean difference from baseline between at 1 and 6 weeks in all directions, whereas the IACI group showed a statistically significant difference in all directions at 1 and 6 weeks except internal rotation.

Table 3 shows the pain and functional outcomes for the shoulder. According to NRS and SPADI-pain, the CPHC group had higher baseline scores than the IACI group. The pain scores declined significantly from baseline at both one week and at six weeks in both groups, while there was a statistically significant difference between groups only at six weeks. Regarding daily function difficulty, the SPADI-disability score at one week and six weeks decreased significantly from baseline in both groups, but there was a significant difference between groups only at six weeks after intervention. The OSS scores also decreased significantly in both groups, but only reached statistical significance between groups six weeks after intervention. These findings suggest that both interventions effectively reduced pain and improved shoulder function, with differences in outcomes becoming more pronounced over time.

Throughout this study, there was no significant difference in the number of acetaminophen tablets used between the two groups at any time. The median (25^{th} and 75^{th} percentiles) of sessions of the hospital-based physical therapy program was 12.0 (10.0-14.0) in the CPHC group and 13.0 (10.0-15.0) in the IACI group, which was not a statistically significant difference. Only one patient in each group discontinued the physical therapy because their NRS was less than two and their ROM was nearly normal. According to the patients' logbooks, all participants completed at least two sessions of the home exercise program each day. Both interventions were tolerated and did not result in adverse events such as vasovagal reaction, infection, hematoma, permanent neurogenic symptoms, steroid-induced arthritis, or skin discoloration.

Table 1. Baseline demographics and clinical characteristics prior to injection of capsule-preserving hydrodilatation with corticosteroid (CPHC) and intra-articular corticosteroid injection (IACI) groups.

	CPHC (n = 26)	IACI (n = 26)	*p*-value
Age (years)[1]	57.6 (9.0)	57.4 (8.1)	0.941[a]
Female[2]	6 (23)	5 (19)	0.733[b]
BMI (kg/m^2)[1]	23.5 (3.5)	25.3 (5.3)	0.141[a]
Duration of symptoms (weeks)[3]	20.0 (12.0-28.0)	20.0 (12.0-24.0)	0.520[c]
Affected side, right[2]	12 (46)	12 (46)	1.002[b]
Dominant side, right[2]	22 (85)	23 (88)	1.004[b]
Diabetes mellitus[2]	7 (27)	9 (35)	0.550[b]
Prior injection:			
Physical therapy (sessions)[3]	8.5 (6.0-12.0)	10.0 (8.0-14.0)	0.242[c]
Acetaminophen[2]	12 (46)	9 (35)	0.404[b]
Oral NSAIDs[2]	17 (65)	14 (54)	0.401[b]
Oral opioid[2]	5 (19)	4 (15)	1.003[b]
Oral muscle relaxant[2]	13 (50)	17 (65)	0.262[b]
Flexion[1]	133.9 (15.9)	131.7 (17.9)	0.640[a]
Abduction[1]	95.8 (24.0)	97.1 (18.2)	0.831[a]
Internal rotation[1]	53.3 (20.3)	55.1 (21.4)	0.760[a]
External rotation[1]	37.4 (15.5)	39.0 (14.4)	0.702[a]
NRS[1]	8.1 (1.2)	7.2 (1.4)	0.015[a]
SPADI- pain[1]	67.3 (13..8)	54.6 (13.9)	0.002[a]
SPADI- disability[1]	56.9 (15.9)	47.9 (15.5)	0.044[a]
SPADI- total[1]	60.9 (14.0)	50.5 (13.7)	0.009[a]
OSS[1]	33.8 (4.7)	31.8 (5.7)	0.182[a]

[1]Mean (SD), [2]number (%), [3]median (25^{th}, 75^{th} percentiles); [a]Unpaired T test, [b]Chi-square test or Fisher's exact test, [c]Mann-Whitney U-test; $p < 0.05$ indicates statistical significance

NSAIDs, non-steroidal anti-inflammatory drugs; NRS, numeric rating scale; SPADI, shoulder pain and disability index; OSS, Oxford Shoulder Score

Table 2. Comparison of outcome data of range of motion (ROM) at baseline, 1 and 6 weeks after injection between the capsule-preserving hydrodilatation with corticosteroid (CPHC) and the intra-articular corticosteroid injection (IACI) groups.

Outcomes	CPHC (n = 26)		IACI (n = 26)		Margin coef.[2] between groups (95%CI)	*p*-value
	Mean (SD)	Mean difference from baseline (SD)	Mean (SD)	Mean difference from baseline (SD)		
Flexion						
Baseline	133.9 (15.9)		131.7 (17.9)			
1 week	145.5 (16.6)	11.6 (11.4)[a]	136.6 (16.4)	5.2 (12.3) a	6.5 (-0.2, 13.1)	0.058
6 weeks	161.3 (15.4)	27.2 (11.0)[b]	146.7 (18.4)	16.1 (14.4) b	10.7 (3.7, 17.7)	0.003*
Margin coef.[1] (95%CI)		15.1 (10.0, 20.2)		10.9 (5.7,16.1)		
p-value		<0.001*		<0.001*		
Abduction						
Baseline	95.8 (24.0)		97.1 (18.2)			
1 week	110.2 (26.7)	14.4 (11.2)[a]	107.4 (21.7)	10.3 (11.3)[a]	4.1 (-2.0, 10.2)	0.186
6 weeks	150.1 (31.4)	52.8 (29.2)[b]	123.8 (28.4)	26.7 (20.2)[b]	26.1 (11.7, 40.5)	<0.001*
Margin coef.[1] (95%CI)		38.4 (27.7, 49.0)		16.4 (5.5, 27.3)		
p-value		<0.001*		0.003*		
Internal rotation						
Baseline	53.3 (20.3)		55.1 (21.4)			
1 week	60.6 (20.6)	7.3 (17.4)[a]	62.8 (21.7)	7.7 (16.8)[a]	-0.4 (-10.8, 10.0)	0.942
6 weeks	74.3 (15.6)	19.9 (23.3)[b]	66.2 (23.0)	13.6 (18.7)[b]	6.9 (-3.9, 17.7)	0.209
Margin coef.[1] (95%CI)		13.1 (5.8, 20.4)		5.8 (-1.6, 13.2)		
p-value		<0.001*		0.123		
External rotation						
Baseline	37.4 (15.5)		39.0 (14.4)			
1 week	46.7 (15.6)	9.3 (7.1)[a]	45.4 (16.1)	6.4 (12.1)[a]	2.9 (-5.0, 10.7)	0.476
6 weeks	65.3 (19.0)	27.8 (16.9)[b]	54.9 (19.4)	15.1 (19.4)[b]	12.3 (4.1, 20.5)	0.003*
Margin coef.[1] (95%CI)		18.3 (11.4, 25.1)		9.4 (2.4, 16.4)		
p-value		<0.001*		0.009*		

There were interaction effects between time and group for all outcomes. Positive change scores (95%CI) of ROM indicates improvement.

Margin coef.[1], margin coefficients comparing mean differences from baseline between 1 week and 6 weeks in marginal effect for mixed models.

Margin coef.[2], margin coefficients for comparing mean differences from baseline between the two groups in marginal effect for mixed models. CI, confident interval; *$p < 0.05$ indicates statistical significance.

[a]Statisitically significant difference between the baseline and 1st week in the same group ($p < 0.05$).

[b]Statisitically significant difference between the baseline and 6th weeks in the same group ($p < 0.05$).

At the end of the study, the investigator decided to perform CPHC on seven participants in the IACI group due to less than expected improvement, but none in the CPHC group. In addition, all participants were asked to guess which intervention they had received. Fifty percent of the participants in the CPHC group and 23.1% in the IACI group gave a correct guess, showing that they had not assumed they had a successful outcome because they were in the trial group.

Discussion

The results of this study demonstrate that both CPHC and IACI followed by hospital-based physical therapy and a home-based exercise program can increase shoulder ROM, reduce pain intensity and improve daily function as early as one week and both can continue to improve at six weeks after the interventions. The difference between the two groups was a statistically significant: CPHC was more effective than IACI in all measured outcomes except internal rotation. The CPHC group had improved internal rotation to a greater extent than the IACI group. The CPHC group also showed a statistically significant mean difference in internal rotation from baseline between 1 and 6 weeks, whereas the IACI group was not statistically significant. Additionally, the data suggest "most likely" improvements in range of motion in all directions, consistent with the previous studies.[25,26]

Many studies have reported no statistically significant difference in ROM, pain, or functional recovery with hydrodilatation combined with corticosteroid compared to corticosteroid alone.[3,4,10] It is believed that hydrodilatation facilitates hydraulic pressure and expands the constricted joint cavity.[24] In the present study, the injections were done using an ultrasound-guided technique to ensure that the joint capsule was distended but was still preserved to allow the injected corticosteroid to remain within the joint capsule and enhance the excellent anti-inflammatory effect.[27,28] This study chose capsular preservation as it has been reported to provide faster improvement than using an aggressive hydrodilatation technique which results in rupture of the joint capsule,[4] a rupture

Table 3. Comparison of outcome data of numeric rating scale (NRS), shoulder pain and disability index (SPADI) and Oxford Shoulder Score (OSS) at baseline, 1 and 6 weeks after injection between capsule-preserving hydrodilatation with corticosteroid (CPHC) and intra-articular corticosteroid injection (IACI) groups

Outcomes	CPHC (n=26)		IACI (n=26)		Margin coef.[2] between groups (95%CI)	*p*-value
	Mean (SD)	Mean difference from baseline (SD)	Mean (SD)	Mean difference from baseline (SD)		
NRS						
Baseline	8.1 (1.2)		7.2 (1.4)			
1 week	5.2 (1.8)	-3.0 (1.6)[a]	4.8 (2.2)	-2.4 (1.8)[a]	-0.6 (-1.6, 0.5)	0.272
6 weeks	2.0 (1.7)	-6.0 (2.0)[b]	3.35 (1.9)	-3.8 (2.2)[b]	-2.3 (-3.3, -1.2)	<0.001*
Margin coef.[1] (95%CI)		-3.1 (-3.8, -2.3)		-1.4 (-2.1, -0.6)		
p-value		<0.001*		<0.001*		
SPADI- pain						
Baseline	67.3 (13.8)		54.6 (13.9)			
1 week	42.7 (14.8)	-24.6 (13.7)[a]	34.3 (15.2)	-20.3 (13.7)[a]	-4.3 (-12.4, 3.8)	0.296
6 weeks	14.1 (15.2)	-53.2 (15.4)[b]	24.6 (14.6)	-29.9 (17.0)[b]	-23.5 (-31.9,-15.1)	<0.001*
Margin coef.[1] (95%CI)		-28.4 (-33.9, -22.9)		-9.2 (-14.8, -3.7)		
p-value		<0.001*		0.001*		
SPADI-disability						
Baseline	56.9 (15.9)		47.9 (15.5)			
1 week	36.0 (14.2)	-20.9 (15.1)[a]	36.2 (17.3)	-11.7 (11.5)[a]	-9.1 (-16.7, -1.6)	0.018*
6 weeks	12.34 (10.8)	-44.8 (14.6)[b]	19.2 (14.8)	-29.0 (14.9)[b]	-16.3 (-24.1, -8.4)	<0.001*
Margin coef.[1] (95%CI)		-24.0 (-29.2, -18.8)		-16.9 (-22.1, -11.6)		
p-value		<0.001*		<0.001*		
SPADI-total						
Baseline	60.9(14.0)		50.5 (13.7)			
1 week	38.6(13.9)	-22.3 (13.0)[a]	35.4 (15.8)	-15.0 (11.1)[a]	-7.3 (-14.3, -0.3)	0.041*
6 weeks	13.0(11.9)	-48.0 (13.0)[b]	21.3 (14.2)	-29.6 (14.2)[b]	-19.0 (-26.3,-11.8)	<0.001*
Margin coef.[1] (95%CI)		-25.7 (-30.5, -20.8)		-13.9 (-18.9, -9.0)		
p-value		<0.001*		<0.001*		
OSS						
Baseline	33.8 (4.7)		31.8 (5.7)			
1 week	25.5 (4.8)	-8.2 (5.7)[a]	25.4 (5.4)	-6.4 (4.1)[a]	-1.8 (-4.5, 0.9)	0.182
6 weeks	18.0 (4.0)	-15.6 (5.1)[b]	20.5 (4.5)	-11.2 (4.6)[b]	-4.2 (-6.9, -1.5)	0.003*
Margin coef.1 (95%CI)		-7.3 (-8.8, -5.7)		-4.9 (-6.5, -3.3)		
p-value		<0.001*		<0.001*		

There were interaction effects between time and group for all outcomes.

Negative change scores (95%CI) of NRS, SPADI and OSS indicates improvement.

Margin coef.[1], margins coefficient comparing mean difference from baseline between 1 week and 6 weeks in marginal effect for Mixed models.

Margin coef.[2], margins coefficient comparing mean difference from baseline between 2 groups in marginal effect for Mixed models.

CI, confident interval; *$p < 0.05$ indicates statistical significance.

[a]Statisitically significant difference between the baseline and 1st week in the same group ($p < 0.05$).

[b]Statisitically significant difference between the baseline and 6th weeks in the same group ($p < 0.05$).

which mainly occurs at the subscapularis recess or the long biceps sheath,[29,30] not at the thickened capsule where the actual pathologies of AC are found.[31] It is possible that the mechanical effect of hydrodilatation allows more motion during therapy and exercise than IACI. This explanation suggests that capsular distension shares a mechanism similar to manipulation under anesthesia.[11]

Both interventions in this study were done under ultrasound-guidance, but used different total injected volumes: 5 mL in IACI.[15,17] In contrast, the higher volume of 20 mL used in CPHC[4],[14,15,32] makes more capsular distension and ruptures. Why did shoulder ROM improve more in patients treated with CPHC? One possible factor is the difference in injected volume between the two interventions in this study: more lidocaine was used in CPHC than in IACI (6 mL vs. 1 mL, respectively). Additionally, local anesthetics are commonly combined with corticosteroids to assist in control of the pain that occurs after an injection. The CPHC group received 6 mL of 1% lidocaine in an attempt at pain alleviation following hydrodilatation, while the IACI group received only 1 mL of 1% lidocaine following conventional therapy to minimize the volume in order to avoid excessive capsular distension. Lidocaine hydrochloride is a fast but short-acting local anesthetic agent,[33] so it would be expected that a greater amount of lidocaine would not increase pain control at one week or at six weeks after the intervention. On the contrary,

a previous systematic review concluded that local anesthetic agents have dose-dependent and duration-dependent chondrogenic effects.[34] Grishko et al. found evidence that a 1% lidocaine-based dose does not significantly decrease cell viability at 24 hours, while 2% lidocaine remains chondrogenic at 24 hours.[35] The effect of a local anesthetic injection into a peripheral joint in vivo, however, is unclear.[34] Based on that information the principal investigator of this study decided to use a smaller amount of 1% lidocaine to avoid possible chondrotoxic effects.

It is believed that corticosteroid inhibits the inflammatory process in the inflamed joint capsule after being distended as well as in the inflamed tendons around the shoulder joint following physical therapy and exercise.[36] The duration of the effect of triamcinolone after intra-articular injection is 2-3 weeks.[37] The appropriate dose of corticosteroids for IACI or hydrodilatation has not yet been determined. Many studies have utilized 40 mg triamcinolone[4,12,38] with both methods. In this study, the injected solution in both interventions contained the same dose of 40 mg of triamcinolone (10 mg/mL). For individuals with diabetes mellitus or those who need to monitor their blood sugar levels, hyaluronate or NSAID injection may be an alternative option.

In this study, ROM between group comparisons revealed statistically significant increases in all directions with the exception of internal rotation. The rotator cuff interval has been defined as the critical structure in the pathogenesis of AC. The coracohumeral ligament (CHL) is often the first component to be compromised. A thickened CHL that covers the rotator interval has been shown to limit shoulder joint external rotation.[24] According to Koide et al.[39], arthroscopic resection of the thickened CHL from the coracoid base to the superomedial capsule is responsible for the restriction of internal rotation.

Recently, a new injection procedure using the anterior approach via the rotator interval and guided by ultrasound has been described. It is anticipated that injection via the anterior approach would raise the local corticosteroid concentration at the pathological site. In 2020, Elnady et al.[40] randomly assigned participants to hydrodilatation with 1 ml of methyl-prednisolone acetate (40 mg), 1 mL of 2% lidocaine, and 15 mL of saline via either the posterior or anterior rotator interval approach. The anterior approach showed a statistically significantly higher level of improvement in flexion, abduction, and external rotation, but internal rotation was not different between the two approaches. Furthermore, in 2021, Wang et al.[24] reported that ultrasound-guided hydrodilatation with triamcinolone achieved better pain relief during motion with injection via the anterior rotator cuff interval than with the posterior approach. However, there was no significant difference in SPADI or ROM recovery. Burkhart et al.[41] demonstrated that in individuals who had restricted internal rotation, the posteroinferior recess and the capsule are constricted and thickened. The limitation of internal rotation may be due to posterior capsular stiffness. In this study, injection into the glenohumeral joint was performed via the posterior approach, and the results showed improved internal rotation with a significant difference from baseline in both groups. The CPHC group also showed a statistically significant mean difference from baseline between 1 and 6 weeks. Why significant improvement was seen in the CPHC group but not in the IACI group is not clear.

The posterior approach using ultrasound guidance provides easy visualization of the joint capsule for needle advancement. The anterior approach needle is carefully inserted between the CHL and the biceps tendon, and needle movement during the procedure should be kept at a minimum to minimize injury to the biceps pulley and supraspinatus muscle. However, this approach through the posterior glenohumeral recess would be more challenging for obese patients. Obesity was not an issue in the present study. In clinical practice, improvements in flexion, abduction, and external rotation as well as internal rotation are the last to appear and may not be regained. Further research, e.g., anatomical, biomechanical, and clinical studies are needed.

Combining intraarticular corticosteroid injection and physiotherapy improved SPADI and disability scores more than physiotherapy alone.[8,42] Buchbinder et al.[9] followed 156 individuals after hydrodilatation. Participants were randomly assigned to either physical therapy (manual therapy and directed exercise) or a placebo (sham ultrasound) and were assessed at baseline, 6, 12, and 26 weeks. Physical therapy following hydrodilatation provided no additional benefits in terms of pain, function, or quality of life. However, it did result in sustained greater active ROM and participant-perceived improvement for up to 6 months. Other previous studies[3,4,10] have demonstrated that hydrodilatation with corticosteroids is as effective as corticosteroid injection alone in patients who received only a home exercise program. Assessing the influence of concurrent physical therapy on the effects of hydrodilatation is challenging. Nonetheless, following hydrodilatation to expand the constricted joint cavity, the synergistic effect of physical therapy and therapeutic exercise may have helped optimize glenohumeral joint ROM by stretching soft tissue near the joint, restoring proprioception, and establishing normal shoulder and trunk biomechanics.[9] Another belief is that the patient's pain would subside following the injection, allowing them to participate in physical therapy.

As with ROM and pain, in this study the SPADI and OSS scores were significantly reduced in both groups with a statistically significant difference between the groups. There was also a clinically significant change from baseline at both the one-week and six-week time points. Clinically, an effective treatment should result in a significant change. The MCID for the SPADI has been reported to be an 8-13-point change.[21] The MCID at six weeks from baseline for the SPADI-total change was 48.0 and 29.6 in the CPHC and IACI groups

respectively. Similarly, the MCID for the OSS has been reported to provide a 5-6-point change.[22,23] The MCID for the OSS is reported to be a 15.6- and 11.2-point change in the CPHC and IACI groups, respectively.

In the present study, the mean differences between groups after six weeks were -19.0 (95% CI [-26.3, -11.8]) for the SPADI-total and -4.2 (95% CI [-6.9, -1.5]) for the OSS. These results surpassed the recommended level of change and the patients showed more clinical improvement and less difficulty in daily function as seen in the CPHC group. These findings are the result of less pain and more ROM in the shoulder.

It has been reported that AC is correlated with diabetes, which impairs collagen cross-linking mediated by hyperglycemia and, consequently, loss of tissue compliance and limitation of joint mobility.[43] It has been reported that diabetic patients with AC have worse functional outcomes compared with non-diabetic persons.[43] In the present study, 27% of the patients in the CPHC group and 35% in the IACI group had diabetes, but there were no statistically significant differences between the two groups. Thus it is unlikely that the lower level of improvement seen in the IACI group was due to diabetes.

To the best of our knowledge, this is the first study to investigate the effects of ultrasound-guided capsule-preserving hydrodilatation with a corticosteroid compared with conventional corticosteroid injection alone, and to combine both approaches with physical therapy and home exercise programs to improve outcomes for AC patients who do not improve with medication and physical therapy alone. In clinical practice, when patients do not respond to medication even after prolonged physical therapy, the physiatrist needs to evaluate pain and ROM. Previous studies have suggested that corticosteroid injection alone is more beneficial in the early stages of AC, which is primarily a continuous inflammatory process. Hydrodilatation was more effective in the later stages.[12,38] The frozen phase lasts for 4 to 12 months, which is consistent with the outcomes of this study that found a duration of about five months. However, hydrodilatation is both more painful and more time-consuming than IACI alone.[4] The procedure should be customized to the stage of the disease. For example, if the pain is severe but there is only a mild limitation of ROM, IACI may be sufficient. However, in cases of pain and severe limitations, CPHC might be of considerable benefit. To provide the most effective therapy for AC patients, physical therapy in the hospital and home exercise programs should be used to improve symptoms and shorten the length of the treatment program.

CPHC and IACI have some advantages. They can be performed as a day-case operation, are cost-saving, and place no additional strain on surgery waiting periods. CPHC may also reduce the probability of the injection being repeated. In this study, seven participants in the IACI group received repeated injections with CPHC. The injector needs to be trained and have experience using an ultrasound-guided approach to enhance the effectiveness of the treatment.

In this study, bias was minimized. The investigator chose the posterior approach for injection into the glenohumeral joint to prevent the patients from seeing the size of the syringe used and thus guessing which intervention they received. As stated in the information provided for informed consent, the hypothesis of the study was that CPHC provides better outcomes than IACI. In addition, both the assessors and the participants were blinded to the intervention.

Limitations

The current study had several limitations. First, the injector was not blinded. Second, the follow-up time periods were limited to short-term (4 weeks) and medium-term (4 to 24 weeks)[8] with no long-term follow-up. Third, capsule-preserved hydrodilatation was attempted; however, without real-time intra-articular pressure monitoring, inadequate distension or capsular rupture might have occurred. Finally, this study was conducted over an extended period due to the limited number of patients who failed physical therapy in the hospital and the outbreak of COVID-19.

Conclusions

The results of this study suggest that capsule-preserving hydrodilatation with corticosteroid combined with physical therapy and a home exercise program provides superior efficacy over intra-articular corticosteroid injection combined with physical therapy and an a home exercise program for treating subacute adhesive capsulitis, improving ROM, reducing pain, and restoring shoulder functions.

Disclosure

The authors declare no conflicts of interest.

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Original Article

A Preliminary Report of the Effects of Dharma Creative Art Therapy on Psychological Impacts and Quality of Life of Thai Cancer Patients: A Non-Randomized Trial

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ABSTRACT

Objectives: To determine the effects of Dharma Creative Art Therapy (CAT) on psychological impacts and quality of life

Study design: Non-randomized trial

Setting: Department of Medicine, Siriraj Hospital

Subjects: Cancer patients during chemotherapy

Methods: This preliminary study recruited eighty-two patients into an experimental group which participated in a 90-minute Dharma CAT session for two consecutive days, while the control group received only a leaflet on holistic approach of cancer palliative treatment. Psychological outcomes of the Dharma CAT were measured using the Hospital Anxiety and Depression Scale (HADS), the Thai Stress Test (TST), the Thai Mental Health Index-15 (TMHI-15), and the EQ-5D-5L, which were evaluated before, immediately after, and one month after the intervention.

Results: After the intervention, the CAT group had significantly improved positive TST and TMHI-15 scores compared to the control (p=0.006 and p=0.018, respectively). The effect size of Dharma CAT on positive TST was moderate (0.568) and was minimal for TMHI-15 (0.373). The success rate of patients after receiving Dharma CAT therapy on anxiety, depression, stress, and mental health presented with a relative risk (RR) of 3.0 (95CI: 0.64, 14.00), 1.5 (95CI: 0.46, 4.92), 2.5 (95CI: 0.85, 7.33), and 0.8 (95CI: 0.23, 2.77), respectively but the changes were not statistically significant. All outcomes were analyzed and compared between groups at baseline, at the end of the study, and at the 1-month follow-up. No statistically significant differences between the groups for any of the outcomes were found.

Conclusions: Dharma CAT reduces stress and improves mental health but does not affect anxiety, depression, or quality of life. It may be considered an adjunctive therapy for reducing stress and improving mental health of cancer patients during chemotherapy.

Keywords: art therapy; anxiety, depression, quality of life, cancer

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Introduction

Cancer is one of the health issues of greatest concern worldwide due to its increasing incidence and high mortality rate. The nature of the disease itself and its treatments have consequences. A cancer diagnosis may be perceived by some patients as a "death sentence" despite a good prognosis for some types of cancer.[1] Physical symptoms of cancers are mostly pain and fatigue, limiting the patient's ability to perform vocational tasks, social activities, and even routine self-care. The physical illnesses and the cascade of impacts that can directly influence the patient's mental health and may later lead to disability and deterioration of their overall well-being and quality of life.[2]

Depression is a common psychological problem among cancer patients. The high prevalence of depression in cancer patients is associated with many factors, including pain, complications from cancer treatment itself, and poor quality of life.[3,4] Alternative treatments could potentially increase the well-being of cancer survivors by improving their psychological status and quality of life by reducing the severity of both somatic and psychiatric symptoms, e.g., the provision of psychotherapy, cognitive-behavioral therapy, and recreational therapy, which involve activity-based intervention to rehabilitate, disabled functions, improved physical health, psychological health, and general well-being. Recreational therapy has been found to be beneficial in patients with life-changing chronic non-communicable diseases, including cancer, providing them more independence and an adapted "new normal" life post-cancer therapy.[5] Creative art therapy (CAT) is a form of recreational therapy that uses art as a medium to provide alternative ways for those being treated to communicate and express themselves.[6] Studies have shown that exposure to CAT can improve many aspects, such as anxiety, depression, and quality of life.[7-9]

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Dharma CAT is a type of creative art therapy that applies Buddhist psychology to therapeutic activities provided to the patient. Studies of mindfulness-based stress reduction based on the Buddhist teaching of the concept of mindfulness have been found to have positive effects on both psychological and physiological stress-related outcome measures among cancer patients.[10] The therapists' role is to guide and encourage participants to engage in the processes and to express their creativity in a safe and relaxed atmosphere. To the best of our knowledge, there have been no published studies on how Buddhist psychology-based CAT affects Thai cancer patients. The purpose of this study was to determine the effects of Dharma CAT on the psychological consequences and quality of life of cancer patients receiving in-patient chemotherapy.

Materials and methods

This study was a non-randomized trial. The study protocol was approved by the Siriraj Institutional Review Board (750/2563(IRB4), and funding was provided by the Routine-to-Research unit ((IO) R016435027), Faculty of Medicine Siriraj Hospital, Mahidol University, registration number TCTR20210401003. The study period was from April 19, 2021 to May 31, 2022.

Patients with cancer who received in-patient chemotherapy service, were aged 18 years or older, were Buddhist, able to communicate verbally in Thai, and willing to participate were recruited. Patients with unstable medical conditions, e.g., alteration of consciousness, unstable vital signs, dyspnea, or a numerical rating scale of pain > 5/10, were excluded. Each participant was informed about the study before signing the consent form.

The primary outcome was assessed using the Hospital Anxiety and Depression Scale (HADS) to detect anxiety and depression. That scale is comprised of 14 items, 7 for anxiety and 7 for depression. Each item is scored from 0 to 3. Scores are summed for each subscale, and a score of ≥ 8 was considered a possible case.[11] The scale has been translated into a Thai version (Thai HADS) which has been shown to be valid and reliable for both depression and anxiety with high sensitivity and specificity.[12]

The Thai Stress Test (TST) is a 24-item test with high construct validity and reliability for secondary outcomes.[13] The first 12 items relate to the adverse effects of stress, and the following 12 items relate to the positive effects. The scores in each part are stratified into five levels and divided into nine groups using a matrix table. Participants in group 1 were considered to be in excellent mental health, groups 2, 3, and 4 were considered to have normal mental health, and groups 5 and 6 were considered to be mildly stressed. Groups 7, 8, and 9 were considered to be stressed.

The Thai Mental Health Indicator-15 (TMHI-15) is a short 2007 version of TMHI–55.[14] Each answer is scored on a scale of 1-4, which are summed and interpreted according to the norm values: 51-60 means good, 44-50 means fair, and 15-43 means poor mental health. In addition, the Thai version of the five-level European QoL-five dimension (EQ-5D-5L) was used to assess the quality of life.[15] The EQ-5D-5L is composed of 5 different dimensions (movement, self-care, daily routine, pain and discomfort, anxiety and depression), each scored from 1-5. The scores of each question were calculated on a utility-scale ranging from -1 to 1, where 1 means the healthiest, 0 means dead-like, and less than 0 means worse than dead. All outcomes were assessed three times: at baseline, immediately after the last session, and 1-month after treatment.

Patients receiving chemotherapy at Siriraj Hospital were recruited and assessed for eligibility. Eligible patients were provided with a patient information sheet explaining the study protocol, and informed consent was obtained. They were then allocated to either the experimental or the control group according to their preference. The experimental group received Dharma CAT, which was carried out in a conference room. The number of participants in each session did not exceed 6, respecting the physical distancing policy during the COVID pandemic. A total of 2 days of Buddhist psychology-based creative art therapy was provided to members of the experimental group by a team of 2 art therapists for 90 minutes per session, one session per day.

Each CAT session was divided into three parts. The first part included warm-up activities that lasted for 30 minutes. It started with meditation with music to create a calm atmosphere and encourage concentration on the therapy. Then a specific warm-up activity familiarized participants with the tool and art activity theme before starting each main activity. Both warm-up activities facilitated participants' getting used to the art mediums and the ambiance of the group therapy.

The second part was the main activity which lasted 45 minutes each session. It was composed of three activities that gave more time to participants and the art medium. The first activity in this part was Clay Talk, which used earthly material to represent emotion. The participants were asked to mould their feelings about the day and to use their hands to mould the clay meditatively into different shapes and forms. This technique helps individuals connect with their inner selves and alleviate stress and anxiety.

The second activity was an Emotional Card activity which used a deck of cards with words of emotion. It aimed to help with emotional awareness and practice of social skills in group therapy. Each participant expressed difficult feelings that were difficult to explain in words. Then the participants were asked to choose two cards. The first card represented the emotion that the participant felt was most desired to express. The second card was a positive emotion that the participant wanted to cultivate more at that moment.

The third activity was the Body Mandala which involved creating a drawing of the body as a map that everyone could read and communicate, knowing that showed where emotional and physical feelings are situated in the body. At the

start of the third activity, all participants were asked to draw a healing symbol for the warm-up session. Mandalas are geometric symbols traditionally used in ceremonies and Buddhist meditation practices. During this creative art activity, the participants metaphorically described their body as a mandala (map) by drawing an outline of the body on paper. During meditation, participants meditated using the technique of body scan, using colors and forms to represent feelings and emotions in each area through a of the body scan. At the end of the body scan, participants were asked to deliver a crucial message to communicate with one particular part of the body, they had chosen and which they felt needed more healing and self-communication.

The third activity also included cool-down activities that lasted 10 minutes. The final session concluded with a review of the purpose of each activity and followed by singing and creating an ending in using Buddhist belief as meditation to dedicate the merit of the goodness we all have done as a group. The session ended with a wishing circle, which made for a positive ending to the session.

In addition, both groups received a leaflet, "Effects of Cancer on Psychological Status and Quality of Life and Choice of Therapies," which contains information about different types of therapies, including Dharma CAT. The control group, which did not participate in the CAT session, received nothing except an only the leaflet.

Coauthors (P.L. and P.Y.) assessed the outcome measurements including giving the case record form containing all the questionnaires to each of the participants at baseline before starting the program and again immediately after the last session. At discharge from the hospital, each of the participants in both groups received a package containing all the questionnaires and was asked to complete them and return them to a researcher 1-month after discharge.

Statistical analysis

According to Bar-Sela et al.'s study on depression and fatigue, participants who received an entire course of art therapy had a mean HADS-Depression score of 8.9 (SD = 3.8) prior to receiving the art therapy.[16] That score decreased by 2.1 to 6.8 (SD = 3.9) after the creative art therapy. With a predefined significance level of 0.05 (type I error = 0.05, 2-sided) and a power of a hypothesis test of a type II error of 0.20, 112 participants were needed. Therefore, a total of 136 participants, with 68 participants per group, were needed if a 20 dropout was expected.

Demographic and baseline characteristics are reported as descriptive statistics. Continuous data are presented as mean ± standard deviation (SD). Categorical data are presented as numbers and percentages. An unpaired t-test was used to compare continuous data, and a chi-square test was used to compare categorical data. The mean difference in all outcomes at post-treatment and the 95 confidence interval (95 CI) between groups adjusted for pre-test scores were analyzed using analysis of covariance (ANCOVA). The differences between pre-and post-treatment within each group were determined using a paired t-test. The changes over time of all outcomes were analyzed using repeated measure analysis of variance (ANOVA) to evaluate the effect of time and intervention on the groups. The effect of treatment on anxiety, depression, TST, and TMHI within groups and between groups was tested using the McNemar test and the chi-square test. A per-protocol analysis was used to analyze the outcomes. A *p*-value of less than 0.05 was considered statistically significant. All data were analyzed using PASW Statistics (SPSS) 18.0 (SPSS Inc., Chicago, IL., USA).

Results

This is a preliminary study report because although the total sample size should have been 136, only 82 eligible patients were recruited. The screening number was 246 cancer patients, but 164 participants were excluded due to not meeting the inclusion criteria (n = 40), having previously participated in a study (n=70), declining to participate (n = 15), inconvenience (n = 16) and pandemic concerns (n = 23). The 82 participants recruited were allocated equally to the experimental and control groups, as shown in the study scheme in Figure 1. There were 41 dropouts (1-month follow-up mail not received: 22 in the experimental group and 19 in the control group).

Demographic and baseline characteristics of the participants are shown in Table 1. The average age of the participants was 48 to 52 years. Most participants were married, had non-hematologic cancers, and were non-recurrent cancer participants. The time after diagnosis varied, with most patients having been diagnosed for more than three months. There were no statistically significant differences in any of the variables, including age, gender, marital status, cancer type, recurrence, and time after diagnosis between the groups ($p > 0.05$).

Table 2 compares all outcomes within and between groups. When compared to the baseline, there were statistically significant differences in the TST negative score ($p = 0.035$) and TMHI-15 ($p = 0.013$) in the experimental group, as well as the EQ-5D-5L in the control group ($p = 0.010$). Concerning the between groups comparison, the TST positive score and TMHI-15 score showed statistically significant differences in improvement between the experimental and control groups ($p = 0.006$ and $p = 0.018$, respectively). When adjusted for the effect size, the TST positive and TMHI-15 had effect sizes of 0.568 and 0.373, respectively. Dharma CAT had a moderate effect on stress (0.5 or higher) and only a minimal effect (0.2 or of patients after receiving Dharma CAT therapy on anxiety/depression, evaluated by HADS and for stress and mental health, are presented with relative risk (RR) of the intervention in Table 3. The relative risk (RR) for anxiety, depression, stress, and mental health were 3.0 (95CI: 0.64, 14.00); 1.5 (95CI: 0.46, 4.92); 2.5 (95CI: 0.85,

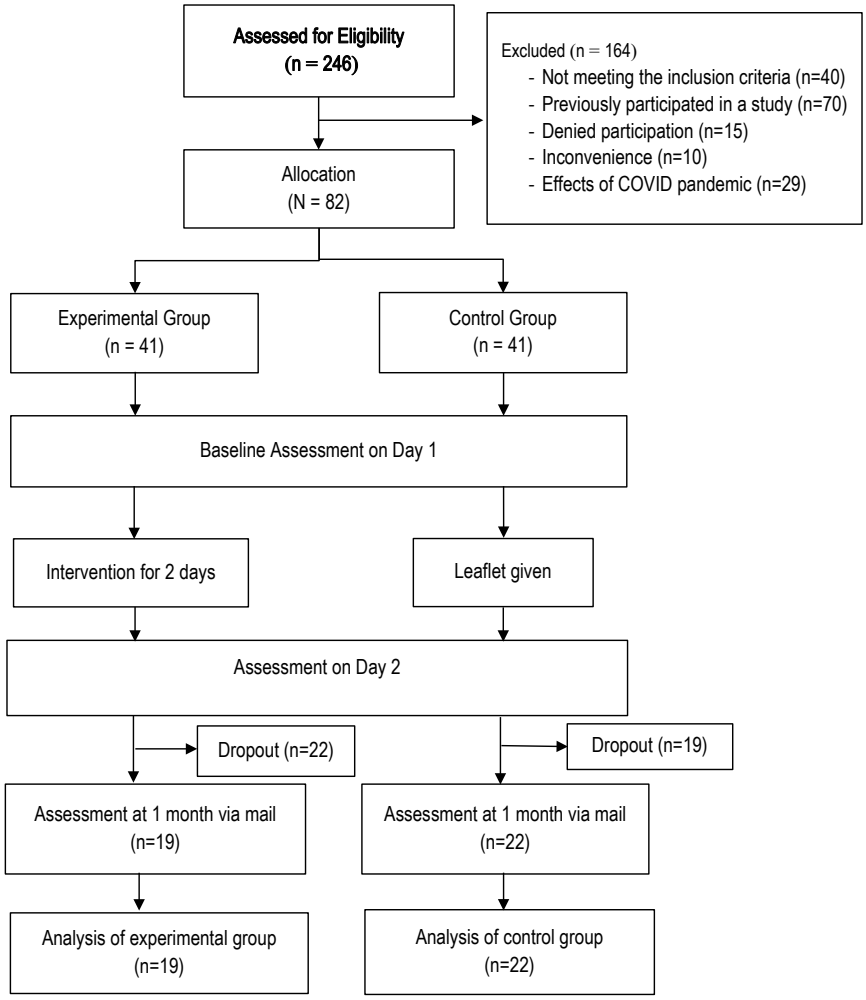

Figure 1. Flow chart of the study procedure

Table 1. Demographic and baseline characteristics

Variable	Experimental group Dharma CAT and leaflet (n = 41)	Control group leaflet (n = 41)	*p*-value
Age (years)[1]	48.2 (13.5)	51.9 (12.5)	0.212
Gender[2]			0.100
Female	31 (75.6)	24 (58.5)	
Male	10 (24.4)	17 (41.5)	
Marital status[2]			0.749
Married	22 (53.7)	24 (58.5)	
Single	17 (41.5)	14 (34.1)	
Divorced	2 (4.9)	3 (7.3)	
Cancer types[2]			0.078
Hematologic	10 (24.4)	4 (9.8)	
Non-hematologic	31 (75.6)	37 (90.2)	
Recurrence[2]			0.078
No	31 (75.6)	37 (90.2)	
Yes	10 (24.4)	4 (9.8)	
Time after diagnosis[2]			0.233
< 3 months	8 (19.5)	5 (12.2)	
3-6 months	12 (29.3)	17 (41.5)	
6-12 months	12 (29.3)	6 (14.6)	
> 1 year	9 (22.0)	13 (31.7)	

[1]Mean (standard deviation), [2]number (%); Data were analyzed using unpaired t-test, Mann-Whitney U test, or chi-square test; *$p < 0.05$ indicates statistical significance
CAT, creative art therapy

Table 2. All main outcomes were compared with baseline (pre-post comparison within the group) and the mean difference (standard deviation) between groups (control and experimental) with effect size

	Experimental group (n = 41)			Control group (n = 41)			Control - experimental		
	Pre	Post	*p*-value	Pre	Post	*p*-value	Difference (95 CI)	*p*-value	Effect size
TST negative score	6.2 (5.7)	5.0 (3.7)	0.035*	8.8 (7.6)	7.9 (7.9)	0.091	0.90 (-0.57, 2.38)	0.225	0.146
TST positive score	26.1 (7.8)	28.3 (7.6)	0.062	23.7 (10.4)	22.2 (10.2)	0.385	-5.10 (-8.68, -1.51)	0.006*	0.568
HADS-A	4.3 (3.1)	4.1 (2.7)	0.668	6.5 (4.2)	6.0 (3.7)	0.289	0.49 (-0.54, 1.53)	0.345	0.149
HADS-D	4.2 (2.7)	3.8 (2.8)	0.301	6.2 (5.1)	5.5 (4.4)	0.186	0.33 (-0.77, 1.43)	0.557	0.089
TMHI-15	48.2 (5.1)	50.4 (5.5)	0.013*	47.6 (7.4)	47.6 (7.1)	0.968	-2.38 (-4.34, -0.42)	0.018*	0.373
EQ-5D-5L	0.8808 (0.1276)	0.8894 (0.1491)	0.538	0.7856±0.2110	0.8361±0.1768	0.010*	0.0190 (-0.0250, 0.0631)	0.392	0.116

Data were analyzed using paired t-tests for comparison within a group.

Data were analyzed using covariance (ANCOVA) analysis to compare between groups adjusted for the pre-test. *$p < 0.05$ indicates statistical significance

TST, Thai Stress Test; HADS-A, Hospital Anxiety Depression Scale-Anxiety; HADS-D, Hospital Anxiety Depression Scale-Depression;

TMHI-15, Thai Mental Health Indicator-15; EQ-5D-5L, Euro quality of life-5 dimensions-5 levels.

Table 3. The success rate of patients for improving anxiety, depression, stress, and mental health after receiving Dhamma Creative Art Therapy (CAT) with relative risk (RR) of the intervention

	Experimental group (n = 41)	Control group (n = 41)	RR (95 CI)	*p*-value
Anxiety	6 (14.6)	2 (4.9)	3.00 (0.64, 14.00)	0.349
Depression	6 (14.6)	4 (9.8)	1.50 (0.46, 4.92)	0.914
Stress test	10 (24.4)	4 (9.8)	2.50 (0.85, 7.33)	0.151
TMHI-15	4 (9.8)	5 (12.2)	0.80 (0.23, 2.77)	0.800

TMHI-15, Thai Mental Health Indicator-15

7.33); 0.8 (95CI: 0.23, 2.77), respectively. However, no statistically significant difference was found for any of the outcomes.

Figure 2. compares the mean (SD) of anxiety, depression, TMHI-15, and EQ-5D-5L at baseline, at the end of the study, and at the one-month follow-up between groups. There were no statistically significant differences between groups for any of the outcomes (HADS-A, $p = 0.055$; HADS-D, $p = 0.105$; TMHI-15, $p = 0.063$; EQ-5D-5L, $p = 0.062$).

Discussion

This study aimed to fill the knowledge gap regarding whether Dharma CAT can positively impact psychological consequences and quality of life in Thai cancer patients receiving chemotherapy. Our study found that Dharma CAT can decrease stress as shown by significant reductions in negative TST scores and increased TMHI-15 scores of patients after receiving the intervention. In addition, comparison between groups found that Dharma CAT significantly increased the TST positive scores and TMHI-15 scores in the experimental group, which was better than the control group. There was no study related to MCID of TST and TMHI-15, so only statistically significant differences between groups could be reported. The RR of TMHI-15 was less than 1, which indicates risk reduction after receiving Dharma CAT therapy; however, the difference was not statistically significant.

The effect of Dharma CAT may not be sufficient to significantly change the anxiety/depression score. For that reason, this report does not include the MCID of the HADS score. It appears that treatment with CAT can decrease the percentage of participants with anxiety/depression, but the difference between the groups was not statistically significant. The failure to find a significant difference may be due to the smaller than anticipated sample size which may have been a result of the COVID-19 pandemic that occurred during recruitment. After performing post-hoc power analysis, we found only 10-11 of power. Thus, this study can be considered only as a preliminary feasibility report. Our sample size was inadequate to demonstrate clearly Dharma CAT's efficacy with cancer patients. In addition, we did not calculate the sample size to include secondary outcomes; further studies with an adequate sample size and with measurement of depression/anxiety resulting from the patient's cancer status should be performed to determine whether CAT can alleviate that psychological reaction.

There have been many studies concerning the effect of creative art.[17-19] Chiang et al. reported that creative art provides a high benefit in minimizing symptoms and maximizing functions with low risk among patients with mental illness.[17] Forzoni et al. demonstrated that art therapy helped reduce stress among most cancer patients while they were receiving chemotherapy treatment.[18] Another study performed by Collette et al. reported on the benefit of art therapy in a palliative care unit and found that art therapy was beneficial in reducing the intensity of anxiety, depression, and pain. In addition, those patients in that study reported their experiences in participating in the art therapy intervention of including

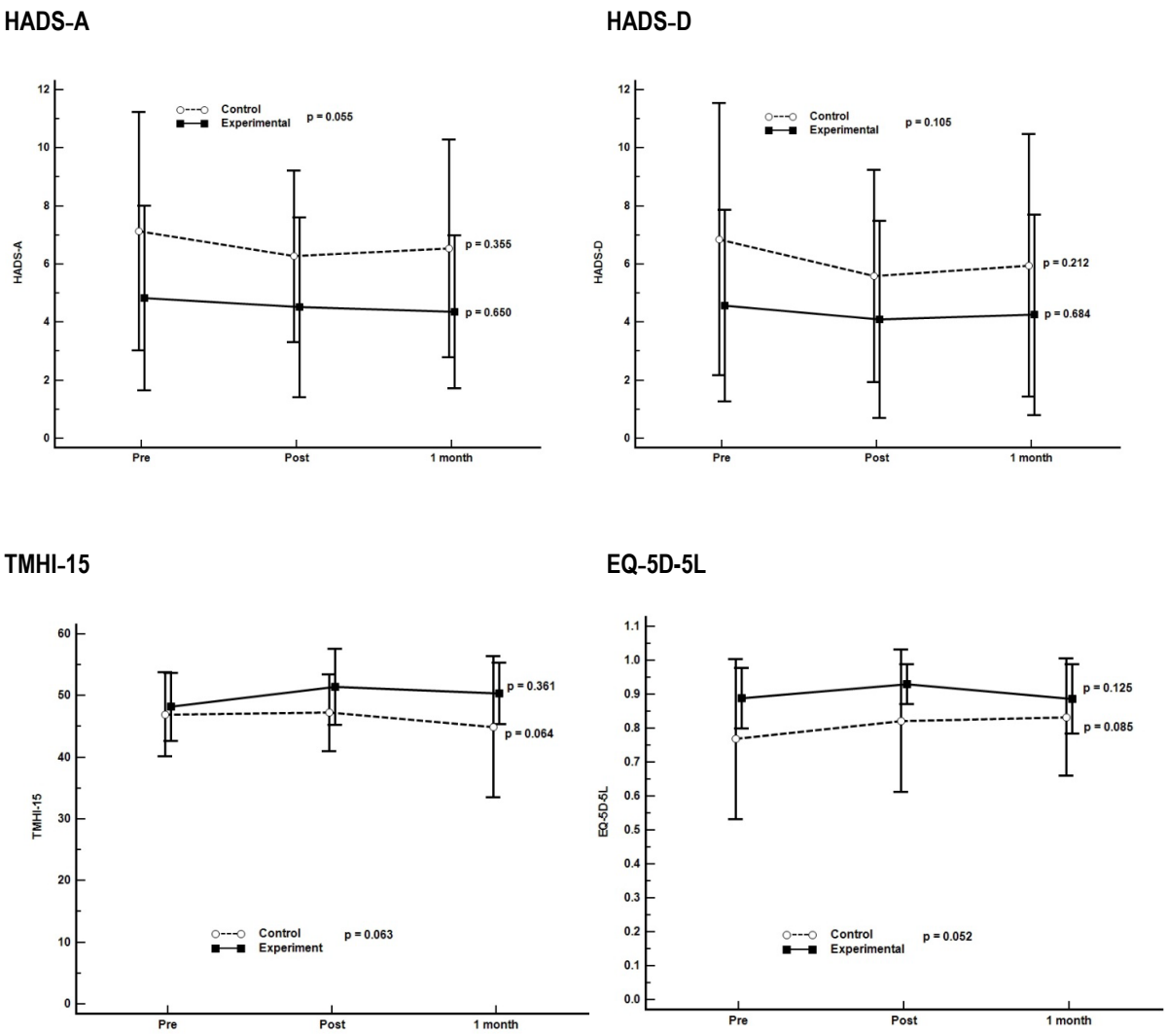

Figure 2. Mean, SD of Hospital Anxiety Depression Scale-Anxiety (HADS-A), Hospital Anxiety Depression Scale-Depression (HADS-D), Thai Mental Health Indicator-15 (TMHI-15), and Euro quality of life-5 dimensions-5 levels (EQ-5D-5L)

feeling calm, being entertained, and being able to express their emotions.[19]

Another issue of concern with the present study is the short duration of the Dharma CAT program. We had initially planned for a 3-day program, but could not deliver that due to the limited resources of the chemotherapy ward and the admission and discharge system in our hospital, i.e., patients admitted on Monday were to be discharged on Wednesday before noon to make room for other patients to be admitted that afternoon and discharged on Friday at noon. The creative art therapists suggested adjusting the schedule to a 2-day program. In comparison, the Chimluang et al. study performed quasi-experimental research on Dharma CAT's effect on palliative cancer patients.[20] In that study, the experimental group received more than our Dharma CAT program (6 activities within three days) and the results showed significantly higher improvement in physical and functional well-being in the experimental group.

Regarding anxiety and depression, Bosman et al. performed a systematic review in 2021 to determine the effects of art therapy on anxiety and depression in cancer patients. They found that art therapy could possibly decrease anxiety and depression and improve the quality of life in adults with cancer.[9] However, our study was not able to demonstrate the effect of art therapy on anxiety and depression. The RR seemed to be greater than 1 (RR 1.5-3.0 for anxiety and depression, respectively), but without statistical significance. This result may be due to several factors, e.g., (1) low scores for anxiety/depression at baseline and the long period since the onset of cancer was detected, (2) most participants (80-88) presented with a time after diagnosis of more than three months and (3) most participants had no cancer recurrence (76-90). All of these factors may have allowed the patients to adjust their psychological status to cope with their cancer better than newly diagnosed patients. This may also be a reason for the lower-than-expected percentage of participants with stress (26.8-56.1), anxiety (14.6-41.4), depression (12.2-36.6), and poor psychological health (17.1-31.8). That is, patients who had been diagnosed sometime ago were able to cope with their cancer better than newly diagnosed patients. Further study among newly diagnosed patients may better demonstrate the benefit of Dharma CAT

in improving the psychological status of cancer patients.

Several limitations might also have influenced the results and applicability of this study. First, we calculated that only 20 would drop out, but we were not able to recruit additional patients due to the COVID-19 pandemic, a situation which limited not only participant recruitment but also protocol continuity and outcome assessment. In addition, the budget for creative art therapists was limited. Second, the medical condition of most of the cancer patients, which included physical fatigue and side effects of medical treatment, may have limited study recruitment and compliance. Third, the study was initially designed as a randomized controlled trial. However, the Dharma CAT requires a group therapy effect, making the randomization process infeasible, influencing baseline characteristics and affecting outcomes. Fourth, the duration of the Dharma CAT sessions may need to be longer. As previously mentioned, due to the limitations of the system of admission to the chemotherapy ward, the treatment duration of Dharma CAT sessions may have been inadequate to have a definite effect on the psychological status of the patients. Fifth, Dharma CAT was performed by specialists in creative art, so the results cannot be generalized to hospitals with no creative art therapists. Sixth, confounding factors for non-randomized trials in this study included cancer recurrence rate and duration of cancer after diagnosis. Fortunately, most patients in both groups had no recurrence (75.6-90.2) and for a relatively time after diagnosis (more than three months) which was not different between the groups. Lastly, there was a high dropout rate during the follow-up period. The final number of participants analyzed, approximately half of the initially included participants, exceeded the expected number of dropouts. Therefore, the probability of beta error was increased, affecting the result's applicability.

Conclusions

Dharma creative art therapy reduces stress and improves mental health. However, no statistically significant results were achieved by the use of CAT with Thai oncology patients in terms of decreasing anxiety or depression and improving quality of life during chemotherapy. Further studies of Dharma CAT with an adequate sample size, appropriate program duration, and being conducted with newly diagnosed cancer patients is recommended.

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Disclosure statement

The authors report that there are no competing interests to declare. Before starting recruitment, this study was registered with the Thai Clinical Trial Registry (No TCTR: 20210401003).

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Author contributions

All authors contributed to the conduct of the study. JJ and VK were responsible for the drafting of the protocol. CA, CH, and KT provided suggestions and cooperated in the recruitment process. PL and PY contributed to the data collection. JJ and VK wrote the manuscript. All authors approved the final version.

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Original Article

A Pilot Study of End-effector Robotic Gait Training for Improving Gait and Balance Abilities in the Older Patients after Hip Fracture Surgery

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ABSTRACT

Objectives: To assess the effect of 'SensibleSTEP' end-effector type robotic gait training on gait and balance abilities in the older patients after hip fracture surgery

Study design: A quasi-experimental pilot study

Setting: The Department of Rehabilitation Medicine, Lerdsin Hospital, Bangkok, Thailand

Subjects: Older patients (aged ≥ 60) who underwent hip fracture surgery between March - September 2023.

Methods: Ten older subjects who had undergone hip fracture surgery were recruited for a robotic gait training program. The program consisted of 30-minute training sessions conducted twice weekly for four consecutive weeks, a total of eight sessions. The investigator evaluated the Functional Ambulation Category (FAC), Timed Up and Go (TUG), Single Leg Stance (SLS), Four Step Square (FSS), gait speed, stride length, cadence, visual analogue scale (VAS), gait aid use, and level of assistance both before and after the training program.

Results: Robotic gait training with SensibleSTEP showed statistically significant improvements in FAC, TUG, FSS, gait speed, and stride length. Trends of improvement were observed in SLS, cadence, VAS, gait aid use, and level of assistance.

Conclusions: End-effector robotic gait training for eight sessions can improve gait and balance abilities in the older patients who had undergone hip fracture surgery

Keywords: Robotic Gait Training, end effector type, older patient, hip fracture, gait, balance

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Introduction

Thailand has become an "aging society," as 17.1% of the current population is aged over 60 years. A significant demographic shift will occur within the next two decades when more than two-thirds of the population will be older than 60. Such an aging demographic presents unique challenges, particularly in the context of health and societal economics.[1]

Falls are recognized as a prevalent issue among older adults, with far-reaching negative impacts on individuals' health and quality of life as well as the economic stability of families and society. It is estimated that up to 10% of older individuals who experience a fall suffer severe injuries, including hip fractures and traumatic brain injuries which can lead to permanent disabilities, escalating the burden of care and support required.[2]

Hip fracture, defined as a proximal femur fracture,[3] can be divided into intracapsular fractures, e.g., femoral neck fractures, and extracapsular fractures, e.g., intertrochanteric and subtrochanteric fractures.[4] Hip fracture mainly occurs in older people[3] and is a leading cause of mortality in that age group.[5] Additionally, 50% of older adults are found to be dependent others for at least one activity of daily living after experiencing a hip fracture,[6] which causes a significant deterioration in their quality of life. This dependency underscores the need for effective preventive strategies and rehabilitation programs to mitigate the impact of such injuries in an aging society.[7]

Previous studies have reported that 41% to 64% of individuals experience at least one fall within a year after hip surgery.[8,9] Eleven percent of these falls occurred during their hospital stay.[8] Increased outdoor activity has also been associated with a higher risk of falling.[10,11] The incidence of falls was even more stark for individuals who transitioned to nursing homes after a hip fracture, with 40% passing away within two years.[12] Furthermore, 19% of older patients who suffered a hip fracture go on to experience a subsequent fracture.[13] Many factors are associated with this risk, including advanced age, poor general health, female gender, and environmental conditions. Among these factors, gait and balance abilities have been identified as predictors of recurrent injury, both of which are modifiable through targeted post-surgery rehabilitation. These associations highlight the importance of such interventions in improving patient outcomes.[9,14]

A variety of methods for rehabilitation in post-hip fracture surgery patients are available. The current conventional program includes range of motion, strengthening exercises, gait, balance, and activities of daily living (ADL) training.[15] Some programs also feature treadmill training either with or without partial body weight support.[16] Among these, it is evident that programs that specifically emphasize ambulatory skills and

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balance, such as those that include tandem walking or task-oriented training while changing position,[17] are more beneficial than conventional training in improving ADL, muscle strength, walking capabilities, and overall quality of life.[3,18,19]

Robotics-based rehabilitation has been mentioned as being superior to conventional therapy because it is able to deliver consistent training as prescribed and provide appropriate forces and movements according to the user's ability.[20] Robotic gait training was first used in rehabilitation in 1994 with a patient who had multiple fractures, delivering a safe and successful outcome.[21] Although studies focusing on robotic gait training for post-hip fracture surgery patients have been limited, a systematic review reported that the outcomes have been promising.[22] Most of the studies included in the review were preliminary, involving small sample sizes[23-25] or single-case reports.[26] Nevertheless, the findings across these studies have been consistently positive, suggesting that robotic assistance may offer superior recovery of gait and balance abilities compared to conventional training methods.[27,28]

"SensibleSTEP" is an end-effector-type robotic gait training device which has been approved by the Thai FDA. It is designed to provide safe and interruption-free body weight-supported gait and balance training with adjustable gait speed, step length as well as adjustable extent of vertical and horizontal weight support to suit the user's needs. Moreover, it gives continuous visual and kinesthetic feedback of the correctness of the magnitude and timing of body weight while shifting up on the moving two-foot plates. Although 'end-effector type' robotic gait training has been successfully deployed in the rehabilitation of subacute, severe, non-ambulatory stroke patients,[29] its efficacy in gait rehabilitation for older adults recovering from hip fracture surgery has not yet been documented. This absence of prior reports suggests a novel opportunity to explore and expand the device's rehabilitative applications.

This pilot study aimed to investigate the efficacy of 'end-effector type' robotic gait training for older patients who had undergone hip fracture surgery, focusing on the potential for improvements in gait and balance abilities.

Methods

Study design

This quasi-experimental pilot study was conducted at the Department of Rehabilitation Medicine, Lerdsin Hospital, Bangkok, Thailand, between March and September 2023. The study protocol was approved by the Lerdsin Hospital Ethics Committee (approval number LH661009).

Participants

Ten patients who had undergone hip fracture surgery, specifically hemiarthroplasty, open reduction and internal fixation (ORIF), or total hip replacement (THR), were recruited. The inclusion criteria were (1) age over 60 years, (2) allowed to engage in and capable of weight-bearing at least as tolerated, (3) sufficient cognitive capacity to understand and comply with the training sessions, and (4) able to adhere to a training schedule.

The exclusion criteria were (1) unstable medical conditions, (2) inadequate cardiovascular fitness to sustain light exercise for a minimum of 15 minutes, (3) painful musculoskeletal conditions or deformities that could potentially interfere with walking training, (4) skin breakdown which limits using a body weight support harness, and (5) individuals with pre-existing walking disabilities before their hip fracture. Patients meeting any of the criteria were excluded to allow accurate assessment of the impact of the postsurgical rehabilitation.

Intervention

Before the commencement of robotic gait training, the investigator evaluated the walking and balancing abilities of the participants. The training protocol involved 30-minute sessions twice weekly for four consecutive weeks, a total of eight sessions. Each session consisted of 20 minutes of practice with the robotic gait training device 'SensibleSTEP' (Figure 1) and 10 minutes allocated for preparation and rest. Vital signs were monitored and any abnormal symptoms were noted before and after each session, with precautions taken to avoid excessive flexion (over 90 degrees), adduction, or internal rotation of the hip joint to prevent adverse effects. All participants had previously participated in conventional physical therapy programs for post-hip fracture rehabilitation

Figure 1. 'SensibleSTEP' Robotic gait training device

from the postoperative period until discharged from the hospital, including muscle strengthening exercises, joint range of motion exercises, balance training, gait training, and proper hip joint positioning.

Outcome measurements

History-taking interviews and physical examinations, including baseline data on gender, age, weight and height as well as data on pre-existing conditions, location of the hip fracture, and pain levels were collected. In addition, participants were assessed for movement function, walking ability, and balance using the Functional Ambulation Category (FAC), Timed up and go (TUG), Single leg stance (SLS), and Four Step Square (FSS).

- FAC was used to assess functional dependency for ambulation, with or without a walking device, with the following scoring system: score '0' indicated unable to walk or in need of assistance from more than two persons, score '1' indicated requirement for firm continuous support from one person who helps with carrying weight and with balance, score '2' indicted requirement for continuous or intermittent support of one person to help with balance or coordination, score '3' indicted requirement for verbal supervision or stand-with help from one person without physical contact, score '4' indicated ability to walk independently on level ground, but requires help on stairs, slopes, or uneven surfaces and score '5' indicated ability to ambulate independently on nonlevel and level surfaces, stairs, and inclines.[30]
- TUG was used to assess functional mobility and balance. Patients were encouraged to walk at their preferred pace using their usual walking aids. The investigator recorded the time taken to rise from a chair with armrests, walk 3 meters, cross a line on the floor, turn around, walk back, and sit down again.[31]
- SLS was use static balance. The time spent standing on a single leg with eyes open was measured.[32]
- FSS was used to assess dynamic standing balance. The FSS is classified on an ordinal scale as follows: score '0' indicated the patient's inability to complete the test, score '1' indicated the patient's ability to complete the test but taking longer than 15 seconds, and score '2' indicated the ability to complete the test within 15 seconds.[33]
- Another essential variable was gait parameters, including average gait speed, cadence, and stride length. Parameters were assessed during a 10-meter walking test at a comfortable speed. Pain level, use of gait aids, and level of assistance required were also assessed during testing.[31] Pain levels were measured using a VAS, which consists of a 10 cm line with two endpoints denoted as 0 ('no pain') and 10 ('as much pain as possible'). Patients were asked to rate their current level of pain by marking it on the line.[34]

These assessments were conducted before the training (pre-training) and at the end of the 8th session (post-training). The collected data were subjected to statistical analysis and summarized to determine the study's outcomes.

Statistical analysis

The data were analyzed using IBM SPSS Statistics 29.0 software. The statistical significance level was set at a *p*-value less than 0.05, and the power of the test was 80%. The demographic data, including gender, age, weight, height, pre-existing conditions, location of the hip fracture, and pain levels, are reported as mean with standard deviation for continuous variable data, median with minimum and maximum values for ordinal variable data, and patient counts for categorical variable data. The following tests, including the FAC, TUG, SLS, FSS, Gait Parameters, VAS, gait aid use and level of assistance required were compared between pre-training and post-training using the Wilcoxon signed rank test and the generalized McNemar chi-square test.

Results

The characteristics of all participants are shown in Table 1. The participants had a mean (SD) age of 75.6 (6.2) years, weight of 51.2 (10.1) kg, height of 157.0 (4.1) cm, and body mass index of 20.7 (3.4) kg/m^2.

Regarding comorbidities, the subjects presented with the following conditions: diabetes (5 subjects), hypertension (7 subjects), dyslipidemia (5 subjects), history of cerebrovascular accident (1 subject), thyroid disorders (2 subjects), and atrial fibrillation (1 subject). All participants had been diagnosed with femoral neck fractures, five on the right side and five on the left side. Surgical interventions were predominantly hemiarthroplasty, performed on eight subjects. Of the remaining patients, one underwent open reduction internal fixation (ORIF) on the femoral neck system and one had a total hip replacement (THR). The median time from surgery to the start of training was 141 days, with an IQR of 17 to 518 days. All subjects were residing at home and were independent in basic activities of daily living (BADL). The number of falls before the study had a median of 0 with an IQR of 0 to 4.

Function and balance test

Patient FAC was categorized prior to training. Three participants were categorized as FAC3, 6 participants were FAC4, and 1 participant was FAC5. Post-training, none of the participants remained at FAC3; the number at FAC4 decreased to 3, and at FAC5 increased to 7. This change in FAC levels was statistically significant, with a *p*-value of 0.046.

The TUG test resulted in pre-training median scores of 31.35 seconds and post-training median scores of 19.65 seconds. The statistical significance of this improvement was a *p*-value of 0.005.

In the SLS test, median scores were 4.10 seconds and 7.54 seconds in pre-training and post-training, respectively, indicating a positive change although not statistically significant (*p*-value of 0.086).

Table 1. Demographics and clinical characteristics of participants

Characteristics	Participants (N = 10)
Age[1] (years)	75.6 (6.2)
Weight[1] (kg)	51.2 (10.1)
Height[1] (cm)	157.0 (4.1)
BMI[1] (kg/m^2)	20.7 (3.4)
Underlying disease[2]	
Diabetes	5 (50)
Hypertension	7 (70)
Dyslipidemia	5 (50)
Cerebrovascular accident	1 (10)
Thyroid disorder	2 (20)
Atrial fibrillation	1 (10)
Fracture[2]: right / left side	5 (50) / 5 (50)
Operation[2]	
Hemiarthroplasty	8 (80)
ORIF with femoral neck system	1 (10)
Total hip replacement	1 (10)
Time from surgery to the start of training (days)[3]	141 (17, 518)
Address[2]: home	10 (100)
BADL[2] (level): independent	10 (100)
Previous fall frequency[3] (times)	0 (0, 4)

[1]Mean (SD), [2]number (%), [3]median (min, max)
BMI, body mass index; ORIF, open reduction internal fixation; BADL, basic activities of daily living

In the FSS test, 6 of 10 participants initially scored '0' due to inability to complete the test during the pre-training evaluation. Whereas after the training, all participants could successfully complete the test with a score of '1' or '2' (Table 2). The statistical significance of this change was marked by a *p*-value of 0.046.

Gait parameters

Median gait speed was 0.30 in pre-training and increased to 0.57 in post-training. The median stride length also rose from 0.52 to 0.80. These improvements were statistically significant, with *p*-values of 0.008 and 0.005, respectively, while changes in cadence did not reach the level of statistical significance, with a *p*-value of 0.114.

The changes in VAS, gait aid use, and level of assistance required did not reach statistical significance, with *p*-values of 0.114, 0.059, 0.063, and 0.172, respectively. However, the trend in these parameters was positive compared to pre-training. The study results are displayed in Table 2.

Discussion

The study evaluated gait and balance abilities in older patients who had undergone hip fracture surgery followed by robotic gait training using the FAC,[35] TUG,[36] SLS,[37] FSS,[38] 10 Meter Walking Test[39], and VAS[40], the validity and reliability all of which have been previously documented. Improvement in the FAC, TUG, FSS, gait speed, and stride length reached statistical significance. Much of our findings are consistent with previously published studies.

Regarding balance abilities, Yang et al.[22] demonstrated similarly significantly improved TUG, and Fujikawa et al.[23] also reported a positive TUG trend, supporting our findings.

Table 2. Comparison of gait and balance abilities before and after robotic gait training (N = 10)

Outcomes	Pre-training	Post-training	*p*-value
FAC[1] (score)			0.046
3	3 (30)	0 (0)	
4	6 (60)	3 (30)	
5	1 (10)	7 (70)	
Balance tests			
TUG[2] (seconds)	31.35 (24.41, 69.02)	19.65 (17.08, 28.09)	0.005
SLS[2] (seconds)	4.10 (0.98, 10.88)	7.54 (3.48, 16.21)	0.086
FSS[1] (level)			0.046
0	6 (60)	0 (0)	
1	3 (30)	7 (70)	
2	1 (10)	3 (30)	
Gait parameters			
Gait speed[2] (me-ters/second)	0.30 (0.18, 0.66)	0.57 (0.48, 0.70)	0.008
Cadence[2] (steps/minute)	79.57 (51.01, 109.47)	91.92 (77.50, 111.01)	0.114
Stride length[2] (meters)	0.52 (0.37, 0.80)	0.80 (0.69, 0.91)	0.005
VAS[2] (score)	0 (0, 1.3)	0 (0, 0)	0.059
Gait aid use[1]			0.063
- None	5 (50)	10 (100)	
- Walker	5 (50)	0 (0)	
Assistance required[1]			0.172
- None	5 (50)	10 (100)	
- Minimal	1 (10)	0 (0)	
- Contact	4 (40)	0 (0)	

[1]Number (%); [2]median (IQR); Wilcoxon signed rank test or the generalized McNemar chi-square test, statistically significant at $p < 0.05$
FAC, Functional Ambulation Category; TUG, Timed Up and Go; SLS, single leg stance; FSS, Four Step Square; VAS, visual analogue scale

The subjects of these two studies were similar to the present study, i.e., Asian older patients who had undergone surgery due to hip fracture and who trained with robotic assistive devices. Although those studies utilized different robot models (trunk control rehabilitation robot and hybrid assistive limb (HAL) lumbar type), they had common features with SensibleSTEP, e.g., all of them directly attached to the patient's lower limbs while training and were able to sense and adjust support according to the patient's movement. In addition, these two studies reported on two other significantly improved balance parameters: the Modified Functional Reach test (MFRT) and the Five Times Sit to Stand (FTSS) test together with references indicating their use in balance evaluation. The first was used to assess trunk balance in a sitting position,[41] and the latter could identify people with a balance disorder.[42]

Regarding gait speed, Röhner et al.[24] reported patients had significant improvement in gait speed after robotic training, which is consistent with our study. The robot in Röhner et al.'s study let the patients walk by themselves under analyzing and voice guidance, while ours worked on the very distal part of the kinetic chain. Both methods of training might be able to improve overall trunk and lower limb muscles. Setoguchi et al.[25] also showed some positive trends in gait speed after training, but the results were not statistically significantly different which the author hypothesized was owing to the limited sample size.

Stride length was significantly improved in our study, similar to Setoguchi et al.,[25] while Röhner et al.[24] did not report any improvement. The robotic device that Röhner et al. studied stands away from the patient, while the SensibleSTEP used in our study and HAL in the Setoguchi et al. study were directly attached and supported with step length adjusted for the patient during training, allowing uninterrupted practice resembling normal walking movement. Cadence, however, was improved in all studies, but this might need to be investigated further to determine its clinical and/or statistical significance.

Regarding improvements in VAS, Yang et al.[22] reported significant improvement in VAS after robotic gait training, in contrast to our study in which the pain level did not significantly change. This difference might be due to the low initial VAS and smaller sample size in the present study. All participants in this study received analgesic medication from orthopaedists, but no changes were made in medication during this study.

It must be noted that comparison between studies incorporating robotic training after hip fracture surgery was highly challenging due to the limited amount of available data, the different types of robots, and the different training protocols.

Another noteworthy result in our study is the improvement in ambulation status. Prior to the robotic training, half the participants (5 out of 10) relied on a walker for support, and the other half needed assistance for mobility. After the training program, none required gait aids or assistance from another individual. Although the change in ambulation status was not statistically significant, this does seem to be a noteworthy clinical improvement as the participants were more independently mobile. Walkers typically aid walking in people with impaired muscle power and balance,[43] so this improvement could be the result of better balance as mentioned above as well as increased muscle strength, especially the hip abductors, as weakness of those muscles is one of the common complications after hip surgery.[44,45]

The 'end-effector type' robot has succeeded in improving ambulation ability, activity of daily living, gait speed, step length, and endurance compared to conventional physical therapy in other situations such as severe non-ambulatory stroke patients.[29] Our study was the first to investigate the effect of 'end-effector type' robotic gait training in older patients after hip fracture surgery. The results showed benefits for this group of patients, suggesting the possibility of using this robotic model for training hip fracture surgery patients. It should be noted that this was a short-term intervention consisting of only eight therapy sessions. The performance of participants at the end of that short period speaks against the general common perception that an extended period might be necessary to achieve progression in geriatric rehabilitation.

The duration of post-surgery training by a robotic device in our study averaged at 4-5 months, ranging from 17 to 518 days. Even though this is quite a wide range, all participants showed improvement in balance and gait parameters, which suggests a possible benefit of training even in patients who have been operated on some time ago and who have already received conventional postoperative training.

There are some limitations in the present study. Being a pilot study, there was no blinding of the assessor and no control group for comparison. The preliminary findings, do, however, suggest the potential for a larger scale, randomized controlled trial to further investigate the efficacy of 'end-effector type' robotic gait training compared to conventional treatments. A longer follow-up period should also be included to determine the long-term effects. In addition, incorporating a health economic analysis into future research could provide valuable insights into the cost-benefit ratio of such interventions for older patients recovering from hip fractures.

Conclusions

End-effector robotic gait training can improve gait and balance abilities in older people following hip fracture surgery with eight training sessions.

Conflicts of interest

The author declares no relevant conflicts of interest in this study.

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Original Article

Predicting the Functional Status of Post-Cardiac Surgery Patients at Six Months After Discharge from Hospital : Utilizing the 6-Minute Walk Test Distance (6-MWT) and Clinical Characteristics at Hatyai Hospital

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ABSTRACT

Objectives: To evaluate the use of the 6-minute walk test (6-MWT) in predicting the functional status of post-cardiac surgery patients six months after discharge

Study design: Prognostic prediction research and retrospective observational cohort design

Setting: Hatyai Hospital, Thailand

Subjects: Post-cardiac surgery pateints at six months after discharge from Hatyai Hospital

Methods: The study retrospectively reviewed pre- and post-cardiac surgery data records. Patients' functional status at six months was assessed using the New York Heart Association (NYHA) Classification. Multivariable logistic regression analysis was employed to identify variables to predict the patients' functional status. The predictive scores were assigned based on coefficient values derived from the regression equation.

Results: A total of 272 post-cardiac surgery patients were followed up six months after discharge, of whom 181 patients (66.5%) exhibited good functional status (NYHA Classification 1). Six variables were predictive of NYHA Classification 1: pre-surgery ejection fraction (EF), length of hospital stay (LOS), metabolic equivalences (METs) pre-discharge, duration of daily exercise at two weeks, duration of daily exercise at six weeks, and the six-minute walk test (6-MWT) at three months. The constructed prediction scores ranged from 0 to 23. The prediction score performed well in predicting the functional status at six months with an area under the receiver operating characteristic curve (AUROC) 0.89, 95%CI: 0.85-0.93. The clinical risk scores were categorized into two groups: low-good functional status scores (< 14) with a positive predictive value (PPV) of 37.5 (95%CI: 20-40, $p < 0.001$) and high-good functional status scores (≥ 14) with a PPV of 95.6 (95%CI: 0.91-0.98, $p < 0.001$).

Conclusions: The combination of pre-surgery EF, METs pre-discharge, LOS, duration of daily exercise at two weeks and six weeks, and the 6-MWT distance at three months can serve as a predictor of the good functional status of post-cardiac surgery patients at six months after discharge.

Keywords: prognostic prediction, 6-minute walk test, cardiac rehabilitation, post-cardiac surgery

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Introduction

The primary goal of cardiac rehabilitation is to restore heart function to a level where patients can engage in their daily activities and pursue a career that aligns with their physical condition, ultimately preventing recurrence. Cardiac rehabilitation programs offered in various settings (center-based, home-based, or through telerehabilitation) can improve functional capacity, physical activity, and health-related quality of life after coronary revascularization.[1] Utilizing the 6-minute walk test (6-MWT) distance has been identified as a simple, cost-effective, and highly efficient method that does not require additional equipment.[2] Moreover, this method is easily employed in clinical practice, serving as a crucial indicator for planning cardiac rehabilitation and appropriately adjusting exercise patterns.[3] The 6-MWT is used to assess the patient's ability to perform activities of daily living.[4]

Following open-heart surgery, patients were normally followed up for an average period of 6.8 months (range 2 to 15 months). Most of the post-operative patients were classified as New York Heart Association (NYHA) Classification 1.[5] Functional capacity was evaluated according to the NYHA Classification before and 18 months after surgery. The functional status improved clinically significantly after coronary artery bypass grafting (CABG) surgery, particularly in physical functioning.[6] At 12 weeks after CABG surgery, patients were advised to engage in daily activities such as self-help and exercise. However, it was found that the patient's ability to perform their duties had decreased compared to prior to surgery. There was also a decline in functional capacity between the 8th and 12th week after surgery, with patients

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performing fewer activities than before. Such limitations may persist for up to three months. Functional capacity represents an individual's maximum potential for carrying out everyday life activities, meeting basic needs, and tolerating various activities as required, constituting an essential aspect of overall functional status.[7] In addition, post-cardiac surgery patients who had responsibilities as either a working professional or as a family leader frequently experienced anxiety when returning to work and daily routines.

A study examining factors predicting functional status in CABG patients found that multiple variables collectively predicted function recovery at the second post-surgery appointment by a statistically significant 17.7%. Specific variables that predicted the levels of functional recovery at the second appointment were ejection fraction (EF) and fatigue.[8] This finding suggests that lower EF and higher fatigue levels are associated with poorer functional recovery outcomes following CABG. The NYHA Classification is used to appraise the status of patients with heart disease and to evaluate treatment outcomes in clinical and research settings. There is an inverse correlation between NYHA Classification 2 and 4 and the 6-MWT in heart failure patients. Significant heterogeneity exists across studies in 6-MWT scores within each NYHA classification, with overlap in 6-MWT performance between NYHA Classification 1 and 2. The NYHA Classification is particularly effective in assessing more symptomatic patients (NYHA Classification 3 or 4) more than less asymptomatic or mildly symptomatic patients (NYHA Classification 1 or 2).

Nonetheless, the NYHA Classification is a practical and widely used tool in routine clinical practice.[9] For that reason, the NYHA Classification was utilized in this study as an assessment tool to effectively reflect the functional status of these patient groups. Patients were divided into 2 groups based on the NYHA Classification: NYHA Classification 1 and NYHA Classifications 2, 3, and 4.

Hatyai Hospital recognizes the importance of comprehensive cardiac rehabilitation services and has established a dedicated clinic to address the needs of pre- and post-cardiac surgery patients. However, despite these efforts, there remains a gap in predicting the outcomes of such rehabilitation interventions.

In light of this, the present study aimed to fill this research gap by focusing on using the distance covered in the 6-MWT as a predictive measure of functional status in post-cardiac surgery patients and to integrate the 6-MWT distance with clinically relevant characteristics such as age, gender, pre-surgery BMI (body mass index), pre-surgery EF, surgical method, post-surgery complications, re-admission occurrences, comorbidities, pre-surgery congestive heart failure (CHF), smoking habits, LOS (length of stay), pre-surgery NYHA Classification, METs (metabolic equivalents) pre-discharge, as well as duration and frequency of daily exercise. Combining these relevant clinical characteristics was used to seek a comprehensive understanding of their collective impact on predicting functional status at six months of post-cardiac surgery patient cohorts.

Methods

Study design

Using Hatyai Hospital's medical record data, a retrospective observational cohort design and prognostic prediction research effort was developed. The study protocol received approval from the Institutional Ethics Committee (Hatyai Hospital Certificate No. HYH EC 071-65-01) and the research was conducted in accordance with the Declaration of Helsinki.

Participants

This study included pre- and post-cardiac surgery patients from the cardiac rehabilitation clinic at Hatyai Hospital from October 2018 to September 2022.

The inclusion criteria were:

1. Entering the cardiac rehabilitation program during both pre- and post-cardiac surgery (Phase I) and continuing participation in the program after discharge from Hatyai Hospital (phases II and III)
2. Continuing the cardiac rehabilitation training program at home following the standard cardiac rehabilitation protocol

The exclusion criteria were:

1. Patients with neurological disease and/or musculoskeletal injuries
2. Patients with incomplete medical records
3. Juveniles with congenital heart disease (CHD)
4. Death

Data collection

Potential clinical predictors included various clinical characteristics, such as age, gender, pre-surgery BMI, pre-surgery EF, surgical method, post-surgery complications pre-discharge (e.g., lung atelectasis, pneumonia, CHF, pleural effusion and pneumothorax), re-admission, comorbidities (e.g., hypertension, diabetes mellitus, hyperlipidemia, and chronic kidney disease (CKD), pre-surgery CHF, smoking, LOS, pre-surgery NYHA Classification, METs pre-discharge, 6-MWT at three different time points (at two weeks, six weeks and three months), frequency and duration of exercise at three different time points (at two weeks, six weeks and three months).

Sample size calculation

The prediction analysis was conducted at six months for post-cardiac surgery patients. The current study incorporated the distance covered in the 6-MWT and relevant clinical characteristics of 20 randomly selected patients assumed to have a pre-surgery EF in the 40% to 49% range. The estimated sample size analysis in this study was classified according to the standard of NYHA Classification, whereby participants classified as NYHA classification 1 were considered to have a 0% risk. Those who were classified as NYHA Classification

2, 3, and 4 were considered to have a 10% risk. For statistical analysis, a two-sided method with a significance level of 0.05 and a power of 0.9, assuming a ratio of 2:1 between NYHA Classification 1 and NYHA Classification 2, 3, and 4 was used. This study anticipated having 162 patients in NYHA Classification 1 and 81 patients in NYHA Classification 2, 3, and 4. Therefore, a total of 243 patients was the minimum number to be recruited into this study.

Outcome measurements

The primary purpose of this study was to evaluate utilizing the 6-MWT at two weeks, six weeks, and three months combined with relevant clinical characteristics to predict good function status (NYHA Classification 1) among post-cardiac surgery patients at six months after discharge from Hatyai Hospital. The NYHA classification was divided into four classifications: Classification 1 (no limitation of physical activity), Classification 2 (slight limitation of physical activity), Classification 3 (marked limitation of physical activity), and Classification 4 (inability to perform any physical activity).[10]

Statistic methods

Statistical analysis

Continuous data are presented as means (M) and standard deviations (SD), while categorical data are presented as frequencies and percentages. The comparison of categorical data was performed using the Chi-square test or Fisher's exact probability test, and unpaired t-tests were used for the analysis of continuous data. Variables that showed significance in the univariate logistic regression were subsequently incorporated into the multivariable logistic regression analyses using STATA version 18 (Stata Corp LLC, College Station, TX, USA, under license of Medical Education Center at Hatyai Hospital). Statistical significance was defined as $p < 0.05$.

Model development

Among the 36 candidate predictors, elimination of predictors was based on various factors, including odds ratio, statistical significance (*p*-value), AUROC, and clinical relevance. Logistic regression analysis was employed to identify predictors of functional status. Initially, univariate analysis was conducted on the clinical characteristics data to avoid bias. The resulting reduced multivariable model was evaluated for its predictive performance in terms of discrimination and calibration. The measure of discrimination is reported as AUROC. The measure of calibration is reported as the Hosmer-Lemeshow goodness-of-fit test, where a nonsignificant χ^2 value indicates a good fit of the model.

The final predictors were assigned logistic regression coefficients. Each predictor's logistic coefficient was divided by this reference, and the results were rounded to the nearest non-decimal integer for practicality. The scores were used to classify individuals into lower or higher-risk categories. The positive predictive value (PPV) was calculated for each score group, providing insight into the average post-cardiac surgery patient predictor associated with each score. Measures of calibration and discrimination were also conducted using regression with the functional status on the score. A calibration plot comparing the score-predicted risk with the observed risk indicated the model's predictive performance. Internal validation was performed through nonparametric receiver operating characteristic (ROC) regression with 1,000 bootstrapped replicates. Statistical significance was established at $p < 0.05$.

Scores were classified into two groups for clinical utility: low and high. In the low-good functional status group, lower cut-off points were chosen to minimize the magnitude of the PPV. In contrast, higher cut-off points were selected in the high-good functional status group to maximize the PPV's magnitude. The model's discriminative ability was assessed using a 95%CI to avoid overlapping with the specific PPV. The potential clinical utility of the model was determined through decision curve analysis. This analysis calculated the net benefit (NB) of applying the model to classify patients across a range of clinically relevant threshold probabilities, comparing the two groups of outcomes (good and poor functional status) in post-cardiac surgery patients at six months after discharge from Hatyai Hospital.

Results

The study grouped medical records according to the NYHA Classification: there were 181 patients in NYHA Classification 1 and 91 patients in NYHA Classification 2, 3, and 4. Therefore, this study's minimum number of participants was 272 patients (Fig. 1). Patient Baseline clinical characteristics are detailed in Tables 1 and 2. Prognostic factors with high predictive performance were chosen, characterized by a statistically significant $p < 0.05$, AUROC of > 0.51 , and clinically meaningful correlation. In the univariable logistic regression analysis, variables, including pre-surgery EF, METs pre-discharge, LOS, daily exercise duration at two weeks, six weeks, and the 6-MWT distance at three months, were identified as critical clinical predictors.

A multivariable logistic regression analysis was conducted to examine six potential clinical predictors, as presented in Table 3. The functional status score was calculated by summing the scores assigned to each variable. Consequently, the constructed prediction score had a range of 0 to 23 scores.

In the multivariate binary logistic regression analysis of the data, clinical features were statistically significant at $p < 0.05$. Although pre-surgery EF were non-statistically significant, they held clinical importance (Table 3). This study transformed the score predictors (β) regression coefficients into a simple score. Subsequently, the researcher developed a simplified model that integrated the distance of the 6-MWT with relevant clinical characteristics, facilitating easy application in clinical practice. Interestingly, the simple score demonstrated excellent discriminative ability (AUROC: 0.89, 95%CI: 0.85-0.93) (Fig. 2), while the Hosmer-Lemeshow good-

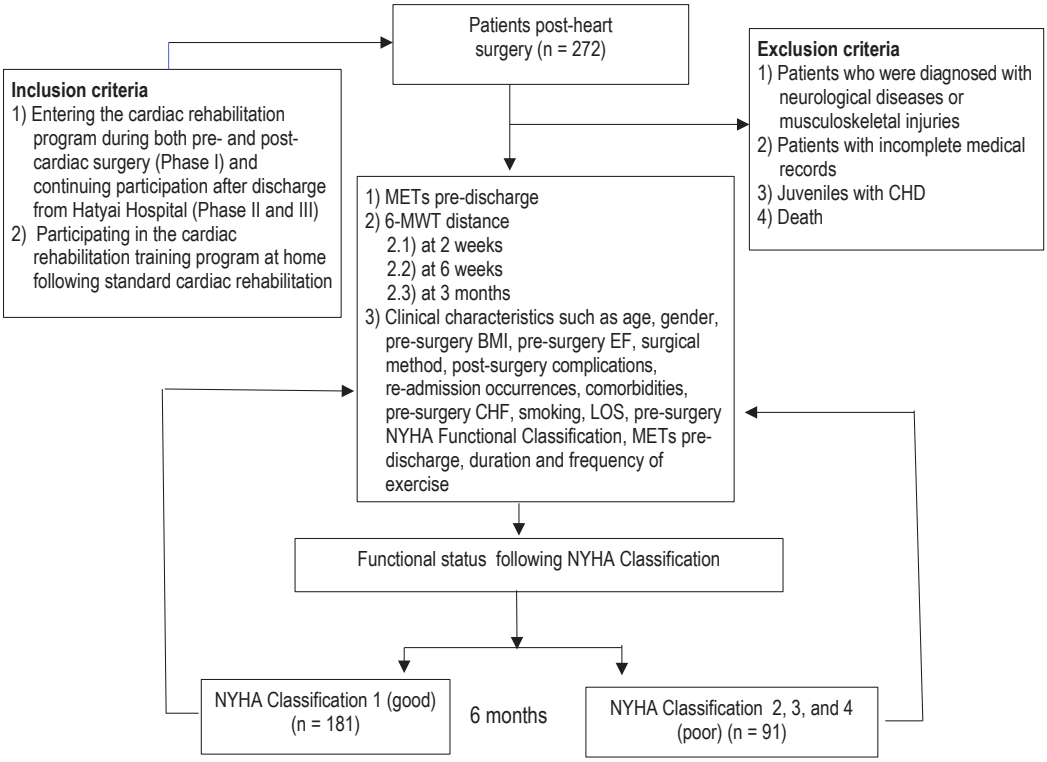

Figure 1. Study flow of the selection of eligible patients for development of a prediction tool for functional status

ness-of-fit test revealed a non-significant *p*-value of 0.64.

Measures of calibration showed strong performance in the developed model. The calibration plot showed that the scores predicted functional status and observed functional status increased concomitantly (CITL = 0.000, slope = 1.000, respectively) (Fig. 3). Internal validation of the model using nonparametric ROC with 1,000 bootstrap sampling replicates demonstrated robust performance (bootstrap shrinkage of 0.990) and an AUROC of 0.889 (95%CI: 0.853-0.927).

The clinical predictions were classified into two groups. The PPVs in the low-good functional status at six months (< 14) and high-good functional status at six months (≥ 14) groups were 37.5 (95%CI: 20-40, $p < 0.001$) and 95.6 (95% CI: 91-98, $p < 0.001$), respectively (Table 4, Fig. 4).

The model's performance regarding clinical usefulness and curve analysis elucidated the net benefit (NB) in predicting. With Functional status at a cut-off probability threshold of 0.665 (the prevalence point), the prediction model demonstrated an NB 4.5 times greater than that without the predictive model (Fig. 5).

Discussion

The present study aimed to evaluate utilizing the 6-minute walk test distance (6-MWT) with relevant clinical characteristics to predict the functional status among post-cardiac surgery patients six months after discharge from Hatyai Hospital, Thailand. Six variables can predict the functional status, including 1) pre-surgery EF, 2) LOS, 3) METs before discharge, 4) duration of exercise at two weeks, 5) duration of exercise at six weeks, and 6) 6-MWT at three months. The scores generated from these variables ranged from 0 to 23 points, indicating a statistically significant difference between patients with a good functional status (NHYA Classification 1) and those with poor functional status (NYHA Classification 2, 3, and 4) at six months (15.6±4.8 and 7.6±3.7, $p < 0.001$). The clinical score demonstrated a capability for predicting good functional status (NYHA Classification 1) at six months, as evidenced by an AUROC value of 0.89 (95%CI: 0.85-0.93, $p < 0.001$). The clinical score was divided into two groups: 1) low-good functional status (score < 14) exhibited a PPV of 37.5 (95%CI: 20-40, $p < 0.001$), while the high-good functional status (score ≥ 14) demonstrated a PPV of 95.6 (95%CI: 91-98, $p < 0.001$) indicating that the developed score has potential for practical clinical use. Rungtiwa et al.[11] reported the mean work ability of the body within two weeks after discharge from the hospital with an average value of 4.5±0.3 METs. This value aligns with the METs associated with moderate-intensity physical activity which typically range from 3 to 5 METs. That study also found that the METs values before discharge from the hospital were significantly different between 2 groups: those with good functional status (3.6±1.3) and those with poor functional status (2.9±1.4), ($p < 0.001$). That is, patients with good functional status before discharge from the hospital demonstrated the ability to perform physical activities at a moderate intensity.

The 6-MWT and clinical characteristics can be collectively utilized to construct clinical prediction scores, effectively predicting functional status according to the NYHA Classification after six months post-cardiac surgery. Patients were also

Table 1. Baseline characteristics of post-cardiac surgery patients with good functional status (New York Heart Association Classification, NYHA 1) and poor functional (New York Heart Association, NYHA 2-4) at 6 months: Univariable analysis

Clinical characteristics	Functional status at 6 months		*p*-value	AUROC (95%CI)
	NYHA Class 1 (n = 181)	NYHA Class 2, 3, and 4 (n = 91)		
Age (years)	54.8 (11.4)	61.4 (8.9)	<0.001	0.66 (0.26, 0.40)
Gender, n (%)				
Female	60 (33.2)	47 (51.7)	0.003	0.59 (0.53, 0.66)
Male	121 (66.9)	44 (48.4)		
Pre-surgery BMI	23.7 (4.0)	23.5 (3.9)	0.697	0.52 (0.45, 0.59)
Pre-surgery EF	55.9 (15.5)	56.2 (16.5)	0.871	0.51 (041, 0.56)
Methods of surgery, n (%)				
CABG	109 (60.2)	54 (59.3)	0.866	0.51 (0.43, 0.56)
Valve surgery	67 (37.0)	33 (36.3)		
Re-valve surgery	2 (1.1)	1 (1.1)		
CABG + valve surgery	3 (1.7)	3 (3.3)		
Post-surgery complication, n (%)				
Atelectasis (Yes)	10 (5.5)	10 (11.5)	0.086	0.53 (0.44, 0.51)
Pneumonia (Yes)	2 (1.1)	11 (12.1)	<0.001	0.55 (0.41, 0.48)
CHF (Yes)	10 (5.5)	10 (11.0)	0.086	0.53 (0.44, 0.51)
Pleural effusion (Yes)	25 (13.8)	16 (17.6)	0.258	0.52 (0.44, 0.53)
Pneumothorax (Yes)	1 (0.6)	1 (1.1)	0.558	0.50 (0.49, 0.51)
Re-admitted, n (%)				
CHF (Yes)	7 (3.9)	8 (8.8)	0.084	0.52 (0.44, 0.51)
Pleura effusion (Yes)	5 (2.8)	2 (2.2)	0.568	0.50 (0.44, 0.51)
Co-morbidities, n (%)				
Hypertension (Yes)	111 (61.4)	64 (70.4)	0.090	0.55 (0.40, 0.51)
Diabetes mellitus (Yes)	42 (23.2)	23 (25.3)	0.0407	0.51 (0.44, 0.55)
Hyperlipidemia (Yes)	98 (54.2)	53 (58.3)	0.305	0.52 (0.42, 0.54)
CKD (Yes)	7 (3.9)	7 (7.7)	0.146	0.52 (0.45, 0.51)
CHF pre-surgery (Yes), n (%)	48 (26.6)	33 (36.3)	0.065	0.55 (0.39, 0.51)
Smoking (yes), n (%)	98 (54.2)	35 (38.5)	0.010	0.58 (0.52, 0.64)
LOS (day)	10.1 (3.7)	13.7 (12.9)	<0.001	0.55 (0.38, 0.53)
METs pre-discharge	3.6 (1.3)	2.9 (1.4)	<0.001	0.63 (0.56, 0.70)
Duration of daily exercise (minutes)				
2 weeks	12.8 (8.3)	8.3 (5.6)	<0.001	0.68 (0.62, 0.75)
6 weeks	22.7 (9.8)	16.5 (9.4)	<0.001	0.70 (0.64, 0.77)
3 months	33.1 (13.2)	22.2 (9.6)	<0.001	0.75 (0.69, 0.81)
Frequency of exercise (day/weeks)				
2 weeks	6.9 (0.4)	7.0 (0.0)	0.266	0.50 (0.48, 0.50)
6 weeks	6.7 (0.9)	6.9 (0.5)	0.120	0.53 (0.44, 0.51)
3 months	6.4 (1.1)	6.6 (0.9)	0.084	0.55 (0.40, 0.50)

Data are presented as mean (SD); $p < 0.05$ indicates statistical significance; AUROC, area under the receiver operating characteristic curve; CI, confidence interval; BMI, body mass index; EF, ejection fraction; CABG, coronary artery bypass grafting; CHF, congestive heart failure; CKD, chronic kidney disease; LOS, length of stay; METs, metabolic equivalents

Table 2. Baseline characteristics of post-cardiac surgery patients with good functional status (New York Heart Association Classification, NYHA 1) and poor functional (New York Heart Association, NYHA 2-4) at 6 months (univariable analysis)

Clinical characteristics	Functional status at 6 months		*p*-value	AUROC (95%CI)
	NYHA class 1 (n = 181)	NYHA class 2, 3, and 4 (n = 91)		
NYHA Class pre-surgery, n (%)				
NYHA Class 1	47 (25.9)	19 (10.9)	0.002	0.62 (0.32, 0.45)
NYHA Class 2	79 (43.7)	40 (43.9)		
NYHA Class 3	51 (28.2)	32 (35.2)		
NYHA Class 4	4 (2.2)	9 (9.9)		
6-MWT distance (meters)				
2 weeks	328.1 (76.9)	238.5 (76.6)	<0.001	0.80 (0.74, 0.85)
6 weeks	397.7 (70.7)	286.4 (77.4)	<0.001	0.86 (0.82, 0.91)
3 months	428.6 (62.5)	315.4 (60.9)	<0.001	0.92 (0.88, 0.95)

Data are presented as mean (SD); $p < 0.05$ indicates statistical significance; AUROC, area under the receiver operating characteristic curve; CI, confidence interval; 6-MWT, 6-minute walk test

Table 3. Best multivariable clinical predictors, odds ratios (OR), 95% confident intervals (CI), logistic regression beta coefficients (β), and assigned item scores

Predictors	OR	95%CI	*p*-value	βeta	Score
EF % (pre-surgery)					
< 40	1.00	Reference	-	-	0
40-49	0.62	0.16, 2.36	0.487	-0.47	1
≥ 50	0.59	0.25, 1.42	0.239	0.52	1.5
METs pre-discharge					
≤ 3	1.00	Reference	-	-	0
> 3	1.59	0.78, 3.26	0.200	0.47	1
LOS (day)					
< 10	1.00	Reference	-	-	0
≥ 10	1.49	0.57, 3.94	0.419	0.40	1
Duration of daily exercise (minutes) at 2 weeks					
< 10	1.00	Reference	-	-	0
10-15	1.61	0.75, 3.47	0.221	0.48	1
> 15	5.73	1.52, 21.59	0.010	1.75	4.5
Duration of daily exercise (minutes) at 6 weeks					
< 15	1.00	Reference	-	-	0
15-30	1.68	0.70, 4.02	0.242	0.52	1.5
> 30	0.44	0.09, 2.25	0.326	-0.82	2
6-MWT (meters) at 3 months					
< 320	1.00	Reference	-	-	0
320-400	5.28	2.02, 13.79	0.001	1.66	4
> 400	134.46	35.59, 494.17	0.000	4.90	12

P < 0.05 indicates statistical significance

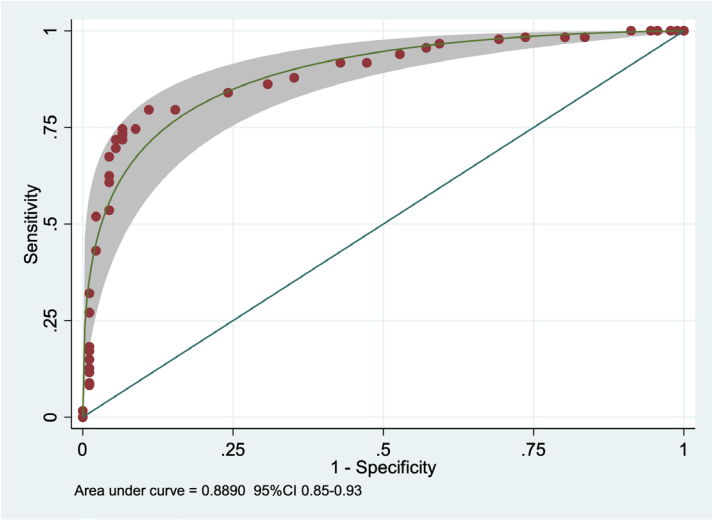

Figure 2. Area under received operating characteristic curve (AUROC) of clinical prediction scores of functional status at 6 months

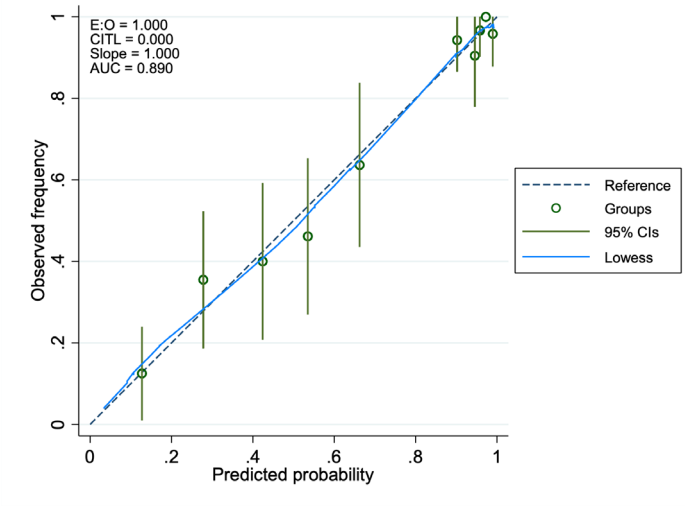

Figure 3. Calibration plot of score-predicted probability of functional status at 6 months and observed functional status at 6 months

Table 4. Distribution of good functional status (New York Heart Association Classification, NYHA 1) and poor functional (New York Heart Association, NYHA 2-4) at 6 months into low and high probability categories

Probability categories	Score	Functional status at 6 months				PPV (%)	95%CI	*p*-value
		NYHA Class 1 (n = 181)		NYHA Class 2, 3, and 4 (n = 91)				
		n	%	n	%			
Low	<14	51	37.50	85	62.50	37.5	0.2, 0.4	<0.001
High	≥14	130	95.59	6	4.41	95.6	0.91, 0.98	<0.001
Mean (SD)		15.6	(4.0)	7.6	(3.7)			<0.001

Data are presented as mean (SD); CI, confidence interval; PPV, positive predictive value; $p < 0.05$ indicates statistical significance

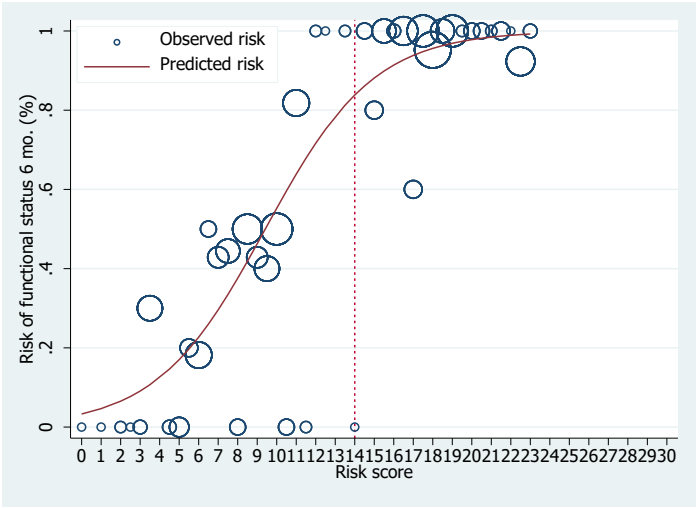

Figure 4. The Risk curve analysis: observed risk of functional status at 6 months (functional status 6 mo) (hollow circles) and predicted risk of functional status at 6 months by scores (solod line), size of circles represents relative number of patients in each score

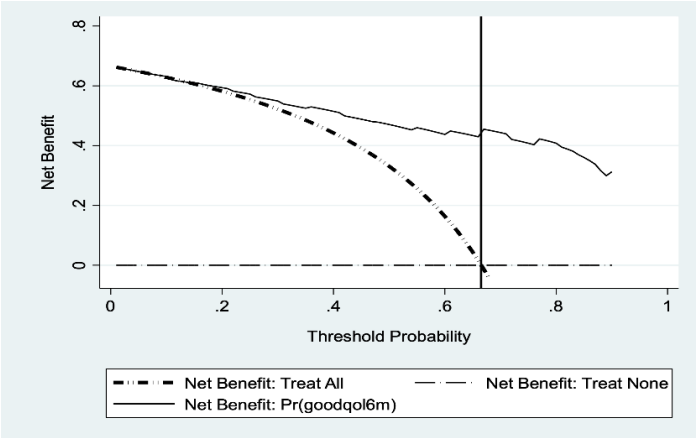

Figure 5. Decision curve analysis of the clinical score

categorized into two groups: those with a good functional status (NYHA Classification 1) and those with a poor functional status (NYHA Classification 2, 3, and 4). After dividing the patients into risk categories according to these levels, the assessment revealed good discriminative performance and good calibration for predicting functional status six months after surgery (Bumrungkittikul, J. et al.[12])The study reported independent predictors and developed an equation for the 6-MWT in post-cardiac surgery patients. The study identified that the 6-MWT at discharge, regular exercise, age, gender, and NYHA classification were the critical factors used to generate an equation to predict the 6-MWT performance at 4-6 weeks after hospital discharge. Surprisingly, existing studies have yet to illustrate the prediction of functional status using NYHA classification. The NYHA classification in the current study can be used to predict functional status in post-cardiac surgery patient cohorts.

The relevant clinical characteristics considered in this study were age, gender, pneumonia, diabetes mellitus, smoking, pre-surgery EF, LOS, NYHA classification pre-surgery, METs pre-discharge from the hospital, and duration of exercise at three different time points (at two weeks, six weeks and three months). These clinical characteristics were used in combination with the distance covered in the 6-MWT to predict the functional status. Previous research has similarly reported that age and gender are common predictors of 6-MWT distance.[3,10] The present study, however, did not assess the distance covered in the 6-MWT before discharge due to limi-

tations associated with inpatient testing locations. Furthermore, a study conducted by Paorod et al.[13] illustrated that the NYHA Classification and pre-surgery EF have a statistically significant influence on the 6-MWT distance (p = 0.003, 0.008, respectively). Duongkamon et al.[8] also found that age, gender, and heart compression values are related to the level of functional ability after CABG surgery. In that study during the second follow-up examination, statistical significance was observed (r = 0.207, r =0.203, and r = -0.201; $p < 0.05$), which is contrary to the current study, in that it did not find pre-surgery EF to be clinically associated with 6-MWT in predicting functional status. Thus, investigation into the complex interplay of pre-surgical factors and post-surgery outcomes requires further investigation.

The present study found significant differences in exercise duration at two weeks, six weeks, and three months between the groups with good and poor functional status. Similarly, a study by Paorod et al.[14] reported a significant within-group difference in the 6-MWT distance after completing a home-based cardiac rehabilitation program compared to the distance before hospital discharge and at the first follow-up (4-8 weeks). This finding suggests that the 8-12-week home-based cardiac rehabilitation program significantly increases exercise capacity in open heart surgery patients. Zanini et al.[15] reported that the 6MWT was significantly higher on day six and on day 30 post-discharge in groups that included exercise training post-surgery. The 6-MWT of the individualized exercise group was significantly higher than the basic exercise group post-surgery at day ten and day 60. The present study found significant differences in exercise duration between groups with good and poor functional status at two weeks, six weeks, and three months post-surgery. This factor can be used to predict functional status at six months. Thus, continuous exercise appears to positively influence function status at six months. Paorod et al.[14] demonstrated that patients undergoing open-heart surgery benefited from a home exercise program, as evidenced by a notable increase in the 6-MWT value from 209.0 (SD = 62.0) meters before discharge and during the first follow-up appointment (4-8 weeks; 306.0 (SD = 88.0) meters) to 337 (SD =69.0) meters at the end of the study (8-12 weeks) with a statistically significant improvement ($p < 0.05$). Hence, a home exercise program spanning 8-12 weeks can effectively enhance exercise capacity among patients undergoing open-heart surgery. Similarly, Zanini et al.[15] observed higher 6-MWT values in the individual exercise group compared to the conventional exercise group, both post-surgery and on days six and 30 after discharge, as well as on day ten and day 60. Herdy et al.[16] also highlighted the efficacy of individualized exercise, which can enhance cardiac function and expedite recovery post-surgery. These findings underscore the pivotal role of exercise, particularly home exercise, in improving functional status. Additionally, Suwanakitch et al.[17] emphasized the importance of multidisciplinary care planning for open-heart surgery patients, including pre-, peri-, and postoperative self-care education to promote good functional status. Thus, intensive exercise and frequent patient follow-ups are warranted for those with poor functional status at six months, while regular and continuous exercise should be maintained for patients with good functional status.

The strength of this study is that it is the first study exploring the use of the 6-MWT distance in combination with relevant clinical characteristics to predict functional status in post-cardiac surgery patients six months after discharge from Hatyai Hospital. Additionally, the NYHA Classification was first employed in this study, as this tool is practical and easily accessible for evaluating functional status. Statistical calculations for predicting a good functional status included Bootstrap score (AUROC 0.889, 95%CI: 0.853-0.927), Bootstrap shrinkage 0.99), calibration plot (CITL=0.000 and Slope=1.000), and decision curve analysis (the prevalence point was 0.665 and the predicted score showed a net benefit of 4.5 times). The results of this study suggest that this clinical model holds promising potential for practical clinical use, enabling the prediction of good functional status and offering valuable insights for patient evaluation, guidance, exercise planning, and treatment design for individuals recovering from post-cardiac surgery.

Limitations of this study include the absence of results from the 6-MWT distance conducted before hospital discharge. This absence was due to limitations for testing at the inpatient building due to its location. Prior studies have suggested that the ideal distance for such tests should be 30 meters.[3,18] In another study, distances ranging from 15-50 meters were considered adequate, although those studies focused on groups not exceeding 20 years of age.[19] The present study's reliance on data from a single hospital setting may restrict the generalizability of findings to broader patient populations. Future research should address these limitations by incorporating multi-center studies and comprehensive pre- and post-surgery assessments. Moreover, future research should be considered to further refine and validate the clinical prediction scores and explore additional predictors of QoL (e.g., psychosocial factors, socioeconomic status, and comorbidities) to enhance the score's predictive accuracy and clinical utility.

Conclusions

Pre-surgery EF, METs pre-discharge, LOS, duration of exercise at two weeks and six weeks, as well as the 6-MWT distance at three months, are associated with accurate prediction of functional status (NYHA Classification 1) among post-cardiac surgery patients at six months after discharge from Hatyai Hospital. This comprehensive set of clinical characteristics can be used for evaluating, providing guidance, and designing exercise and treatment plans for patients recovering from post-cardiac surgery. Importantly, the clinical characteristics identified in this study can help researchers to enhance

assessment and management during the post-surgery period, which can contribute to improving patient outcomes and overall functional status.

Author contributions

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Original Article

Reliability and Validity of a Thai Version of a Modified Frenchay Activities Index for Use with Stroke Patients

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ABSTRACT

Objectives: To evaluate the reliability and validity of the Thai version of the modified Frenchay Activities Index (mFAI) questionnaire for use with stroke patients

Study design: Descriptive study

Setting: Department of Rehabilitation Medicine and Neurology Division, Department of Medicine, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand

Subjects: Stroke patients visiting the Outpatient Department of the Rehabilitation Medicine and Neurology Division, Department of Medicine, from March 2020 to August 2020

Methods: Data were collected using a Thai version of the modified Frenchay Activities Index (Thai-mFAI). Of 75 patients, 70 met the inclusion criteria. After the initial assessment, all 70 participants were reassessed 3-7 days later to determine test-retest reliability. Validity was assessed from 59 participants by evaluating the correlation between the Stroke Impact Scale (SIS) and the Timed Up-and-Go test (TUG).

Results: The Thai-mFAI showed good content validity (CVI = 0.95), fair construct validity (convergent validity; r=0.287-0.310, discriminant validity; r=-0.259), excellent test-retest reliability (ICC3,1=0.929) and excellent internal consistency (Cronbach's alpha = 0.936).

Conclusions: The Thai-mFAI was found to have good content validity, fair construct validity, excellent test-retest reliability, and excellent internal consistency. These suggested that Thai-mFAI is suitable for evaluating how well active stroke patients can perform activities of daily living.

Keywords: Frenchay Activities Index (FAI), instrumental activities of daily living (IADL), reliability, validity, stroke

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Introduction

Cerebrovascular disease is a heterogeneous disorder. It comprises several distinct pathologies, including transient ischemic attack, different pathological types of stroke (ischemic stroke, intracerebral hemorrhage, subarachnoid hemorrhage) as well as etiological subtypes and other intracranial vascular diseases, each of which has different epidemiological and management features. Stroke is the most important and devastating clinical manifestation of all cerebrovascular disorders.[1] Cerebrovascular disease is a major global public health problem. Statistics from the World Health Organization showed that in 2016 cerebrovascular disease was the second leading cause of death in the world, and studies in Thailand have found cerebrovascular disease in 1.88% of patients aged 45-80 years.[2] Stroke was the third-leading cause of death and disability combined (as expressed by disability-adjusted life-years lost - DALYs) in the world in 2022.[3] The major impact of stroke is disability or impairment. According to the World Stroke Organization (WSO), there are more than 50 million patients with disabilities from stroke.[4]

Rehabilitation care aims to help patients regain an average or near-normal level of competence or at least the ability to carry out daily activities independently. Measuring the ability to carry out daily activities helps to know the patient's skill level. The most commonly used assessment is the Barthel Index (BI), an essential routine assessment.[5] However, rehabilitation focuses on a person's ability to return to a near-normal level. This means that a stroke patient should have regained a higher level of proficiency in real-life situations, e.g., a stroke patient should be able to perform a more advanced routine (instrumental activities of daily living or IADL) including contributing to society. Patients' ability to conduct more advanced routine activities should be assessed.[6] To that end, a patient activity assessment was developed for assessing IADL competency levels. Scales for evaluating IADL include the Nottingham extended ADL (NEADL) and the Frenchay Activity Index (FAI). FAI is a frequently used IADL scale for measuring stroke outcomes.[7] In 1983, the Frenchay Activity Index (FAI) was invented for use in assessing the daily life of stroke patients and to provide a more substantial and broad-spectrum measurement of the patient's daily routine.[8] The FAI consists of 15 activities divided into three main areas: domain 1: home activities, domain 2: work/leisure activities, and domain 3:

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outdoor activities. In 2013, the FAI was adjusted to include daily activities. In the 21st century, FAI has been modified and included increasing the activity index to 16 items, adding the ability to use a telephone and adjusting details of outdoor walking activities and travel patterns to align with today's lifestyle. We chose this questionnaire for the present study because it comprises a range of activities in real daily routine life, i.e., not only the basic activities of daily living (BADL) but also the IADL, social functions, and avocations. The mFAI also measures changes in frequency of activities compared to pre-stroke levels, self-reported causes of changes, and satisfaction with activity performance. Thus, mFAI results show the active performance level, while NEADL only evaluates activities done in specific activities. A study of the modified FAI (mFAI) in Sweden has shown that the tool provides more comprehensive information.[9]

Evaluation and monitoring of stroke patients' ability to perform independently are important in the follow-up of rehabilitation treatment. The study focused on the mFAI questionnaire which is related to the daily life routines of stroke patients. Although studies have been conducted on the FAI to determine its validity and reliability,[10] it has not yet been translated into Thai. Therefore, the researcher translated the mFAI questionnaire into Thai and calculated its reliability and validity to obtain an accurate Thai mFAI for future use in rehabilitation and research work.

Methods

The study protocol was approved by the Siriraj Institutional Review Board (SIRB) of the Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand (COA no. 545/2562 [EC1]). This study complied with all of the principles set forth in the Declaration of Helsinki and all of its subsequent amendments, and all participants provided written informed consent to participate in the study.

Participants

Outpatient stroke patients from the Department of Rehabilitation Medicine and Neurology Division, Department of Medicine, Faculty of Medicine, Siriraj Hospital, Mahidol University who met the inclusion criteria and were willing to participate were eligible for recruitment.

Inclusion criteria

- Age more than 18 years
- Onset of stroke ≥ 3 months
- Normal consciousness
- TMSE questionnaire score ≥ 24
- Able to walk independently, at least inside the house, without assistance

Exclusion criteria

- Non-Thai nationality
- Inability to read and understand the Thai language

After obtaining written informed consent, demographic and clinical data were collected and recorded.

Sample size calculation

The sample size was calculated based on a study by Imam et al.[10], who developed the Chinese version of mFAI. That study reported the test-retest reliability of the Chinese version assessed using an intraclass correlation coefficient was 0.86. Concerning about reliability, the sample size was calculated at 95% confidence interval with prehypothesized ICC 0.8 precision of 0.2. For validity assessment, based on the same study, correlations between the Chinese version and Timed Up & Go test was -0.68 (r= -0.68). Using type 1 error (0.05), 95% power Fisher's z test of the null hypothesis that the Pearson correlation coefficient r = 0.0, detect the alternative hypothesis r of 0.5. And an add-on of 10% was used to compensate for dropouts for any cause. The estimated numbers of participants for the reliability and validity tests were 65 and 55, respectively.

Translation

The modified FAI, which assesses three domains: home activities, leisure/work activities, and outdoor activities, was used. The questionnaire was translated into Thai after receiving permission from Professor Susanne Iwarsson. The translation of the questionnaires followed the recommended guidelines for the process of cross-cultural adaptation.[11] The mFAI questionnaire was translated by two English language professionals: the first was involved in the medical field, and the second was a linguistic expert from the Research Institute for Languages and Cultures of Asia, Mahidol University, who was not involved in the medical profession.

Our research team synthesized the results of those two translation questionnaires into one translation. After that synthesizing step, the Thai language questions were back-translated into English by different linguistic experts to prevent/minimize bias. That back-translated English version was then sent to another expert whose mother tongue is English for comparison with the original English language version of the mFAI.

Validity

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

Content validity

The Thai-mFAI was given to 5 experts to determine its content validity, including a neuro-rehab physiatrist, a general physiatrist, a physiotherapist, an occupational therapist, and a nurse experienced in caring for stroke patients. They were asked to rate each of the 16 questions regarding their comparability or relevance to the original version. Each question was then individually rated using a 4-point scale (1 = not relevant to 4 = highly relevant). Any item judged irrelevant by receiving a rating of 1 or 2 by more than 20% of the experts was amended. We then calculated the item content validity index (I-CVI), the percentage of the total items rated as 3 or 4, for all questions.

An I-CVI score of 0.8 or higher indicates good item content validity. Additionally, we determined the content validity for the entire questionnaire using the content validity for scale (S-CVI). Using that score, > 0.8 indicates a good S-CVI, the same as the I-CVI cut-point score.[12]

Construct validity

We evaluated the correlation between Thai-mFAI and the Stroke Impact Scale (SIS) using Spearman's correlation coefficient to assess convergent validity. Since the mFAI indicates how active the respondent was, we assumed that the Thai-mFAI would positively correlate with the SIS. The SIS, one of the stroke-specific quality of life measurements, evaluates the effects of stroke better than other tools.[13] It consists of 59 questions divided into eight parts (strength, communication, memory, emotion, social participation, the activities of daily living (ADL), mobility, hand function, and composite physical). A higher score indicates a better quality of life. The SIS was translated into Thai and showed good test-retest reliability and acceptable validity for use with stroke survivors.[13]

The Timed Up and Go (TUG) test is an objective clinical measure for assessing functional mobility balance and the risk of falling. It measures an individual's time to rise from a chair, walk 3 meters, turn, walk back, and sit down.[14] The cut-off score in stroke patients is > 14 seconds.[15] The TUG test has been revealed to be a high validity, reliable, and easy-to-administer clinical tool for assessing advanced functional mobility in people with chronic stroke.[14] Another study reported that the TUG test can reflect mobility, walking ability and ADL.[16] The lower the TUG time, the more active a person is. To determine discriminant validity, we analyzed by Spearman's correlation coefficient between the Thai-mFAI and the TUG test. We hypothesized that the Thai-mFAI would be negatively correlated with the TUG test.

Reliability

Reliability was performed using test-retest evaluation. We re-administered the Thai mFAI to 65 patients who took the Thai mFAI at least three days but not more than seven days apart. The content of both the test and retest were the same, but the questions were alternated to prevent a memory carry-over effect. Reliability was evaluated by the coefficient of stability using intraclass correlation (ICC3,1 = Two-way mixed effects model).

Statistical analysis

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

The interpretation results of CVI, construct validity, ICC3,1, and internal consistency are shown below.

Range of construct validity[17]

Size of correlation	Interpretation
0.750 to 1.000 (-0.750 to -1.000)	Very good to excellent relationship
0.501 to 0.750 (-0.501 to -0.750)	Moderate to good relationship
0.251 to 0.500 (-0.251 to -0.500)	Fair degree of relationship
0.000 to 0.250 (0.000 to -0.250)	Little or no relationship

Range of internal consistency[18] Cronbach's alpha	Internal consistency
$0.9 \leq \alpha$	Excellent
$0.8 \leq \alpha < 0.9$	Good
$0.7 \leq \alpha < 0.8$	Acceptable
$0.6 \leq \alpha < 0.7$	Questionable
$0.5 \leq \alpha < 0.6$	Poor
$\alpha < 0.5$	Unacceptable

Range of intraclass correlation coefficient[19]	Interpretation
≥ 0.90	Excellent
0.75 ≤ ICC < 0.90	Good
0.50 ≤ ICC < 0.75	Moderate
< 0.50	Poor

Results

Seventy stroke patients (42 men, 28 women; mean age 58 years (SD8.9) were enrolled between March and August 2020. Table 1 shows the participants' characteristics. After a stroke, there was a markedly increase in retirement/unemployment among the patients.

Five experts were asked to judge the content validity of the Thai m-FAI. All of them gave the highest possible score with the exception of questions number 10A, 10C, 11, 13, and 15 which one expert scored 2 out of 4. When all scores were calculated for the item content validity index (I-CVI), however, the result showed that the overall I-CVI was 0.95, a good I-CVI. Likewise, the content validity for the scale result (S-CVI) was 0.95, which also means a good S-CVI (Table 2).

Spearman's correlation coefficient between the Thai-mFAI and the SIS was used to evaluate convergent validity. This study found a statistically significant fair degree relationship between the Thai-mFAI frequency summary score and part 1 (strength), 5 (ADL/IADL), and 8 (participation and role function) of the SIS, with correlation coefficient scores of 0.287, 0.289, and 0.310, respectively ($p < 0.05$). When analyzing of each Thai-mFAI subgroup found that domain 1 had a significant fair degree relationship with the SIS in parts 1 (strength), 5 (ADL/IADL), and 8 (participation and role function), with correlation coefficient scores of 0.316, 0.266 and 0.284, respectively (p-values all < 0.05). The Thai-mFAI domain 2 had a fair positive correlation with only two parts of the SIS, parts 5 (ADL/IADL) and 8 (participation and role function). (Table 3) There was, however, no relationship between Thai-mFAI domain three and the SIS. For discriminant validity, the correlation score between the Thai-mFAI domain 1 and the TUG test was -0.259 ($p < 0.05$). This finding indicates a significant

Table 1. Characteristics of participants

Variables	Number (%)
Sex	
Male	42 (60)
Female	28 (40)
Average age (years)*	58 (8.9)
Education level	
Below high school	10 (14)
High school	15 (21)
Diploma	8 (11)
Bachelor's degree	25 (35)
Post-graduate degree	12 (17)
Marital status	
Single	10 (14)
Married	57 (81)
Divorced	3 (4)
Living at home	70 (100)
Career before stroke	
Government official and/or state enterprise employee	25 (35)
Private company employee	9 (12)
Trading and private business	20 (28)
Worker	7 (10)
Student	2 (2)
Retired, housewife or unemployed	7 (10)
Career after stroke	
Government official and/or state enterprise employee	11 (15)
Private company employee	2 (2)
Trading and private business	16 (22)
Worker	4 (5)
Student	2 (2)
Retired, housewife or unemployed	35 (50)
Co-morbidities**	
Diabetes	20 (28)
Hypertension	54 (77)
Dyslipidemia	56 (80)
Coronary artery disease	4 (5)
Previous stroke	6 (8)
Others diagnosis***	10 (14)
Type of stroke	
Ischemic stroke	61 (87)
Hemorrhagic stroke	9 (12)
Onset of stroke	
3-6 months	6 (8)
6-12 months	14 (20)
≥ 1 year	50 (71)
Hemiparesis side	
Left	36 (51)
Right	31 (44)
Bilateral	3 (4)
Underwent rehabilitation program	
Yes	39 (55)
No	31 (44)
TMSE score*	28 (1.39)
Timed up and go test (seconds)*	13.2 (9.74)

*Mean (SD), **some patients had more than one underlying disease, ***asthma, chronic kidney disease, gout, thyrotoxicosis, and breast cancer

fair negative correlation between Thai-mFAI and the TUG test. (Table 4)

Regarding the Thai-mFAI test-retest reliability, the ICC3,1 was 0.929 (95% CI, 0.881 to 0.957), which indicates excellent reliability. Cronbach's alpha of 0.936 showed excellent internal consistency.

Discussion

In this study, we translated the mFAI into Thai and assessed the validity and reliability of the Thai version. Regarding validity, the Thai mFAI showed overall good I-CVI and S-CVI, which indicates good content validity.

Regarding the convergent validity, there was a fair positive correlation (r= 0.25-0.50) (Table 3) with the SIS. The Spearman's correlation coefficient between the Thai-mFAI sum score and the SIS part 1 (strength) showed r=0.287, part 5 (ADL/IADL) showed r= 0.289, and part 8 (participation and role function) showed r=0.310. Other SIS parts (memory and thinking, emotions, communication, mobility, and hand function) compared with the Thai-mFAI had a low positive relationship. When we calculated each domain of the Thai-mFAI, domains 1 and 2 had a fair positive correlation with the SIS part 5 (ADL/IADL) (r=0.266, 0.276) and part 8 (participation and role function) (r=0.284, 0.308). In addition, domain 1 of the Thai-mFAI also had a fair relationship with the SIS part 1 (strength) (r=0.316). However, there was no correlation between Thai-mFAI domain 3 (outdoor activity) and all of the parts of the SIS. This finding may be due to a cultural tendency of Thai individuals with illnesses or medical conditions to prefer staying home.

Referring to the former study which translated the FAI into a Chinese version[10], the correlation coefficient was r= 0.610, which indicates moderate to good positive correlation compared with the Reintegration to Normal Living Index (RNLI). The same test could not be directly compared because of language-related limitations. Even though the study used a Chinese language questionnaire, the survey was conducted in Canada. We want to point out that different cultures can potentially have differences in routine lifestyle. For example, in general most people living in countries outside Asia either live independently or live in a health care unit or a nursing home. Conversely, most Asian cultures are based on extended families. In addition, most middle-class Thai families often include a housewife or a servant who does the housework. Moreover, these two tests, FAI and SIS, measure different dimensions. The FAI answers questions about the frequency/how often people do the activities, while the SIS answers questions about rating the difficulty level of the activities. Similarly, the RNLI in the Chinese version of the study evaluates the degree to which a patient has been able to return to normal life activities. These two tests, the SIS and RNLI, ask patients to estimate how capable they are in doing activities. Thus, due to the differences in the kind of answers, culture, and lifestyles could result in our validity study results being not as robust as earlier studies conducted in non-Asian countries. Another confounding factor is the COVID-19 pandemic which caused the majority of the population to stay away from usual

Table 2. Content validity of the Thai modified Frenchay Activity Index (Thai-mFAI)

Question No.	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	No. in agreement	CVI
1	√	√	√	√	√	5	1.00
2	√	√	√	√	√	5	1.00
3	√	√	√	√	√	5	1.00
4	√	√	√	√	√	5	1.00
5	√	√	√	√	√	5	1.00
6	√	√	√	√	√	5	1.00
7	√	√	√	√	√	5	1.00
8A	√	√	√	√	√	5	1.00
8B	√	√	√	√	√	5	1.00
9	√	√	√	√	√	5	1.00
10A	√	X	√	√	√	4	0.80
10B	√	√	√	√	√	5	1.00
10C	√	X	√	√	√	4	0.80
10D	√	√	√	√	√	5	1.00
10E	√	√	√	√	√	5	1.00
10F	√	√	√	√	√	5	1.00
11	√	X	√	√	√	4	0.80
12	√	√	√	√	√	5	1.00
13	√	X	√	√	√	4	0.80
14	√	√	√	√	√	5	1.00
15	√	X	√	√	√	4	0.80
16	√	√	√	√	√	5	1.00
Total	1.00	0.77	1.00	1.00	1.00		0.95

√ means scores 3-4 out of 4 points rating scale (acceptable); x means scores 1-2 out of 4 points rating scale (unacceptable)

Table 3. Convergent validity of the Thai modified Frenchay Activity Index (Thai-mFAI) compared with the Stroke Impact Scale (SIS)

Spearman's correlation coefficient (*p*-value)	Thai-mFAI sum score	Domain 1 home activities	Domain 2 work/leisure
Part 1 strength	0.287 (0.028)*	0.316 (0.015)*	0.212 (0.108)
Part 2 communication	-0.007 (0.960)	0.064 (0.631)	-0.025 (0.851)
Part 3 memory	0.049 (0.713)	0.174 (0.188)	0.021 (0.875)
Part 4 emotion	0.070 (0.597)	0.141 (0.286)	0.036 (0.789)
Part 5 ADL, IADL	0.289 (0.027)*	0.266 (0.042)*	0.276 (0.035)*
Part 6 mobility	0.135 (0.309)	0.202 (0.124)	0.124 (0.351)
Part 7 hand function	0.252 (0.054)	0.255 (0.051)	0.216 (0.100)
Part 8 social participation	0.310 (0.017)*	0.284 (0.029)*	0.308 (0.018)*

*$p < 0.05$ indicates statistical significance

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

Table 4. Discriminant validity of the Thai modified Frenchay Activity Index (Thai-mFAI) compared with Timed Up and Go (TUG)

Spearman's correlation coefficient (*p*-value)	Thai-mFAI sum score	Domain 1 home activities	Domain 2 work/leisure
TUG	-0.248 (0.058)	-0.259 (0.047)*	-0.179 (0.175)

*$p < 0.05$ indicates statistical significance

socializing and outside routine activities during the period of the study.

In discriminant validity, there was a fair negative correlation between the Thai-mFAI domain 1 and the TUG test (r= -0.259). In contrast, a previous study found a moderate to good negative correlation (r= -0.68).[10] Each Thai-mFAI activity domain consists of various activities. Some activities do not require ambulation or the ability to walk, e.g., pursuing hobbies and reading books in domains 2 and 3. In the Thai-mFAI domain 1, all activities require the ability to walk, so there was some correlation between the TUG and Thai-mFAI domain 1. Additionally, there is a possibility that the TUG test evaluation in our study group had some level of ceiling effect due to the relatively good walking ability of the majority of the study population.

The Thai-mFAI was used to study reliability and to assess IADL performance by patients recovering from a stroke. Analyis via Cronbach's alpha coefficient found that the Thai-mFAI questionnaire has excellent internal consistency (Cronbach's α = 0.936), the same as the Lin et al. study (Cronbach's α = 0.99)[20], while the Tse et al. study showed good internal consistency (Cronbach's α = 0.85).[21]

In determining the coefficient of stability using the test-retest method of analyzing the intraclass correlation coefficient (ICC3,1), we found that the Thai-mFAI has excellent test-retest reliability. The ICC3,1 in our study (0.929) was better than the ICC3,1 in the Chinese version-FAI (0.86).[10] Our better result may have been the result of differences in the retest period in the two studies, i.e., Imam et al.[10] conducted the retest 2 weeks after the first test to reduce memory bias, while our retest period was shorter. We defined the retest within 3-7 days after that. The memory carry-over effect may have influenced our findings.

The study has some limitations. First, it was conducted during the COVID-19 pandemic which might have affected outdoor activity and/or social participation. Second, this study focused mainly on the reliability and validity of the Thai-mFAI and did not collect data about depression, which might have affected the IADL of stroke patients. Future studies of IADL should include an evaluation of depression.

Conclusions

The Thai-mFAI was found to have good content validity, fair construct validity, excellent test–retest reliability, and excellent internal consistency. The Thai-mFAI can be used to evaluate how active stroke patients are in being able to do certain activities.

Disclosure

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

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FRENCHAY ACTIVITETS INDEX (FAI) ฉบับขยายความและเพิ่มเติมสเกล	ความถี่				การเปลี่ยนแปลง			สาเหตุ* ↓ / ↑	การช่วยเหลือ				ความพึงพอใจ				
	0	1	2	3	↓ *	→	↑ *	รหัส 1 -5	แบบแตะต้องตัว	แบบไม่แตะต้องตัว	เป็นทางการ	ไม่เป็นทางการ	1	2	3	4	5
1 ประกอบอาหารมื้อหลัก																	
2 ล้างจาน																	
3 ซักผ้า																	
4 งานบ้าน (เบา)																	
5 งานบ้าน (หนัก)																	
6 จับจ่ายซื้อของในละแวกบ้าน																	
7 การร่วมงานสังคม																	
8A เดินเล่นนอกบ้านมากกว่า 15 นาที																	
8B ใช้รถเข็นวีลแชร์นอกบ้านมากกว่า 15 นาที																	
9 ทำงานอดิเรก																	
10A ขับรถยนต์ รถจักรยานยนต์																	
10B เดินทางโดยรถโดยสาร รถไฟ																	
10C ใช้รถจักรยาน จักรยานไฟฟ้า																	
10D ใช้รถเข็นนั่งไฟฟ้า																	
10E โดยสารรถยนต์ส่วนตัว แท็กซี่																	
10F ใช้บริการขนส่งพิเศษ เช่นรถฉุกเฉินรพ.																	
11 เดินทางท่องเที่ยว /เดินทางโดยรถยนต์																	
12 ทำสวน																	
13 ดูแลรักษาเครื่องมือเครื่องใช้ในบ้าน/รถยนต์																	
14 อ่านหนังสือ																	
15 ทำงานที่มีรายได้																	
16 ใช้โทรศัพท์																	

ความพึงพอใจ *: 1 = ไม่พอใจมาก 2 = ไม่พอใจ 3 = เฉยๆ 4 = พอใจ 5 = พอใจมาก*

▽ สำหรับกิจกรรมที่มีความถี่เป็นศูนย์และความพึงพอใจที่ไม่เปลี่ยนแปลงจะไม่ถูกรายงาน

การเปลี่ยนแปลง: ↓ = ความถี่ต่ำลงเมื่อเปรียบเทียบกับช่วงก่อนเป็นโรคหลอดเลือดสมอง

→ = ความถี่ไม่เปลี่ยนแปลงเมื่อเปรียบเทียบกับช่วงก่อนเป็นโรคหลอดเลือดสมอง

↑ = ความถี่มากขึ้นเมื่อเปรียบเทียบกับช่วงก่อนเป็นโรคหลอดเลือดสมอง

ความถี่: ดูคู่มือแนวทางปฏิบัติ

การช่วยเหลือที่เป็นทางการ = เจ้าหน้าที่ ฯลฯ (บริการทางสังคม ฯลฯ)

การช่วยเหลือที่เป็นไม่ทางการ = คู่สมรส ญาติ เพื่อน เพื่อนบ้าน

สาเหตุของการเปลี่ยนแปลง: 1,2,3,4,5 ดู ลิสต์รหัส

Short Communication

Comparison of the Sit-to-Stand Test with the 6-Minute Walk Test in Post-Coronary Artery Bypass Graft Patients

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ABSTRACT

Objectives: To compare the sit-to-stand test and the 6-minute walk test in cardiac rehabilitation patients who had undergone coronary artery bypass graft (CABG) surgery

Study design: Cross-sectional study

Setting: Department of Physical Medicine and Rehabilitation, Phramongkutklao Hospital, Ratchathewi District, Bangkok

Subjects: Thai adults aged between 20 and 79 years who had undergone CABG and came to the hospital to receive cardiac rehabilitation as an outpatient

Methods: Participants started with the 6-minute walk test. After adequate rest, the participants then performed the sit-to-stand test. The 6-minute walk distance and sit-to-stand test results were recorded, along with blood pressure, heart rate and the rating of the perceived exertion scale before and after the tests.

Results: There were a total of 43 participants. The correlation coefficient (r) between the 6-minute walk test and the sit-to-stand test was 0.58 ($p < 0.001$), indicating a moderately significant correlation. The exercise intensities from both the sit-to-stand and 6-minute walk tests were light were considered safe.

Conclusions: A moderately significant correlation was demonstrated between the sit-to-stand test and the 6-minute walk test in post-CABG patients. The intensity of both tests was light and safe. The sit-to-stand test should be considered an alternative submaximal exercise test in outpatient cardiac rehabilitation services.

Keywords: sit-to-stand test (STST), 6-minute walk test (6MWT), coronary artery bypass graft (CABG), cardiac rehabilitation

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Introduction

Cardiac rehabilitation is an integrated rehabilitation program for patients with cardiovascular problems that provides recommendations for safe exercise programs and lifestyle modification. The primary purpose of a cardiac rehabilitation program is to increase the functional capacity of individual patients in order to allow them to return to their vocation, improve their quality of life, and reduce the recurrence of events, morbidity, and mortality.[1] The American College of Cardiology (ACC) and the European Society of Cardiology (ESC) both recommended that all cardiovascular patients participate in a cardiac rehabilitation program (class I recommendation).[2,3] Exercise training is an essential part of the program and is begun during the first phase of cardiac rehabilitation. It is further recommended that all patients complete an exercise test before starting the exercise program.[4] Both the cardiopulmonary exercise test (CPET) and the electrocardiogram exercise stress test (EST) provide comprehensive information. However, those methods require expensive equipment and an experienced technician. As a result, they are not widely applied.

A walk test is an indicator for assessing the efficiency and effectiveness of overall treatment and a patient's hospital discharge readiness.[5] The 6-minute walk test (6MWT) is a submaximal functional test which is widely used in cardiac rehabilitation clinics because it is easy to conduct, requires less time, and produces results that are associated with basic activities in daily life.[5,6] However, 6MWT results can be affected by a variety of factors unrelated to cardiopulmonary status, including age, sex, height, and weight.[7,8] The sit-to-stand test (STST), which counts how many times a participant can stand up from and sit down on a chair in one minute, is used to measure lower body muscular strength and endurance and has been accepted as an indicator for functional testing.[9] The STST has been found to be moderately correlated with the 6MWT in healthy young adults.[10] It has been used with patients with a chronic obstructive pulmonary disease (COPD) and has shown a good correlation with the 6MWT.[11,12] The STST is less hemodynamically stressful, so it can be used to estimate exercise capacity in patients who have low functional capacity or gait impairment.[13-15] Furthermore, the test can be performed in a limited space and in a short period of time. This study aims to evaluate the relationship between the STST and 6MWT among post-coronary artery bypass graft (CABG) patients in a cardiac rehabilitation clinic.

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Methods

Study design and participants

The present cross-sectional study was conducted between January and November 2022. The eligibility criteria were Thai adults age between 20 and 79 who had undergone CABG and had come to the hospital receive cardiac rehabilitation as an outpatient. All participants were given an explanation of the study's procedure and provided written informed consent prior to participating in the study. Participants who had contraindications for the 6MWT and submaximal exercise testing according to the American Thoracic Society (ATS) guidelines were excluded.

Ethical considerations

Ethical approval for this study was obtained from the Institutional Review Board, Royal Thai Army Medical Department (IRB number: R084h/64), and all the subjects provided informed consent for their participation.

6-Minute walk test

The participants were instructed to walk as far as possible in six minutes, going back and forth along a straight line 15-meter route. Before the actual test, the participants practiced walking the route one time to reduce the learning effect. If they became exhausted, participants were allowed to stop or reduce their walking speed without stopping the counting of the time. The examiner announced the time remaining every minute following the ATS guidelines. The distance covered during the test was recorded in meters.

Sit-to-stand test

The sit-to-stand test (STST) used a 46-cm high chair with no armrests which was placed against a wall to prevent movement of the chair. The participants sat upright on the chair with both hands at their waist. Their feet were flat on the floor, spaced at the same width as their shoulders. Before the test began, the participants were instructed to do two practice repetitions. During the test they stood up and sat on the chair as many times as possible in one minute, moving at a speed they felt safe. If they became too exhausted, participants could stop, although the counting down of the time continued. The examiner announced when 15 seconds was left, and when the examiner said, "Time is up," the participants had to stop. Only the repetitions in which participants were able to stand upright without support were counted. The participants did not practice before this test because no learning effects have been found and the practice could cause lower limb fatigue.[15]

Physiological responses to the tests

The patients' heart rate, oxygen saturation, blood pressure, any abnormal signs or symptoms, and the modified Borg Rating of Perceived Exertion Scale (CR10 RPE scale) results before and after the test were recorded. Exercise intensity was calculated using the Karvonen method, with the estimated maximum age-related heart rate calculated using Tanaka's formula (208 - 0.7 × age). All participants performed the 6MWT first, followed by the STST. There was a rest period between the two tests and all parameters were allowed to return to baseline values before the next test was started.

Statistical analysis

The calculated sample size was 43, assuming alpha (α) 0.05, (β) 0.10, and a correlation coefficient of 6MWT with STST in COPD patients of 0.75.[11] The baseline and clinical characteristics of the patients were recorded as mean and standard deviation (SD) for continuous data, and as frequency and percentage for categorical data. The 6MWT and the STST correlation was evaluated using Pearson's correlation coefficient.

Results

Of the 43 participants who had undergone CABG within the previous six months, the majority were male (90.7%) with a mean age of 62.8 (8.5) years and a range of 45-78 years. The mean left ventricular ejection fraction (LVEF) was 56.2% and the mean body mass index was 23.2 (2.2) kg/m^2. Of the participants, 69.8% were categorized in the minimal risk group for cardiac rehabilitation, and 86.5% had triple vessel disease, as shown in Table 1. Physiological responses, including peak heart rate, oxygen saturation, blood pressure, and the modified Rating of Perceived Exertion Scale, are shown in Table 2. The mean 6MWT and STST exercise intensities were 33.9 (14.7) and 26.9 (11.3), respectively, indicating the light intensity of both tests. The scatter plot between the 6MWT and the STST is displayed in Figure 1. A moderate positive correlation between the 6MWT and STST was found (r=0.58, *p*

Table 1. Demographic data and clinical characteristics of the participants (n = 43)

Variables	
Age (years)[1]	62.8 (8.5)
Body mass index (kg/m^2)[1]	23.2 (2.2)
Left ventricular ejection fraction (%)[1]	56.2 (15.6)
Male[2]	39 (90.7)
Risk[2] (AACVPR stratification)	
Minimal	30 (69.8)
Moderate	8 (18.6)
High	5 (11.6)
Type of coronary diseases[2]	
Single vessel	3 (7.0)
Double vessel	3 (7.0)
Triple vessel	37 (86.0)
6-minute walk test (m)[1]	404.6 (76.5)
Sit-to-stand test (repetitions)[3]	22 (19-25)

[1]Mean (SD), [2]Number (%), [3]median (IQR)
AACVPR, American Association of Cardiovascular and Pulmonary Rehabilitation

Table 2. Physiological parameters of the tests

Parameters	6MWT	STST
Peak heart rate	102.7 (15.3)	98.3 (14.2)
Oxygen saturation (%)	97.5 (1.1)	97.6 (0.9)
RPE	2.2 (1.2)	2.1 (1.0)
Systolic blood pressure (mmHg)	158.5 (24.3)	148.9 (19.4)
Diastolic blood pressure (mmHg)	84.0 (13.8)	81.3 (14.7)
Intensity	33.9 (14.7)	26.9 (11.3)

Values are presented as mean (SD),
6MWT, 6-minute walk test; STST, sit-to-stand test, RPE, rating of perceived exertion

< 0.001). Importantly, no adverse events related to either of the two tests were found in this study.

Discussion

The primary aim of the present study is to evaluate the relationship between the 6MWT and the STST among post-CABG patients who received treatment in an outpatient cardiac rehabilitation program. The results indicate that the STST has a moderate positive correlation with the 6MWT (r=0.58), which in concordance with previous studies.[12,14] However, some studies conducted in an COPD population by Ozalevli et al. and Reychler et al. have reported a higher correlation (r=0.75 and 0.71, respectively) than the present study.[11,15] A possible explanation for this difference is that all participants in the present study performed the 6MWT before the STST, so some participants may have felt tired after the long walk and completed the STST at a slower speed than they otherwise could.[11,15] Regarding cardiorespiratory parameters during the STST and 6MWT (Table 2), there were no significant differences in peak heart rate, oxygen saturation, RPE, blood pressure, or level of intensity between two tests in the post-CABG patients. This differs from previous studies by Meriem et al. and Reychler et al.[14,15], which reported variations in heart rate and pulsed oxygen saturation were significantly different between the two tests and that the STST was found to be less hemodynamically stressful than the 6MWT in COPD patients.

The most critical significant potential barrier to using 6MWT is that it requires more space and takes more time than the 6MWT, which is only commonly available requiring physical and staff resources which may be limited in some clinical settings. The present study found that the STST required less time and space than the 6MWT, so the STST could be considered a more suitable alternative functional test in some clinical settings. Based on the linear regression model, the estimated distance covered during the 6MWT can be calculated using the formula D = 7.71[STST] + 1.75[LVEF] + 136.3, where D is the estimated walking distance. STST is the number of Sit-To-Stand repetitions, and LVEF is the left ventricular ejection fraction. In the present study, the correlation coefficient (r) between the estimated 6MWT distance and the actual distance was 0.68 (Figure 2).

Several limitations of this study should be considered. All participants performed the 6MWT first, followed by the STST which may have caused the results from STST to be lower than they would otherwise have been. The 6MWT in this study was performed along a 15-meter-long corridor, which is shorter than the standard distance of 30 meters, so participants had to reverse direction twice as often. Additionally, participants in this study were post-CABG patients in an outpatient cardiac rehabilitation program, so the results cannot be directly applied to other patient groups. Additionally, almost all participants were male (90.7%), so the results might not be generalizable to females. Finally, the sample size was relatively small.

Conclusions

The STST demonstrated a moderately significant correlation with the 6MWT in post-CABG patients. The test is of light intensity and is regarded as safe. Thus, it should be considered an alternative submaximal exercise test in outpatient cardiac rehabilitation services.

Acknowledgments

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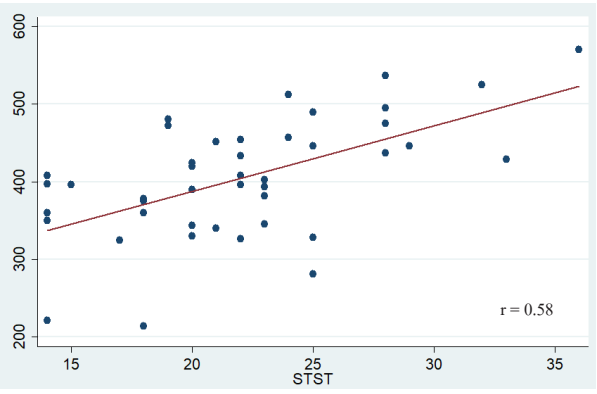

Figure 1. Scatter plot between 6-minute walk test (Y axis) and sit-to-stand test (X-axis)

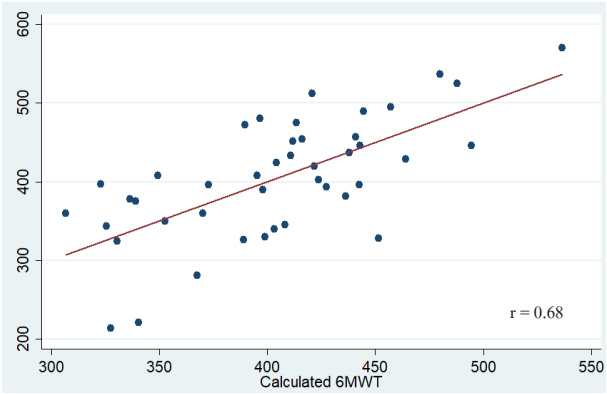

Figure 2. Scatter plot between 6-minute walk test (6MWT) (Y axis) and calculated 6MWT (X-axis)

Conflicts of interest

The authors report no conflicts of interest.

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