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Content

Treatment of Shoulder Pain

Shoulder pain, either sub-acute or chronic, is a common presenting symptom that brings patients to visit a rehabilitation physician or physiatrist. Some have been diagnosed with supraspinatus tendinitis, whereas others with frozen shoulder or adhesive capsulitis. In practice, supraspinatus tendinitis is common among middle-aged and elderly persons, whereas the frozen shoulder is commonly seen in patients with stroke.

Physical modalities have been the mainstay of treatment for shoulder pain. In the past, physiatrists or rehabilitation physicians prescribed ultrasound therapy and shortwave diathermy and ponophoresis. Nowadays, newer physical modalities, e.g., laser therapy and shock wave therapy are the more popular choices. Shock wave therapy in particular is frequently used by physiatrists and physical therapists for treatment of various musculoskeletal disorders, e.g., lateral epicondylitis, plantar fasciitis, calcific tendinitis of the shoulder. Physiologically, shock wave therapy enhances neovascularity, promotes tissue regeneration and inhibits inflammation. However, these modalities will not be effective if they are used in isolation. Physical modalities need to be combined with active exercise programs to optimize the pain reduction, increase in range of motion and maximize gain of upper extremity functions.

When physical modalities fail to provide symptomatic relief and resolution of soft tissue lesions, a more invasive treatment can be considered. Some physiatrists choose treatments such as intra-articular steroid injection, ultrasound-guided capsular hydrodilation with normal saline or glucose solution. As physiatrists are trained in performing chemo-neurolysis, e.g., motor-point block, to reduce spasticity, it is common for them to perform peripheral nerve block.

In this issue, there are three interesting original articles using different modalities and treatments for shoulder pain of various causes. One article demonstrated that phonophoresis with diclofenac gel provided better pain reduction compared to ultrasound therapy alone in participants with trapezius myofascial pain. Another article is a randomized controlled trial for treating non-calcific adhesive capsulitis. The study shows that adding focus shock wave therapy to home exercise was no better than home exercise alone. The third article shows that neither a supra-scapular nerve block or an intra-articular steroid injection was superior in reducing hemiplegic shoulder pain. These articles can provide readers with some insight on which modalities and invasive procedures to consider when treating shoulder pain.

Apichana Kovindha, MD, FRCPhysiatrT
Editor-in-chief

Original Article

Focused Extracorporeal Shockwave Therapy in Non-Calcific, Adhesive Capsulitis: A Randomized Double-Blind Controlled Trial

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ABSTRACT

Objectives: To study the efficacy of focused extracorporeal shockwave therapy (f-ESWT) combined with an exercise program to reduce pain, improve function, and increase range of motion (ROM) in patients with non-calcific, adhesive capsulitis (NCAC) of the shoulder.

Study design: A randomized double-blind controlled trial.

Setting: An out-patient rehabilitation clinic.

Subjects: Patients with a confirmed diagnosis of NCAC

Methods: Patients were randomly allocated to either f-ESWT (experimental) or sham (control) groups. The f-ESWT group (n = 14) received f-ESWT whereas the sham group (n = 12) received a sham ESWT once a week for 6 weeks. A weekly individualized supervised home-based exercise program was provided to participants in both groups. The numeric rating scale of pain (score 0-10), the Shoulder Pain and Disability Index (SPADI) questionnaire and shoulder ROM were evaluated prior to and at 2, 4, 6, and 10 weeks after the initial treatment.

Results: The numerical rating scale of pain, the functioning SPADI score, and shoulder ROM were significantly improved in both groups. Improvement was significantly apparent at the 2nd and the 4th week after treatment and continued through the 10th week of follow-up. However, there was no significant difference in any of the measured outcomes between the two groups.

Conclusions: In treating non-calcific adhesive capsulitis shoulder, f-ESWT plus exercise is not superior to a home exercise program alone in reducing pain, improving function, and increasing ROM.

Keywords*:* extracorporeal shockwave therapy, bursitis, adhesive capsulitis, pain, exercise therapy

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Introduction

Adhesive capsulitis (AC) or frozen shoulder is a common problem characterized by pain and stiffness in the shoulder joint which causes limitation of activities in daily living. The exact cause is not clearly understood, especially in idiopathic AC, but is generally considered to be a result of scarring, thickening, and shrinkage of the joint capsule. Although AC is a self-limiting condition in which the symptoms gradually resolve over a period of 1-3 years, the estimated substantial burden, both to patients and to society, suggests that effective early treatment of AC is warranted in order to attempt to accelerate recovery and to prevent complications.[1] Treatment is focused on symptomatic relief of pain and improvement in shoulder range of motion (ROM). There has been no consensus regarding the scientific evidence for the efficacy of any single treatment for AC, although there is a general agreement that non-operative management is the initial treatment of choice for AC. Physical therapy programs, including various modalities and exercises, are considered to be able to relieve pain and restore shoulder motion.[2,3]

Extracorporeal shockwave therapy (ESWT) is a widely known emerging modality which has become a leading choice in the treatment of various orthopedic disorders, including plantar fasciitis,[4] lateral epicondylitis,[5] and calcific tendinitis of the shoulder.[6] However, its clinical efficacy in treating non-calcific tendinopathy of the shoulder remains controversial.[7] The shock waves in ESWT are characterized by high peak-pressure amplitudes (500 bar) with rise times of less than 10 ns, a short lifecycle (< 10 ms), and a frequency spectrum ranging from 16 Hz to 20 MHz.[8] There are several available shock wave generators, including piezoelectric systems that are characterized by piezoelectric crystals mounted to a spherical surface producing a focused pressure pulse which is created by the geometrical shape of the sphere.[9] Although the mechanisms by which the shock wave induces a biological effect is not fully understood, it is hypothesized that the mechanotransduction is a response to mechanical stimulation converting physical forces into biochemical signals which stimulate extracellular matrix binding proteins and nucleus via the cell cytoskeleton, leading to tissue regeneration. Effects include enhanced neovascularity, accelerated growth factor release, selective neural inhibition, and inhibition of molecules that have a role in inflammation.[10,11]

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These findings suggest that ESWT could potentially have a positive effect on the healing of chronic tendinosis which is characterized by hypovascularity.

In the treatment of shoulder pathology, ESWT has been demonstrated to be effective in pain reduction and providing functional improvement of calcific tendinitis.[12,13] However, recent evidence has provided inconsistent results for ESWT in the treatment of non-calcific AC (NCAC) of the shoulder.[14-16] Currently, there is no consensus as to which treatment is the most effective for AC, although according to recommendations of the Philadelphia Panel, therapeutic exercise seems to be an acceptable intervention.[17] A systematic review of 39 studies found that a combination of therapeutic exercises and mobilization therapy were strongly recommended for reducing pain and improving ROM and function in patients with AC stages 2 and 3.[18]

There is still controversy regarding the efficacy of combined exercise and f-ESWT in the treatment of shoulder pathology,[19,20] and there have been no studies of NCAC. This study aimed to investigate the efficacy of f-ESWT combined with home-based exercise in the treatment of NCAC and to compare that to a home-based exercise program alone.

Methods

Study design

This study, a randomized double blinded (patient and assessor) controlled trial, was approved by the institute's ethical committee and was registered with the clinical trial registry [Registry number TCTR20160810002]. It was conducted from July 2016 to August 2017 in an outpatient rehabilitation setting. All enrolled subjects provided written informed consent prior to participation.

Participants

Patients who met the following criteria were recruited: (i) diagnosis of unilateral AC without calcification as determined by physical examination, ultrasonography, and/or magnetic resonance imaging; (ii) age over 18 years, (iii) shoulder pain with a numeric rating of at least 4 (from a maximum score of 10); (iv) restricted shoulder ROM in at least two directions, including external rotation; (v) no alternative therapy, including injection and ESWT, within a month prior to enrollment in the study. Patients were excluded if they had a massive rotator cuff tear, calcific tendinopathy, or a history of trauma, tumors, surgery, uncontrolled systemic diseases or neuromuscular disorder.

Sample size was determined using the pre- and post-treatment Shoulder Pain and Disability Index (SPADI) score from Vadathpur et al.,[21] with an assumed study power of 90% ($\beta = 0.10$) and a statistical significance level of 5% ($\alpha = 0.05$). The calculated required sample size was 13 patients per group.

Randomization and blinding

Randomization was done by computer, with patients assigned to receive either actual f-ESWT (experimental group) or sham ESWT (control group) at a 1:1 ratio. All assignments were concealed in sequentially numbered, opaque sealed envelopes. The patients and the assessor (one of the investigators) were blinded to the treatment allocation.

Interventions

The piezoelectric shockwave device (Swiss Piezoclast, EMS Electro Medical System S.A., Nyon, Switzerland) was used for f-ESWT. Patients were treated in a sitting position with the affected shoulder in internal rotation. They received f-ESWT with a total of 1,500 pulses of 0.1-0.3 mJ/mm^2 (adjusted to the individual patient's tolerance) at a frequency of 8 Hz.[22] The gel pad applicator penetration depth was either 15 mm or 20 mm depending on the patient's body mass index (BMI) (15 mm for BMI < 25, and 20 mm for BMI > 25). The f-ESWT probes were placed at three sites around the shoulder joint as follows: (i) anterior, one finger breath lateral to the coracoid process; (ii) lateral, one finger breath below the acromion tip; and (iii) posterior, under the lateral border of the scapular spine. A total of 500 pulses were given at each area, for a total of 1,500 pulses per session. Patients received this treatment once a week for over a six-week period (six sessions).

Patients in the control group received sham ESWT treatment using an identical-appearing probe. The patient was shielded from the shock wave by a polyethylene foil sheet placed between the silicone pad and the shockwave probe. The probe emitted the same sounds as the ESWT probe. All other procedures in the sham (control) group were the same as in the experimental group.

Exercise programs (Figure 1)

Patients in both groups were instructed in a home-based exercise program by a physical therapist who was blinded to group allocation. The therapist advised each patient individually and scheduled a weekly follow-up appointment (a total of six times) during which the therapist prescribed/demonstrated the exercises step-by-step according to individual patient's symptoms. The program included five stretching exercises (pendulum stretch, towel stretch, finger walk, cross-body reach and armpit stretch) and two strengthening exercises (outward rotation and inward rotation) (Figure 1).

The patients also received a leaflet with pictures of the seven exercises and were advised to repeat all seven exercises 5-10 times daily at home and to record the exercises in an exercise diary.

They were provided acetaminophen and were told they were allowed to take 1-2 tablets 500 mg/tablets every 8 h for a maximum of 6 tablets/day, and were instructed to record their tablet intake. No other drug or pain therapy was allowed during the study.

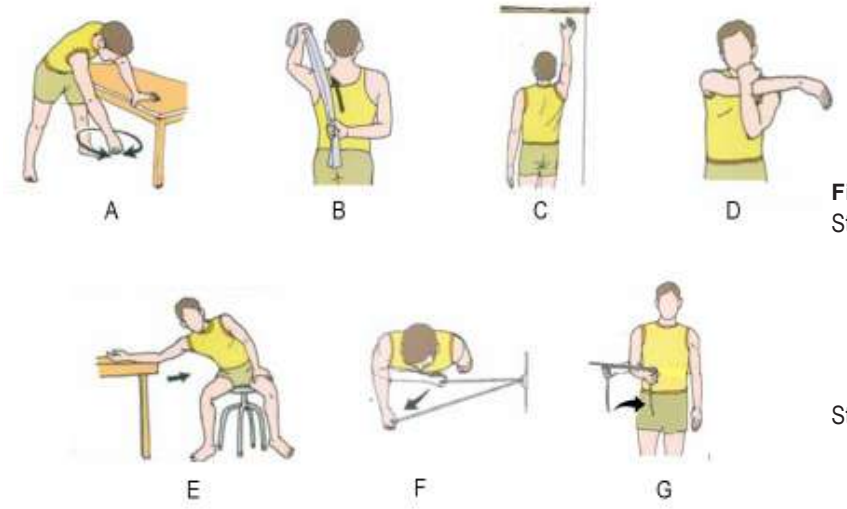

Figure 1. Exercise program activities.
Stretching:
A) pendulum stretch,
B) towel stretch,
C) finger walk,
D) cross-body reach,
E) armpit stretch;
Strengthening:
F) outward rotation,
G) inward rotation

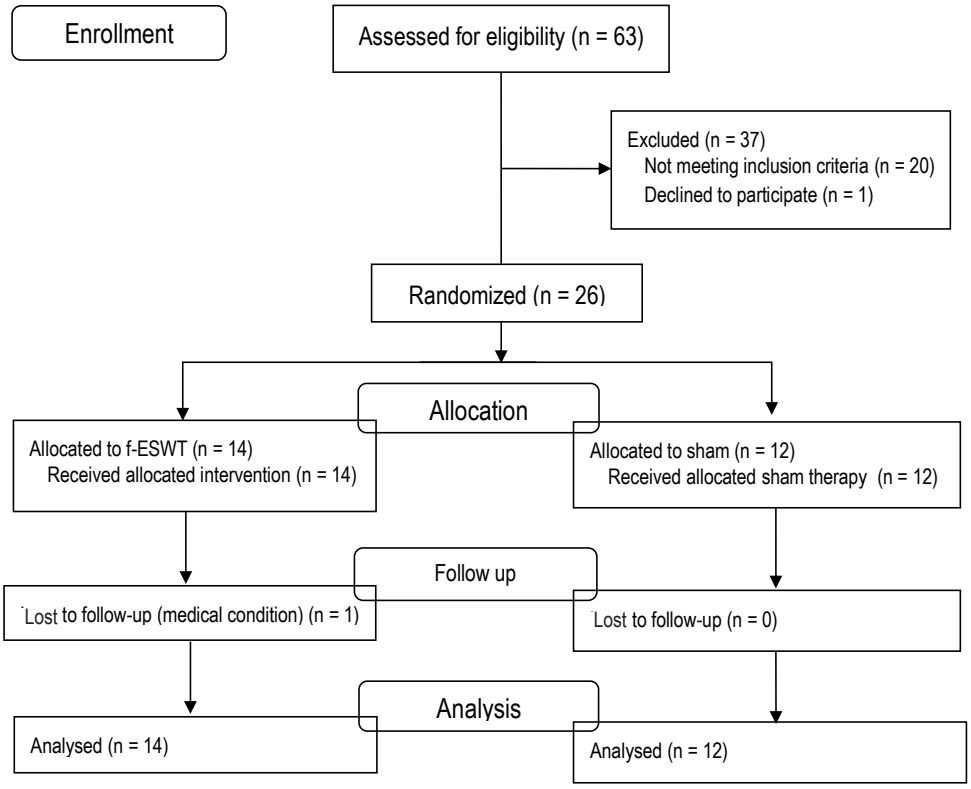

Figure 2. Consort diagram showing participants' progress through the phases of the study

Outcome measurements

A well-trained physical therapist who was blinded to the patients' treatment group was assigned to measure and document outcomes at baseline, and at 2, 4, 6, and 10 weeks after the first treatment as follows:

1. Shoulder Pain and Disability Index (SPADI):[23] a self-administered questionnaire that contained a total of 13 items in two subscales, pain and functional activities. The pain subscale consisted of five items related to the severity of the individual's pain. Functional activities were assessed with eight items designed to measure the degree of difficulty an individual has with various activities of daily living that require upper-limb use. Each of the 13 items was scored on a numeric rating scale (NRS) of 0-10 where 0 = no pain and 10 = the worst pain imaginable. The scores from each of the subscales were combined to give a maximum score of 50 for each subscale and a total score of 100 for the two subscales together.

The SPADI questionnaire had previously been demonstrated to have good internal consistency, test-retest reliability, and criterion and construct validity. It also appeared to be able to detect changes in the patient's status over time.[23]

2. Range of motion (ROM): the involved shoulder was measured using a goniometer for flexion, abduction, and extension plus internal and external rotation.

Statistical methods

The data were analyzed using the Statistical Package for the Social Sciences version 22.0 (SPSS Inc., Chicago, Illinois). Demographic data are shown as mean and standard

Table 1. Baseline demographics and clinical characteristics of the patients in this study

	f-ESWT group (n = 14)	Sham (n = 12)	*p*-value
Age (years)[1]	59.9 (8.9)	55.9 (7.3)	0.532[a]
Female gender[2]	10 (71.4)	9 (75.0)	0.555[b]
BMI (kg/m^2)[1]	22.8 (3.7)	22.9 (3.3)	0.955[a]
Duration of symptoms (months)[1]	6.4 (4.3)	6.2 (3.5)	0.869[a]
Affected side, right [2]	6 (42.9)	4 (33.3)	0.635[b]
Dominant side, right[2]	13 (92.9)	11 (91.7)	0.829[b]
NRS pain[1]	6.4 (1.8)	6.7 (1.3)	0.710[a]
SPADI:			
SPADI-pain[1]	23.1 (10.1)	22.1 (6.9)	0.777[a]
SPADI-disability[1]	38.0 (15.9)	31.3 (11.7)	0.236[a]
SPADI-total[1]	61.1 (24.6)	53.3 (17.2)	0.370[a]
Range of motion:			
Flexion[1]	120.2 (23.8)	126.2 (21.1)	0.457[a]
Abduction[1]	100.0 (24.6)	105.4 (27.6)	0.863[a]
External rotation[1]	34.4 (12.9)	33.7 (17.9)	0.911[a]
Internal rotation[1]	38.5 (21.8)	35.9 (24.7)	0.780[a]

[1]Mean (SD), [2]number (%); [a]Unpaired T test, [b]Chi-square test
BMI, body mass idex; NRS, Numeric rating scale; SAPDI, Shoulder Pain and Disability Index

deviation (SD) or percentage. For comparison of the baseline characteristics between the two groups, the unpaired t-test or chi-square test was performed as appropriate. For intra-group comparisons between pre-treatment and at 2, 4, 6, and 10 weeks after the first treatment, repeated ANOVA was performed, while two-way ANOVA was performed for inter-group comparisons. Analyses were conducted according to the intention-to-treat principle. Statistical significance was accepted at the $p < 0.05$ level.

Results

A total of 63 patients were assessed for eligibility of whom 26 were recruited into the study. Fourteen patients were randomly allocated to the f-ESWT group and 12 to the sham (control) group. Figure 2 shows a schematic flow chart of the participants, reasons for exclusion and follow-up throughout the study. The patients' mean age was 58.04 years and the mean symptom duration prior to the study was 6.31 months. Seventy-three percent of the subjects were women.

The baseline demographic and clinical characteristics of patients in the f-ESWT and the sham (control) groups were compared as shown in Table 1. No significant differences were observed between the two groups. One subject in the f-ESWT group was lost to follow-up due to a subsequent medical condition.

In both groups, there was significant improvement in the NRS and SPADI scores and in ROM between pre- and post-treatment. The f-ESWT group showed early improvement in the SPADI disability subscale and the flexion ROM at 2 weeks after the 1st treatment, but there was no significant difference in the mean change between the two groups (Table 2). Two patients in the sham (control) group reported taking acetaminophen tablets, but none in the f-ESWT group did so. The average energy flux density used in the f-ESWT group was 0.16 ± 0.07 mJ/mm^2. No complications were found in either group.

Discussion

This randomized controlled trial investigated the efficacy of f-ESWT in the treatment of NCAC. It was found that the f-ESWT group showed early improvement, but that there was no significant difference in clinical outcomes between the experimental and the control groups, i.e., there was no evidence that f-ESWT plus home-based exercise had a more beneficial effect than home-based exercise alone in patients with NCAC.

The results of our study are concordant with previous studies of ESWT in other non-calcific shoulder pathologies,[24,25] although, in contrast to the present study, none of those studies used f-ESWT. A recent systematic review by Surace et al.[26] concluded that there were very few clinically important benefits of ESWT for rotator cuff disease either with or without calcification based on currently available low- to moderate-certainty evidence due to the diversity of treatment protocols used. A standard treatment protocol has yet to be determined.

A few studies have investigated the efficacy of ESWT in the treatment of AC,[21,22,27] but more evidence is needed to draw conclusions regarding its effectiveness.[7] To the best of our knowledge, this study is the first to incorporate f-ESWT as the only intervention along with a supervised home-based exercise program in the treatment of NCAC in a comparison with a sham f-ESWT plus supervised home-based exercise. A 2014 study examined 40 patients with primary AC randomized between f-ESWT and oral steroid treatment, but with no sham group.[22] In that study, both groups showed improvement in short-term functional outcomes, but the group receiving f-ESWT showed faster and greater improvement.

Table 2. Comparison of outcome data of numeric rating scale (NRS), shoulder pain and disability index (SPADI) score and range of motions (ROMs) at 2, 4, 6, and 10 weeks after the first treatment between the f-ESWT and the sham groups

Outcomes	f-ESWT (n = 14)		Sham (n = 12)		Mean difference between group (95% CI)	Time* group effect	
	Mean (SD)	Mean difference from baseline (95% CI)	Mean (SD)	Mean difference from baseline (95% CI)		F	*p*-value
NRS						0.184	0.946
2 week	5.7 (0.5)	-0.6 (0.7,-2.1)	5.5 (0.4)	1.2 (0.4,-2.7)	0.3 (-1.2,1.8)		
4 week	4.1 (0.6)	-2.5 (-0.4,-4.5)*	3.8 (0.3)	-2.8 (-1.5,-4.1)*	0.3 (-1.2,1.8)		
6 week	2.4 (0.5)	-4.3 (-3.3,-6.2)*	2.7 (0.5)	-3.9 (-2.0,-5.7)*	0.3 (-1.9,1.2)		
10 week	2.2 (0.4)	-4.5 (-2.5,-6.5)*	2.0 (0.3)	-4.7 (-3.4,-5.9)*	0.2 (-1.0,1.5)		
SPADI-total						0.288	0.885
2 week	52.5 (6.7)	-9.2 (-.01,-18.2)*	46.08 (5.17)	-7.3 (1.5,-16.0)	6.5 (-11.4,24.4)		
4 week	32.7 (5.6)	-30.5 (-14.0,-47.0)*	33.42 (4.64)	-19.9 (-9.5,-30.3)*	0.7 (-16.1,14.7)		
6 week	21.0 (5.1)	-43.1 (-24.5,-61.6)*	22.00 (3.05)	-31.3 (-12.6,-50.1)*	0.9 (.13.8,12.0)		
10 week	17.5 (5.1)	-46.7 (-23.5,-70.2)*	15.25 (2.43)	-38.1 (-23.1,-53.0)*	2.3 (-10.1,14.7)		
SPADI-pain						0.210	0.932
2 week	19.1 (2.8)	-3.6 (-1.9,-9.1)	18.25 (2.24)	-3.8 (1.0,-8.6)	1.6 (-6.13,9.09)		
4 week	11.7 (2.3)	-12.2 (-2.4,-22.1)*	12.42 (1.92)	-9.7 (-4.9,-14.3)*	0.7 (-7.12,5.72)		
6 week	7.0 (1.8)	-17.2 (-8.1,-26.4)*	9.08 (1.96)	-13.0 (-5.4,-20.5)*	2.0 (-7.53,3.50)		
10 week	5.8 (1.8)	-18.5 (-8.9,-28.2)*	5.25 (1.23)	-16.8 (-11.6,-22.1)*	0.6 (-4.08,5.29)		
SPADI-disability						0.351	0.843
2 week	32.8 (4.1)	-5.5 (-1.1,-9.9)*	27.83 (3.21)	-3.4 (1.5,-8.4)	5.0 (-6.0,16.1)		
4 week	21.0 (3.5)	-18.3 (-9.1,-27.5)*	21.00 (3.09)	-10.2 (-3.4,-17.1)*	0.0 (-9.9,9.9)		
6 week	14.0 (3.4)	-25.8 (-14.0,-37.7)*	12.92 (1.68)	-48.3 (-6.5,-30.1)*	1.0 (-7.3,9.5)		
10 week	11.7 (3.4)	-28.3 (-13.4,-43.2)*	10.00 (1.50)	-21.2 (-9.9,32.5)*	1.7 (-6.5,9.9)		
ROM-flexion						0.443	0.777
2 week	138.6 (4.8)	19.8 (1.9, 37.8)*	133.0 (6.4)	6.9 (-0.5, 14.3)	5.5 (-10.8,21.9)		
4 week	149.0 (4.4)	31.0 (11.5, 50.5)*	142.9 (6.6)	16.7 (6.5, 27.0)*	6.1 (-9.9,22.1)		
6 week	158.8 (4.3)	34.1 (14.7, 53.5)*	151.9 (6.9)	25.7 (11.7, 39.7)*	0.1 (-16.5,16.3)		
10 week	153.8 (4.7)	36.2 (14.3, 58.1)*	157.5 (6.4)	31.3 (14.6, 48.1)*	3.6 (-19.7,12.5)		
ROM-abduction						0.219	0.927
2 week	115.1 (5.6)	12.0 (-0.5, 24.7)	111.7 (7.8)	6.3 (-1.4,14.1)	3.3 (-16.2,22.8)		
4 week	126.2 (5.9)	24.1 (8.7, 39.6)*	121.8 (7.3)	16.4 (3.0, 29.8)*	4.4 (-14.8,23.7)		
6 week	135.6 (6.9)	34.2 (16.3, 52.2)**	137.7 (7.4)	32.3 (5.4, 59.3)*	2.1 (.23.1,18.9)		
10 week	139.7 (7.9)	36.2 (11.6, 65.7)*	146.9 (8.3)	41.5 (9.9, 73.1)*	7.1 (-30.9,16.7)		
ROM-internal rotation						0.259	0.904
2 week	41.7 (4.1)	7.9 (-1.3, 17.2)	36.3 (5.4)	6.3 (-2.9.8.2)	5.3 (-8.6,19.3)		
4 week	50.7 (4.9)	17.7 (6.9, 28.5)*	49.4 (5.5)	16.4 (4.8, 26.7)	1.3 (-13.9,16.6)		
6 week	55.7 (5.3)	23.0 (8.9, 37.2)*	56.0 (5.1)	22.4 (8.87,35.9)	0.3 (-15.7,15.2)		
10 week	61.1 (5.5)	28.8 (12.3,45.3)*	65.9 (5.5)	32.2 (12.8,44.0)	4.7 (-21.0,11.4)		
ROM-external rotation						0.103	0.981
2 week	45.3 (6.0)	7.4 (-3.9,18.2)	41.1 (7.8)	5.2 (-2.7,13.2)	4.1 (-15.9,24.3)		
4 week	54.4 (5.6)	17.2 (5.4,28.9)*	52.8 (7.7)	16.9 (2.3,31.5)*	1.6 (-17.7,20.9)		
6 week	59.9 (5.1)	23.1 (11.7,34.6)*	56.9 (6.3)	21.0 (6.7,35.3)*	3.0 (-13.7,19.7)		
10 week	61.1 (5.3)	24.3 (11.6,37.0)*	64.3 (6.5)	28.4 (12.8,44.0)*	3.2 (-20.6,14.1)		

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

Negative mean difference scores (95%CI) of NRS and SPADI are indicative of improvement, whereas positive change scores (95%CI) of ROM indicates improvement.

Our study adopted a f-ESWT protocol similar to that of Chen et al.[22] in terms of the locations and numbers of shots at each treatment, but we added a comparison of the effect with a sham treatment group. We also observed significant improvement, i.e., pain and SPADI score reduction and increased ROM, as early as 2 weeks after the first f-ESWT treatment, but the amount of improvement was not significantly different from that of the sham f-ESWT (control) group for any of the outcome measures. The discrepancy between our results and those with Chen et al.[22] may be due to a dose-dependent effect of f-ESWT. The energy flux density (EFD) used in Chen et al.[22] was 0.6 mJ/mm^2, which is considered a high-energy ESWT. In contrast, in our study we were unable to increase the EFD to higher levels due to the limit of the

individual patient's tolerance to pain, so the average EFD in our study was some 3.75-fold lower (0.16 ± 0.07 mJ/mm^2), which is considered a low-energy ESWT. A systematic review by Bannuru et al.[28] categorized an EFD ≥ 0.28 mJ/mm^2 as high-energy and concluded that high-energy ESWT was significantly better in decreasing pain and improving function in chronic calcific shoulder tendinitis, while no similar effect was found in non-calcific tendinitis. Additionally, high-energy f-ESWT has been reported to be an effective treatment for Duputren's disease[29] which historically has been classified as a fibrotic disorder akin to AC.[30]

In another study, Vahdatpour et al.[21] compared f-ESWT to sham therapy in 40 patients with a frozen shoulder. In that study, both groups were given 2-3 exercises, less than the number of exercises in our study. They also received a different sham therapy: turning off the device while placing it on the patient's shoulder. They reported that f-ESWT seemed to have a positive effect on pain and SPADI scores, with a quicker return to daily activities and improvement in the quality of life. But in that study a strong bias was introduced as both groups received an injection of 40 mg of triamcinolone into the involved shoulder joint before starting the treatment. Hussein et al.[27] also reported a significant improvement in functional outcome, pain level, and ROM in the treatment of radial ESWT compared to a sham group for 106 patients with AC. In both studies, a low energy EFD was used, but the location of the shockwave application was different from that used in our study. That study suggested that the anterior-posterior direction was more effective in locating adhesions. The study also stated that a more effective response was obtained with a higher energy level and appropriate session intervals. In our study, 1,500 impulses were applied to three separate locations. For that reason, we assume that the total energy for each location of the f-ESWT application in our study was insufficient to induce either an anti-inflammatory or an anti-fibrotic effect.

The comparable improvement in the pain level, ROM, and functional score in both groups in our study can be attributed to both groups using the same home-based exercise program. The physical therapist advised and tracked all of the patients in our study on a weekly basis to ensure that they were following the home-based program correctly. In a meta-analysis by Marinko et al.,[31] therapeutic exercise was reported to be an effective intervention for the treatment of a painful shoulder condition. Home-based exercise following the instructions of a physical therapist, including pendulum exercise, shoulder stretching, and strengthening exercises, offers a significant benefit in shoulder function improvement, pain relief, and increased ROM in patients with chronic shoulder pain[32] as well as in a frozen shoulder.[33]

In our study, patients were individually instructed on exercises tailored to their symptoms and participated in six weekly follow-up sessions with the physical therapist, which is a larger number of sessions than in previous studies.[32,33.] The effect of the exercises could possibly have altered the outcome and/or camouflaged the effect of the f-ESWT. Other limitations in our study include that the sample sized was relatively small which might limit the generalizability of the results. Moreover, the follow-up period of only 10 weeks was relatively short. Although previous studies have found satisfactory results after a short-term follow-up, some studies have reported that improvement was still observable at a 6-month follow-up.[34,35]

Further studies are needed to evaluate different applications of f-ESWT in order to achieve optimal energy levels within the tolerance limits of the patient and to investigate specific responses as well as any adverse effects of f-ESWT across the various stages of AC to allow a standard treatment protocol to be established.

Conclusions

Based on the findings of our study, low-energy f-ESWT once a week for 6 weeks plus a home-based exercise program provides no additional benefit over a home-based exercise program alone in patients with non-calcific adhesive capsulitis in terms of pain reduction, activities of daily living, and range of motion.

Disclosure

The authors have no conflicts of interest to declare.

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Original Article

A Comparison of the Efficacy of Diclofenac Phonophoresis and Ultrasound Therapy in Upper Trapezius Myofascial Pain Syndrome: A Double-Blinded Randomized Controlled Trial

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ABSTRACT

Objectives: To compare the pain numeric rating scale (NRS) and active cervical lateral flexion between diclofenac phonophoresis (DPP) and a conventional ultrasound therapy (UST) in treating myofascial pain syndrome (MPS).
Study design: A double-blinded randomized controlled trial.
Setting: Department of Physical Medicine and Rehabilitation, Taksin Hospital, Thailand.
Subjects: Fifty-two participants (41 females, 11 males, mean age 42 years, mean MPS duration 2 months) with myofascial pain syndrome at the upper trapezius muscle
Methods: Participants were allocated by block randomization into 2 groups, the UST Group (n = 26) treated with a conventional UST using a 1-MHz applicator, a standard coupling agent, stroke technique, continuous mode, intensity of 1 watt/cm^2 for 10 minutes, and the DPP Group (n = 26) treated with the same UST technique but using a mixture of 4 grams of diclofenac gel and a standard coupling agent in a ratio of 1:4 instead of the standard coupling agent. Each participant was treated 3 times per week for 3 weeks for a total of 9 treatments. All participants rated their pain on a numeric rating scale (NRS). Active cervical lateral flexion was measured by an assessor prior to the initial treatment and following the final treatment. All participants and the assessor were blinded to the treatments received.
Results: Before the treatments, there was no statistically significance in NRS (p = 1.00) or active cervical lateral flexion (p = 0.75) between the two groups. After the treatments, NRS of the DPP group was significantly lower than the UST group (p = 0.03). However, active cervical lateral flexion was not significantly different between the groups (p = 0.29). Group analysis found that NRS was significantly reduced, by 2.58 in the UST group (p = 0.00) and by 3.46 in the DPP group (p = 0.00). Active cervical lateral flexion motion was significantly increased in the DPP group (p = 0.02) but not in UST group (p = 0.08) after the 3-week therapy.
Conclusions: Diclofenac phonophoresis can reduce pain in myofascial pain syndrome at upper trapezius muscle better than conventional ultrasound therapy.

Keywords*:* phonophoresis, ultrasound diathermy, myofascial pain syndrome, trapezius muscle, diclofenac gel

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Introduction

Myofascial pain syndrome (MPS) is defined as sensory, motor, and autonomic symptoms caused by myofascial trigger points.[1] Myofascial trigger points are hyperirritable spots within a taut band of skeletal muscle.[1] MPS causes a physical and financial burden to society. The prevalence of MPS in middle-aged adults (30-60 years of age) was reported to be 37% in males and 65% in females.[2] MPS treatments include pharmacological intervention, e.g., analgesic drugs, non-steroidal anti-inflammatory drugs (NSAIDs), tramadol, muscle relaxants, antidepressants, anticonvulsants as well as non-pharmacological treatments involving both non-invasive and invasive techniques. Non-invasive techniques include spray and stretch, ergonomic adaptation, laser therapy, transcutaneous electrical nerve stimulation (TENS), ultrasound therapy (UST), massage and ischemic compression therapy, while invasive techniques include dry needling and trigger point injection. Invasive techniques are associated with a risk of adverse events such as pneumothorax, hematoma, soft tissue infection, post injection soreness.[3,4] For that reason, some patients prefer pharmacological treatment and take NSAIDs to reduce pain.

Mechanisms of NSAIDs include analgesic, antipyretic, and anti-inflammatory properties via cyclo-oxygenase (COX) in the arachidonic acid cascade to inhibit prostaglandin production. Most common NSAIDs are available in an oral form which can have gastrointestinal side effects, whereas topical forms do not have such side effects and so can be prescribed for individuals who cannot tolerate the oral forms.[5] To enhance absorption and penetration of topical medications into deeper tissues, phonophoresis (PP), a non-invasive technique, can be applied.[6] Therapeutic effects depend on different factors, e.g., rate and amount administered and the specific topical drug.6 Diclofenac gel is one of the highly effective topical NSAIDs in terms of absorption and penetration via tissues.[6,7] In previous studies, UST significantly reduced pain as measured on the visual analog scale (VAS) and increased the short-term pain pressure threshold (PPT) in MPS.[8,9] Phonophore-

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sis (PP) has been used effectively in the treatment of carpal tunnel syndrome,[10] MPS,[11,12] and osteoarthritis of the knee.[13] A recommended setting of UST for PP is a continuous 1.0 W/cm^2 and 1-MHz frequency application.[13] To demonstrate the efficacy of diclofenac PP (DPP) in reducing pain and increasing neck range of motion (ROM) at trapezius muscle in patients with MPS, this study compared applying UST alone and DPP with diclofenac gel.

Methods

This double-blinded randomized controlled trial was approved by the Bangkok Metropolitan Administration Human Research Ethics Committee (Approval number S022h/63).

Participants

Patients diagnosed with MPS at the trapezius muscle based on the Travel and Simon's clinical criteria[6] who visited the Physical Medicine and Rehabilitation outpatient clinic at Taksin Hospital between December 2020 and April 2021 were invited to join the study. After giving their informed consent, they were recruited into the study. The inclusion criteria consisted of age between 18-75 years old. Patients with any of the following were excluded from the study: fibromyalgia, cervical disc herniation, cervical radiculopathy, cervical myelopathy, a trigger point injection or physical therapy during the previous 7 days, a history of neck surgery or trauma during the previous 6 months, a NSAID allergy, a communication disorder as well as women who were pregnant or lactating. Using block randomization, the recruited participants were divided into two groups, the UST group and the DPP group.

Procedure

The assessor, a physiatrist, interviewed participants regarding their demographics and occupation, reviewed their medical records, identified the affected side and duration of MPS, asked about their maximum pain intensity at the affected trapezius muscle, and measured the angle of active lateral flexion of the neck toward the affected side. The assessor was blinded to the treatment that the participants received. All participants were assessed twice: before the first treatment and after the final treatment.

Three physical therapists in the department were assigned to provide treatment according to a randomization process. All therapists used a Sonopuls 190 ultrasound diathermy unit, a 1-MHz applicator in continuous mode with an intensity of 1 W/cm^2 and using a stroke technique on the skin over the affected trapezius muscle for 10 minutes. Ultrasound gel (Hydrosonic gel) was applied in the UST group while a mixture of diclofenac gel (Antenac® gel) and the ultrasound gel in a ratio of 1:4 was applied in the PP Group. The therapist applied the gel at the ultrasound applicator. The gels used in both groups were odorless and light blue in color in a total volume of 15 mL for each use. All participants received 3 treatments per week for 3 weeks, a total of 9 sessions.

Outcome measures

The primary outcome measure was subjective pain intensity which was determined using a numeric rating scale (NRS) where 0 means no pain and 10 means the most severe pain. The assessor asked participants for the maximum pain at that moment. The secondary outcome was active cervical lateral flexion of the neck toward the shoulder of the affected side which was measured using a standard goniometer.[12] If both sides of the trapezius muscle were affected, the assessor measured the side with the worst pain intensity. This trial was double-blinded to avoid bias. Participants did not know which group they belonged to. If participants had ongoing pain during treatment, they were allowed to take acetaminophen (500 mg 1 tablet q 6 hours), but no other pain medications were allowed during the study e.g., tramadol and oral NSAIDs.

Statistical analysis

Demographic data of participants in both groups were analyzed. Quantitative data is shown as means and standard deviations. Qualitative data is shown as frequencies and percentages. STATA version 14 was used for statistical analysis. Mean differences in NRS and active cervical lateral flexion between groups were analyzed using the unpaired t-test for parametric data with a statistically significant confidence level of $p < 0.05$. Before and after treatment analysis within groups was done using the paired t-test for parametric data with statistical significance set at $p < 0.05$.

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

Results

A total of 56 patients were initially screened, of whom 52 were enrolled. All 52 participants were allocated to groups of whom 47 completed the study, a dropout rate of 9.6% (Figure 1). All participants were included in the statistical analysis according to the group to which they were assigned. Most participants in the study (78.8%) were females with a mean age of 42 years and duration of symptoms of 2 months. In the UST group, the mean age was 45 years and the mean duration of MPS was 1.4 months, while in the DPP group the mean age was 40 years and the mean duration was 3 months. The right trapezius muscle was affected less in the UST group than in the DPP group (54% vs. 73%). The most common occupation was office clerk (Table 1).

In this study, an intention to treat analysis was used in table 2, there were no statistical differences in pain on the NRS before treatment between the two groups (mean difference = 0.00, $p = 1.00$). At the end of the study, NRS was significantly reduced in the UST group, 2.58 ($p = 0.00$) and 3.46 in the DPP group ($p = 0.00$), a statistically significant difference (mean difference = 0.88, $p = 0.03$).

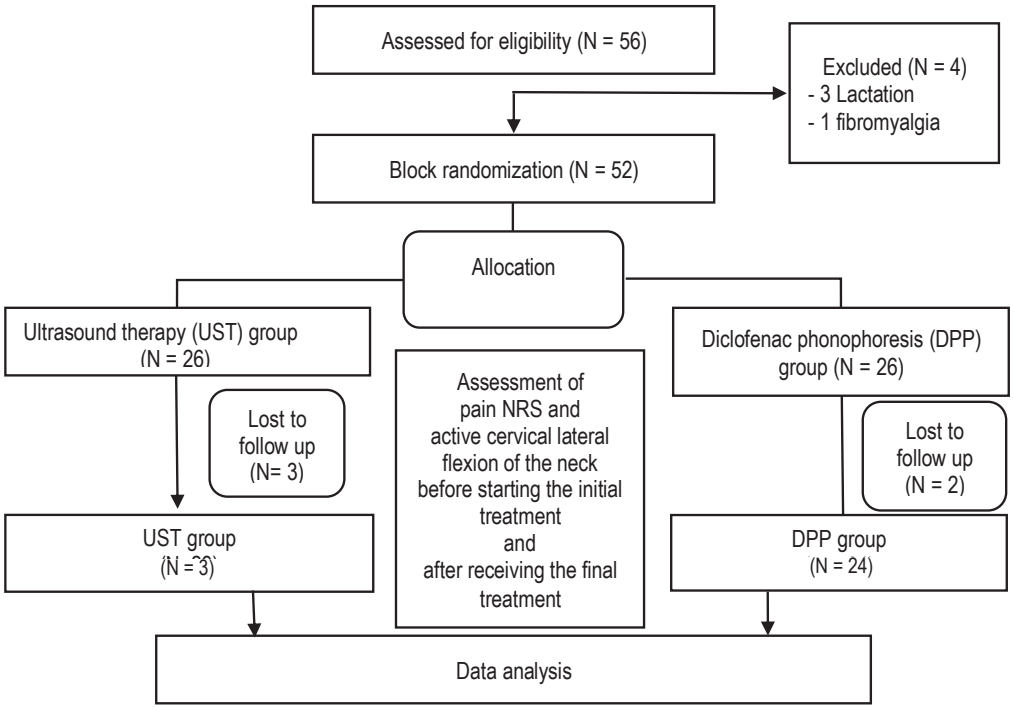

Figure 1. Schematic flow diagram of the study

Table 1. Comparison of demographic data of participants with myofascial pain syndrome (MPS) at the trapezius muscle between the ultrasound therapy (UST) and the diclofenac phonophoresis (DPP) groups.

	UST group (n = 26)	DPP group (n = 26)
Age (years)[1]	45 (10)	40 (9)
Gender[2]		
Female	21 (81)	20 (77)
Male	5 (19)	6 (23)
Affected side[2]		
Right	14 (54)	19 (73)
Left	12 (46)	7 (27)
Duration of MPS (months)[1]	1.4 (2)	3 (4)
Occupation[2]		
Office clerk	16 (61)	13 (50)
Healthcare worker	2 (8)	10 (38)
Laborer	4 (15)	1 (4)
Housewife	2 (8)	2 (8)
Salesperson	2 (8)	0 (0)

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

At the beginning of the study, there were no differences in active cervical lateral flexion toward the affected side between the groups. After the 3-week therapy, active cervical lateral flexion motion had significantly increased in the DPP group (p = 0.02), but the change was not statistically significant in the UST group (p = 0.08) (Table 2).

Six participants in the UST group reported taking acetaminophen as an add-on drug therapy to relieve pain, whereas only 1 participant in the DPP group did so. No participants in DPP group had side effects from the topical diclofenac gel, e.g., skin allergy.

Discussion

UST in one of the noninvasive treatments for MPS. It produces a high-frequency sound wave that increases local mechanisms, circulation and extensibility of connective tissue through a deep heat mechanism. DPP is a form of UST that facilitates transdermal penetration of diclofenac gel to

Table 2. Comparison of outcome parameters between the ultrasound diathermy (UST) group and the diclofenac phonophoresis (DPP) group

Parameters	UST group	DPP group	Mean difference	95% CI	Between groups p-value
Pain numeric rating scale					
At the beginning of the study	6.81 (1.60)	6.81 (1.61)	0.00	-0.91 to 0.91	1.00
At the end of the study	4.23 (1.45)	3.35 (1.83)	0.88	0.07 to 1.70	0.03*
Before and after, p-value	0.00*	0.00*			
Active cervical lateral flexion (degrees)					
At the beginning of the study	27.00 (5.73)	26.50 (7.81)	0.50	-2.70 to 3.70	0.75
At the end of the study	29.81 (5.40)	31.42 (6.60)	-1.61	-4.69 to 1.46	0.29
Before and after p-values	0.08	0.02*			

Mean (SD)

Between groups analysis used the unpaired t-test; within group analysis used the paired t-test, *significance level $p < 0.05$

deeper subcutaneous tissue[6] and may be an option for treating MPS patients who have gastrointestinal side effects from oral forms of NSAIDs.

This double-blinded randomized controlled trial compared the efficacy of DPP and UST in patients with MPS. Prior to the beginning of the three-week treatment, there were no significant differences in the baseline pain of NRS or active cervical lateral flexion between the two groups. At the end of the study, there was a significant difference in pain NRS between the two group, with the DPP group having significantly lower pain NRS scores than the UST group. However, there was no difference in active cervical lateral flexion between the groups. These results suggest that DPP is more effective than UST in reducing pain intensity in MPS at the trapezius muscle, but that it does not improve active cervical lateral flexion. The decrease in pain NRS in the DPP group was in line with the fact that a larger proportion of participants in the UST group took acetaminophen than in the DPP group.

In this current study, following the 3-week therapy pain NRS was significantly reduced in the UST group, a result which is in line with a study done by Majlesi et al,[8] although that study reported a greater reduction in pain. The difference in the level of pain reduction is likely due to the fact that the Majlesi study used a high-power pain threshold ultrasound technique in the treatment of active myofascial trigger points while the present study did not. Several studies have similarly reported that UST can reduce pain and increase PPT,[8,9,14-19] while others have reported no difference between UST and other treatments.[20-23] For example, Srbely and Dickey[9] applied the UST at the trigger point and measured the pain threshold, reporting that pain pressure threshold scores increased an average of 44.4 (14.2%) after UST. Gam et al.[20] reported no difference in pain reduction between the group given UST and the group that received sham UST, but that might be due to the fact that participants in both groups in that study also received massage and exercise. In this study, pain reduction can be attributed exclusively to the analgesic effect of UST via both thermal and non-thermal mechanisms.[19]

In this study, the DPP group had greater pain reduction than the UST group which suggests that diclofenac gel can reach the target tissue and enhance the UST efficacy. NRS was significantly reduced (by 2.58 in the UST group and 3.46 in the DPP group). Active cervical lateral flexion motion was significantly increased in the DPP group, was not statistically significantly changed in the UST group between preintervention and postintervention (after the 3-week therapy). This result is in line with a study done by Ay et al.[6] and Takla et al.[17] Ay et al.[6] found that there were statistically significant improvements in pain severity, the number of trigger point (NTP), PPT, ROM and NPDI scores both with PP and UST. Takla et al.[17] reported that PP was superior to UST in reducing pain, but that none of the treatment groups were found to be superior in increasing range of motion. The efficacy of a topical agent is dependent on its being absorbed through the skin surface and its ability to reach the target tissue.[19] Additionally, PP can decrease pain and NTP better than other techniques.[10-13] Yildiz et al.10 found that ketoprofen PP and splinting for carpal tunnel syndrome resulted in a lower pain score than both sham UST and splinting as well as UST and splinting at the 8th week of treatment. Sarrafzadeh et al.[11] found that phonophoresis of hydrocortisone and pressure release techniques could decrease pain and PPT and could also increase cervical lateral flexion more than UST alone in latent MPS at the upper trapezius muscle. Ustun et al.[12] found that EMLA Cream phonophoresis significantly decreased NTP compared to UST in MPS at the trapezius muscle. Luksurapan et al.[13] found that reductions in VAS scores and improvements in WOMAC scores were greater with piroxicam phonophoresis than with UST.

This study has some limitations. First, the study did not assess long-term outcomes. Second, the study included more than one physical therapist, although they did use the same protocol. Third, this study used NRS for pain assessment. Although all participants were able to communicate very well, NRS is a subjective measurement. Further study is needed to explore clinical outcomes in terms of the carry-over effect after using DPP for certain periods of treatment.

Conclusions

A 3-week treatment with diclofenac phonophoresis provides more pain reduction than conventional ultrasound diathermy in patients with myofascial pain syndrome at the trapezius muscle.

Disclosure

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

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Original Article

Suprascapular Nerve Block versus Intra-articular Steroid Injection for Hemiplegic Shoulder Pain: A Preliminary Double-Blind Randomized Controlled Trial

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ABSTRACT

Objectives: To compare the analgesic efficacy of two alternative injections in improving passive shoulder range of motion and shoulder function in patients with hemiplegic shoulder pain.

Study design: A double-blind randomized controlled trial.

Setting: Rehabilitation Medicine Clinic, University Malaya Medical Centre, Kuala Lumpur, Malaysia.

Subjects: Patients with hemiplegic shoulder pain of at least two weeks duration were recruited into this study

Methods: Either a suprascapular nerve block or an intra-articular steroid injection were administered to all patients. Maximal tolerable passive range of motion and the corresponding numerical rating scale pain score were documented at pre-injection and at one hour, one month and three months post-injection. The Shoulder Pain and Disability Index questionnaire was completed by the participants at pre-injection and at one month and three months post-injection. All outcome measures were analysed using repeated measures ANOVA.

Results: Thirty-one patients were enrolled in this study. The mean age was 57.7 years (SD 8.1). Mean stroke duration was 16.9 months (SD 24.2). Twenty-six of the strokes (83.9%) were of ischaemic aetiology. Significant pain reduction, passive range of motion and shoulder pain and disability index over time were evaluated in both groups. The intra-articular steroid group had an analgesic effect earlier (at one month) than the suprascapular nerve block group (at three months). No significant differences in pain, shoulder passive range of motion or shoulder pain and disability index between the two groups were observed at any point in this study.

Conclusions: Neither injection technique was found to be superior in terms of pain reduction, passive range of motion increase or reduction in Shoulder Pain and Disability Index score. However, this result could be due to the small sample size. The intra-articular steroid group evidenced an analgesic effect at one month, earlier than the suprascapular nerve block group.

Keywords*:* hemiplegia, shoulder pain, stroke, scapular nerve block, intra-articular steroid injection

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Introduction

Hemiplegic shoulder pain is a common clinical consequence of stroke, with a frequency reported to be as high as 84%.[1] Although hemiplegic shoulder pain can occur as early as one-week post-stroke, the onset is more common at two to three months.[2] Hemiplegic shoulder pain can be due to musculoskeletal and/or neuropathic causes. Musculoskeletal causes include structural injury from glenohumeral subluxation, capsular contracture or rotator cuff pathology, impingement syndrome, bicipital tendinopathy, adhesive capsulitis and myofascial pain.[3] Neuropathic causes of hemiplegic shoulder pain include central poststroke pain and peripheral nerve entrapment.[3]

Patients with hemiplegic shoulder pain manifest with pain on passive movement of the shoulder as well as limitations on the range of motion of shoulder movement. Poorly managed hemiplegic shoulder pain can affect post-stroke rehabilitation participation resulting in significant disability and reduction in quality of life.[2,4] Management of hemiplegic shoulder pain focuses on reducing pain, improving active and passive range of motion (PROM), shoulder positioning with slings or strapping, massage therapy, percutaneous electrical muscle stimulation and intramuscular botulinum toxin injection.[5]

Minimally invasive treatment of hemiplegic shoulder pain with intra-articular shoulder steroid injection and suprascapular nerve block have lately gained interest. Published studies have reported significant reduction of pain both after suprascapular nerve block and after intra-articular steroid injection compared to placebo.[6,7] However, head-to-head comparisons of the analgesic effects of suprascapular nerve block versus intra-articular steroid are limited.[8,9] Studies done to date comparing both injection methods only followed patients for up to one month. There have been no studies so far comparing the functional outcome between these two minimally invasive methods.

In this randomized double-blinded control trial, we compared the analgesic effect of suprascapular nerve block and

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of intra-articular steroid among members of the Malaysian stroke population. We also evaluated improvement in passive shoulder range of motion and functional outcome using the Shoulder Pain and Disability Index (SPADI) for up to three months following the minimally invasive interventions.

Methods

An unfunded prospective, single centre, double-blinded, parallel group preliminary randomized control trial was conducted in the Rehabilitation Medicine Clinic, University Malaya Medical Centre. The study was registered with Clincialtrials.gov (NCT04128605, protocol ID 201945-7301) as well as the Malaysian National Medical Research Register, Ministry of Health, Malaysia (NMRR-19-2997-3554). This study received ethical approval from the University of Malaya Medical Centre Medical Research Ethics Committee (MEC ID Number: 201945-7301).

The sample size was calculated based on a previous study using G*Power 3.1.9.2. to have a power of 0.8 and an alpha value of 0.05.[9] With allowance for a 25% attrition rate, a total of 86 subjects were needed for this study. Statistical analysis was done using Statistical Package for Social Science (SPSS) software version 20 for tests of normality, the independent t-test for continuous data, the chi-square test for categorical data and repeated measure analysis of variance (ANOVA) for changes over time and for between group comparisons of primary and secondary outcomes.

Eligible subjects were recruited over an 11-month period between July 2019 and June 2020; data collection for the 3 months of follow-up was completed by September 2020. The inclusion criteria were stroke evidenced by brain lesion recognized on Computed Tomography or Magnetic Resonance Imaging scans, hemiplegic shoulder pain of at least two weeks of duration, age between 20-70 years, minimal pain score of at least 3 out of 10 on movement as expressed using the numerical rating scale (NRS) and a Mini Mental State Examination score of at least 24 out of 30.

The exclusion criteria were neuropathic pain including chronic regional pain syndrome or central poststroke pain, severe aphasia, previous trauma to the affected shoulder, preexisting shoulder pain prior to the stroke, previous shoulder injection within three months of the study and spasticity of the latissimus dorsi and pectoralis major muscles with a Modified Ashworth Scale (MAS) score of at least 3.

A co-investigator randomly assigned the subjects using a computer-generated randomization sequence to one of the two study arms in a 1:1 ratio. The allocation was done prior to the injection and was known only by the interventionist who was not involved in the assessment of the patients. The subjects and the investigator performing the assessment (Tuan Ibrahim TF) were blinded from the intervention allocation. On enrolment, demographic data including duration and aetiology of stroke, shoulder ultrasound findings and MAS for pectoralis major and latissimus dorsi muscles were documented. Clinical assessments included maximum tolerable PROM for shoulder flexion, abduction, internal and external rotation as well as the corresponding pain intensity expressed in NRS. Shoulder PROM were measured with a goniometer with the subject in the supine position and the shoulder stabilized. Shoulder flexion and abduction PROM were measured with the elbow in extension; internal and external rotation were measured with elbow flexed at 90° and shoulder abducted at 90° with the forearm in the mid-prone position. SPADI pain and disability components were included in the functional assessment. Clinical and functional assessments were repeated after one hour, one month and three months by the investigator who was blinded to the intervention allocation.

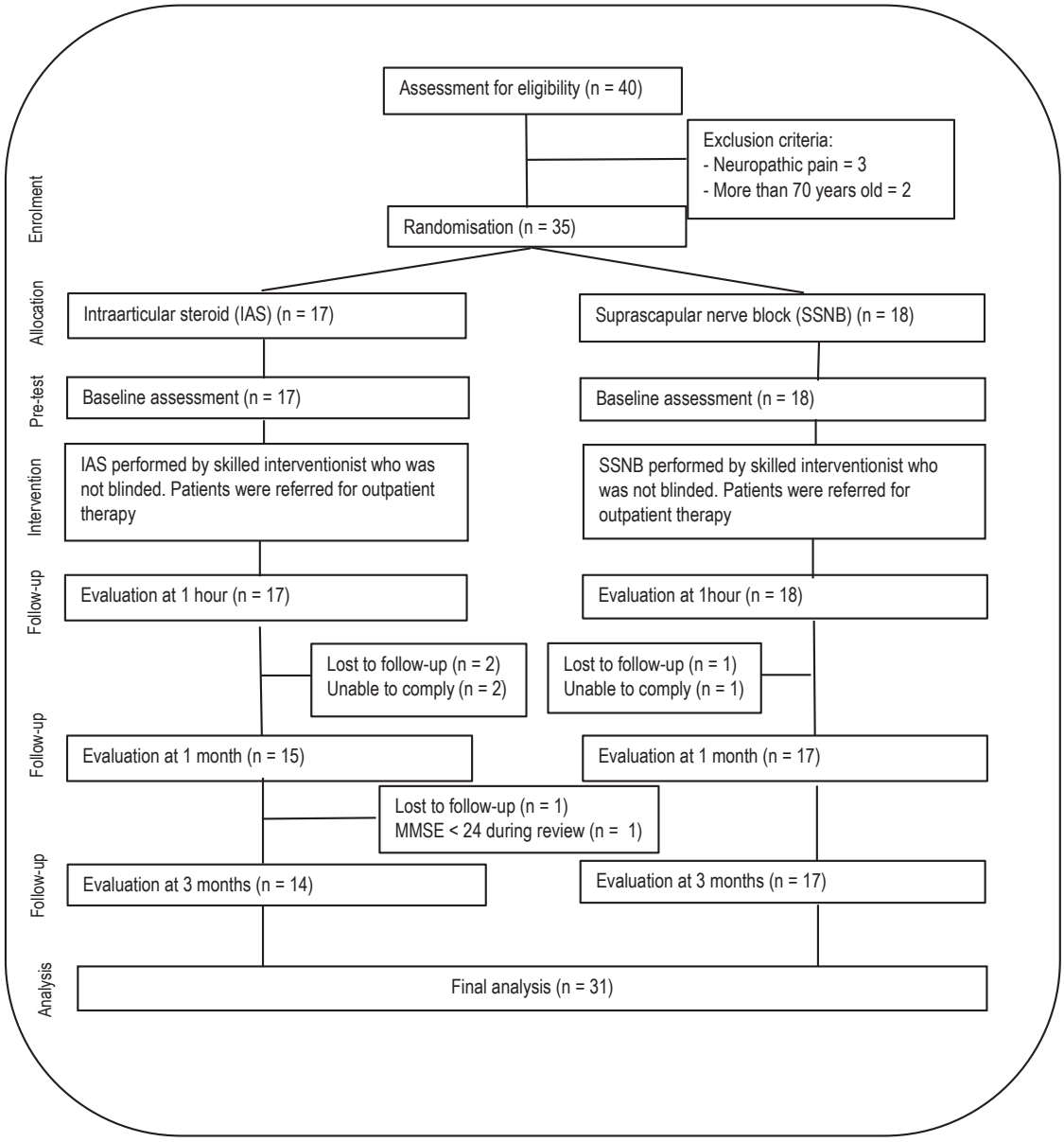
Shoulder injections were performed by a skilled interventionist (Suhaimi A), who was not blinded for safety reasons. Injections were given at the posterior aspect of the affected shoulder under ultrasound guidance while the subject was asked to face away from the injection. The suprascapular nerve block was performed by infiltrating the site of the needle insertion with Lidocaine 1% following sonographic identification of the suprascapular fossa. After cutaneous anaesthesia, a 22-gauge spinal needle (Spinocan, B. Braun) was directed towards the target under sonographic guidance. A mixture of 5 mL of Bupivacaine 0.5%, 5 mL of Lidocaine 1% and 10 mL of normal saline was delivered with real-time visualisation of the needle tip during the procedure. Intra-articular steroid injection was also performed under sonographic guidance following cutaneous anaesthesia of the area posterolateral to the acromion. The glenohumeral joint was accessed posteriorly under sonographic guidance to confirm the needle tip position between the posterior labrum and the humeral head. A mixture of 40 mg of Triamcinolone Acetonide and 2 mL of Lidocaine 1% was delivered with real time visualisation of the needle tip shaft.

Results

Out of the 35 patients enrolled in the study, 4 were lost to follow-up while 31 patients completed the study: 14 patients in the intra-articular steroid group and 17 patients in the suprascapular nerve block group. The baseline demographic data are described in Table 1. There were no statistically significant differences in demographic data between the two groups ($p < 0.05$).

We also documented shoulder ultrasound findings of patients performed prior to the interventions as described in Table 2 below. There were no statistically significant differences between the two groups in the ultrasound findings except for the occurrence of subacromial subdeltoid bursitis ($p = 0.003$) and mixed echogenicity of subscapularis which were higher in the suprascapular nerve block group ($p = 0.036$).

The MAS for spasticity of the pectoralis major and the latissimus dorsi were documented prior to injection. There were no statistically significant differences between the two



MMSE, Mini mental state examination

Figure 1. Flow chart showing patients' progress through the study

Table 1. Demographic comparison of patients in the intra-articular steroid group and the suprascapular nerve block group

	Intra-articular steroid (n = 14)	Suprascapular nerve block (n = 17)	*p*-value
Gender (male: female)	9:5	8:9	0.337[a]
Mean age (years)[1]	58.64 (7.38)	56.88 (8.85)	0.557[b]
Duration of stroke (months)[1]	15.79 (19.58)	17.88 (27.98)[1]	0.815[b]
Affected side[2]			
- Right	6 (42.9)	12 (70.6)	0.119[a]
- Left	8 (57.1)	5 (29.4)	
Aetiology of stroke[2]			0.467[a]
- Ischaemia	11 (78.6)	15 (88.2)	
- Haemorrhagic	3 (21.4)	2 (11.8)	

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

[a]Chi-square test, [b]Independent t-test

($p > 0.05$) was considered statistically significant

Table 2. Comparison of shoulder ultrasound findings between the intra-articular steroid and the suprascapular nerve block groups

Ultrasound findings	Intra-articular steroid (n = 14)	Suprascapular nerve block (n = 17)	*p*-value
No scan done	2 (14.3)	1 (5.9)	0.665
No abnormality detected	0 (0)	1 (5.9)	0.356
Bicipital tendinitis	11 (78.6)	13 (76.5)	0.889
Subacromial subdeltoid bursitis	1 (7.1)	10 (58.8)	0.003
Mixed echogenicity supraspinatus	5 (35.7)	6 (35.3)	0.981
Mixed echogenicity subscapularis	5 (35.7)	1 (5.9)	0.036
Acromioclavicular joint pathology	2 (14.3)	3 (17.6)	0.800
Dynamic impingement	3 (21.4)	3 (17.6)	0.791

Number (%), Chi-square test

Table 3. Comparison of pre-injection measurements between intra-articular steroid and suprascapular nerve block groups

Measurement	Intra-articular steroid	Suprascapular nerve block	*p*-value
NRS			
Flexion	6.71 (2.23)	4.82 (2.32)	0.029*
Abduction	7.21 (2.29)	6.24 (1.39)	0.194
Internal rotation	5.86 (2.38)	5.06 (2.11)	0.330
External rotation	6.43 (2.14)	5.76 (2.28)	0.413
Average	6.55 (1.86)	5.47 (1.58)	0.090
PROM			
Flexion	106.64 (27.39)	116.88 (21.41)	0.252
Abduction	89.64 (16.48)	87.58 (14.07)	0.711
Internal rotation	61.50 (16.53)	54.53 (19.71)	0.301
External rotation	26.43 (16.42)	39.71 (21.99)	0.072
SPADI			
SPADI-total	65.99 (16.61)	61.88 (13.86)	0.459
SPADI-pain	55.32 (20.00)	51.56 (17.05)	0.576
SPADI-disability	73.56 (19.51)	69.36 (20.76)	0.569

Mean (SD); Independent t-test, *significant at $p < 0.05$

NRS, numerical rating scale; PROM, passive range of motion; SPADI, Shoulder Pain and Disability Index

groups for either MAS of the pectoralis major ($p = 0.708$) or the latissimus dorsi ($p = 0.664$).

There were no significant differences between the two groups in assessments of pre-injection for maximum tolerable PROM and corresponding NRS measured at passive flexion, abduction, internal rotation, external rotation or average NRS except for NRS at shoulder flexion which was higher in the intra-articular steroid group ($p = 0.029$) as shown in Table 3. There were likewise no significant pre-injection differences in SPADI, SPADI-Pain or SPADI-Disability between the two groups ($p > 0.05$).

NRS of both groups at maximum tolerable passive flexion, abduction, internal rotation, external rotation as well as average NRS were measured at four different times: pre-injection; one hour, one month and three months post-injection. Measurements changed significantly with time ($p < 0.05$) as shown in Table 4. However, there were no significant differences in NRS at flexion, abduction, internal rotation and external rotation or in average NRS between the two groups at any point after injection.

Figures 2 and 3 below show the mean changes in NRS in all four planes of shoulder movement as well as the average NRS at specified post-injection periods in both groups. It was noted that both groups showed improvement of pain both at one hour and at three months compared to baseline.

The suprascapular nerve block group showed incremental increases in pain between one hour and one month after treatment in all four planes of shoulder movements with the average NRS having declined again at three months. Average NRS, on the other hand, showed a similar reduction in both groups from pre-injection to three months: 2.1 (31.8%) reduction in NRS in the intra-articular steroid group and 1.6 (30.1%) reduction in the suprascapular nerve block group.

Maximum tolerable PROM of both groups at flexion, abduction, internal rotation, external rotation also changed statistically significantly with time as shown in Table 5. Similar results were observed in repeated measurements of SPADI, SPADI-Pain and SPADI-Disability at pre-injection, one month and three months in both groups. However, there were no significant differences between the groups for PROM at flexion,

Table 4. Repeated measures ANOVA of Numerical Rating Scale (NRS) for flexion, abduction, internal rotation and external rotation within subject factors and between group comparisons

Outcome measure	Intra-articular steroid	Suprascapular nerve bloc	Repeated measures ANOVA within subject factor		Between group comparison
			F	P	P
NRS Flexion			4.264	0.007	
Pre	6.71 (2.23)	4.82 (2.32)			0.029
1 hour	4.43 (2.68)	4.06 (2.46)			0.692
1 month	4.71 (3.20)	5.47 (2.43)			0.460
3 months	4.71 (3.02)	3.94 (2.84)			0.470
NRS Abduction			8.26	0.000	
Pre	7.21 (2.29)	6.24 (1.39)			0.194
1 hour	4.64 (2.79)	4.64 (2.45)			0.996
1 month	4.57 (2.24)	5.59 (2.87)			0.289
3 months	5.00 (3.01)	4.41 (2.83)			0.580
NRS Int rotation			4.810	0.008	
Pre	5.86 (2.38)	5.06 (2.11)			0.330
1 hour	4.07 (2.76)	4.00 (2.40)			0.939
1 month	3.93 (3.12)	4.35 (2.74)			0.690
3 months	3.57 (3.20)	2.82 (3.15)			0.519
NRS Ext rotation			3.795	0.013	
Pre	6.43 (2.14)	5.76 (2.28)			0.413
1 hour	4.21 (2.94)	4.76 (2.36)			0.567
1 month	4.86 (2.66)	5.18 (2.92)			0.755
3 months	4.86 (3.16)	4.12 (2.85)			0.499
Average NRS			6.696	0.001	
Pre	6.55 (1.86)	5.47 (1.58)			0.09
1 hour	4.34 (2.58)	4.37 (2.23)			0.974
1 month	4.52 (2.53)	5.15 (2.47)			0.490
3 months	4.54 (2.85)	3.82 (2.55)			0.469

Mean (SD)

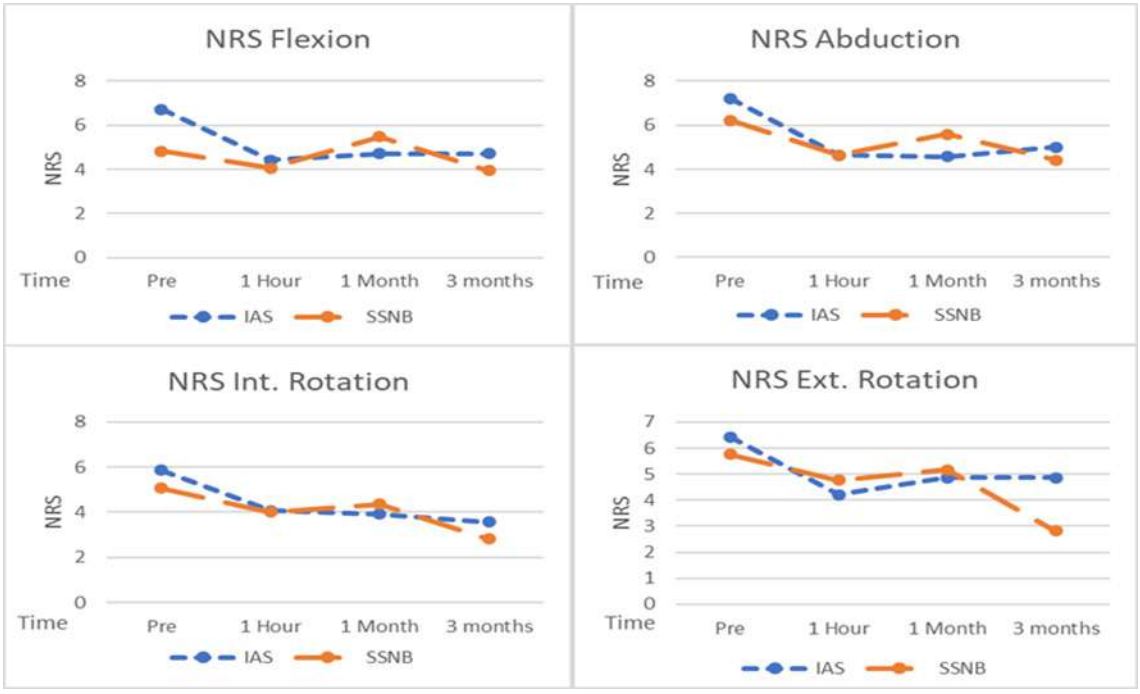


Figure 2. Line chart showing changes over time in means of NRS at maximum tolerated flexion, abduction, internal and external rotation over time for the IAS and SSNB groups

NRS, numerical rating scale; IAS, intra-articular steroid; SSNB, suprascapular nerve block

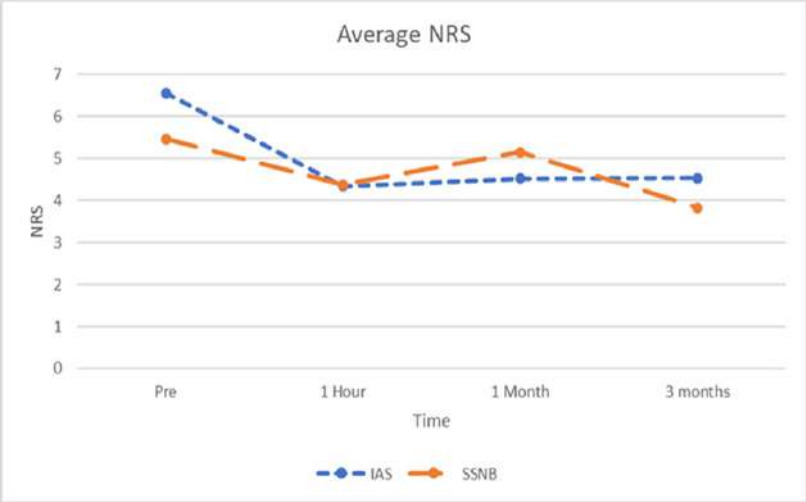


Figure 3. Line chart showing changes over time of average NRS for the IAS and SSNB groups

NRS, numerical rating scale; IAS, intra-articular steroid; SSNB, suprascapular nerve block

Table 5. Repeated measures ANOVA of shoulder passive range of motion (PROM) and Shoulder Pain and Disability Index (SPADI) within subject factor and between group comparison ($p < 0.05$)

Outcome measure	Intra-articular steroid	Suprascapular nerve bloc	Repeated measures ANOVA within subject factor		Between group comparison
			F	P	P
	PROM flexion		6.653	0.000	
Pre	106.64 (27.39)	116.88 (21.41)			0.252
1 hour	124.00 (23.49)	133.59 (22.80)			0.260
1 month	128.50 (20.25)	128.24 (18.78)			0.970
3 months	120.64 (28.35)	132.18 (20.74)			0.201
	PROM abduction		4.529	0.005	
Pre	89.64 (16.48)	87.58 (14.07)			0.711
1 hour	102.50 (22.14)	101.76 (26.50)			0.935
1 month	100.64 (18.70)	102.29 (27.06)			0.848
3 months	100.50 (20.53)	104.65 (32.00)			0.679
	PROM Int rotation		4.016	0.010	
Pre	61.50 (16.53)	54.53 (19.71)			0.301
1 hour	63.86 (16.54)	70.59 (21.47)			0.345
1 month	74.36 (16.62)	63.53 (19.75)			0.114
3 months	70.86 (16.44)	70.06 (17.59)			0.898
	PROM Ext rotation		6.225	0.001	
Pre	26.43 (16.42)	39.71 (21.99)			0.072
1 hour	41.36 (23.98)	48.53 (21.35)			0.386
1 month	39.43 (20.06)	48.76 (18.10)			0.184
3 months	39.86 (19.33)	45.65 (18.81)			0.406
	SPADI		23.455	0.000	
Pre	65.99 (16.61)	61.88 (13.86)			0.459
1 month	48.08 (20.94)	49.36 (19.69)			0.862
3 months	47.44 (23.26)	40.18 (21.51)			0.375
	SPADI-pain		21.839	0.000	
Pre	55.32 (20.00)	51.56 (17.05)			0.576
1 month	27.74 (26.55)	35.79 (20.08)			0.344
3 months	25.89 (28.95)	27.79 (24.14)			0.843
	SPADI-diability		13.616	0.000	
Pre	73.56 (19.51)	69.36 (20.76)			0.569
1 month	63.76 (24.07)	59.08 (24.44)			0.597
3 months	63.00 (23.99)	47.95 (28.12)			0.124

Mean (SD)

Figure 4. Line chart showing means of changes of maximum tolerable PROM at flexion, abduction, internal and external rotation with time for IAS and SSNB group.

PROM, Passive range of motion; IAS, Intra-articular steroid; SSNB, Suprascapular nerve block

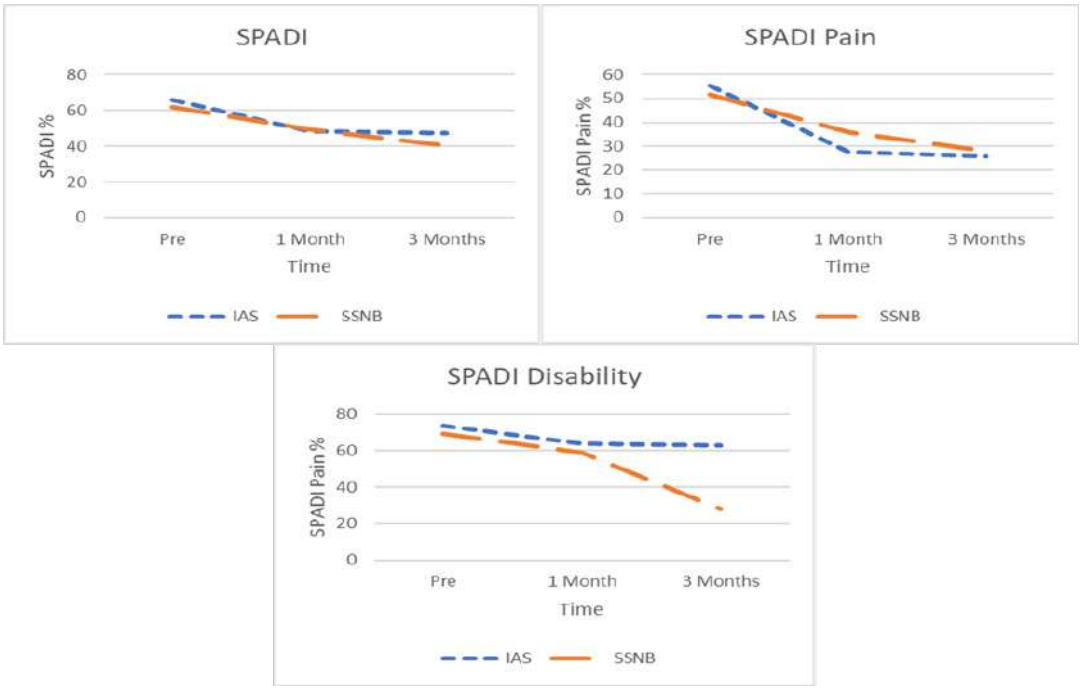


Figure 5. Line chart showing changes in means of SPADI, SPADI Pain and SPADI Disability scores with time for the IAS and SSNB groups.

SPADI, Shoulder pain and disability index; IAS, Intra-articular steroid; SSNB, Suprascapular nerve block

abduction, internal rotation or for SPADI, SPADI-Pain and SPADI-Disability at any time point after injection.

Figures 4 and 5 above show the mean changes in PROM in flexion, abduction, internal rotation and external rotation as well as SPADI, SPADI-P and SPADI-D with time in both groups. The most notable change in PROM from pre-injection to three months in the intra-articular steroid group was in external rotation where improvement of 13.4 degrees (50.8%) was observed. In the suprascapular nerve block group, PROM in internal rotation improved most between pre-injection and three months, by 15.5 degrees (28.5%).

Out of the 3 SPADI scores, SPADI Pain showed the most improvement with time in both groups: 29.4 in mean difference (53.2%) in the intra-articular steroid group and 23.8 (46.1%) in the suprascapular nerve block group.

Discussion

This study found that both intra-articular steroid and suprascapular nerve block showed statistically significant improvement in the primary outcome of pain reduction with time but neither injection method was found to be superior to the other. Similar results were observed for secondary outcome measures of PROM in all four planes of shoulder movement and in outcome measures of SPADI, SPADI-Pain and SPADI-Disability scores.

Both interventions were found to be safe and produced similar outcomes at three months in patients with hemiplegic shoulder pain. To the best of our knowledge, this is the first study that compared the efficacy of intra-articular steroid and suprascapular nerve block on hemiplegic shoulder pain and PROM scores that followed the subjects for up to three months and also included functional outcome measures of SPADI. Shoulder ultrasound findings were documented along with spasticity of the latissimus dorsi and pectoralis major.

Both groups showed significant improvement in pain between baseline and three months, with an average NRS reduction of 2.1 (31.8%) in the intra-articular steroid group and 1.6 (30.1%) in the suprascapular nerve block group. These NRS reductions exceeded the minimal clinically important difference (MCID) standard for changes in pain intensity in chronic musculoskeletal pain (a score of one, representing a 15% reduction).[10]

However, in the suprascapular nerve block group, the pain relief effect became pronounced later (at three months). NRS at all four planes of shoulder movements showed an increment of pain at one month in the suprascapular nerve block group but not in the intra-articular steroid group. This result is not consistent with a similar study done earlier that reported a visual analogue score increment for pain at one month in all three groups: the intra-articular steroid group, the suprascapular nerve block group and the combination group.[9]

One explanation for the increase in pain at one month in the suprascapular nerve block group in this study is the higher number of patients with subacromial subdeltoid bursitis in that group: 10 (58.8%) compared to one (7.1%) in the intra-articular steroid group. Subacromial subdeltoid bursitis is one of the ultrasonographic features associated with hemiplegic shoulder pain.[11] The greater number of patients with mixed echogenicity of the subscapularis muscle in the intra-articular group compared to the suprascapular nerve block group (five or 35.7% versus one or 5.9%) did not influence the primary pain outcome as this ultrasound finding is not associated with hemiplegic shoulder pain.[11]

Changes in hemiplegic shoulder pain can include impaired motor control and tone changes that can lead to glenohumeral subluxation as well as spasticity.[12] Subluxation of joints such as the shoulder can cause mechanical stress to ligaments stabilizing the shoulder joint. Noxious mechanical stimuli to fibrous structures such as ligaments and fibrous capsules can elicit pain.[13] An important mechanism for heightened pain sensitivity is an increase in the mechano-sensitivity of joint afferents, as joint nociceptors can be reliably sensitized to mechanical stimuli.[14]

A variety of inflammatory mediators, e.g., bradykinin and histamine, are produced and released into the joint during pathophysiological conditions.[14] This leads to activation of arachidonic acid pathways that result in the production of prostaglandins, thromboxanes, leukotrienes and cytokines that can activate nociceptors leading to pain.[14]

Intra-articular injection of the steroid triamcinolone acetonide inhibits phospholipase A2 enzyme on the cell membranes' phospholipid layer, and thereby hinders the breakdown of leukocyte lysosomal membranes and prevents the formation of arachidonic acid.[15] It also prevents the biosynthesis of prostaglandins and leukotrienes.[16] In addition, it has anti-inflammatory effects and appears to reduce nociceptor sensitivity and central sensitization leading to a reduction of pain.[17] The resulting reduction of synovial inflammation will decrease capsular fibrosis and allow for improvement of PROM with time.[18]

Bupivacaine administered jointly with a suprascapular nerve block will bind to the intracellular portion of the voltage-gated sodium channel on axonal membranes and prevent an influx of sodium ions and depolarization causing reversible loss of sensation.[19]

Interestingly, despite the short duration of action of Bupivacaine, studies have shown that the suprascapular nerve block has a prolonged analgesic effect lasting for up to three months.[20] It has been proposed that the prolonged analgesic effect is possibly due to an effect on C fibres that interrupts the cycle of feedback amplification which can occur in chronic pain.[21] A depletion of substance P and nerve growth factor in the synovium and afferent C fibres of the glenohumeral joint after the blockade may also contribute to the longer pain relief effect.[22] Another factor contributing to longer pain relief might have been a decrease in central sensitization of the dorsal horn nociceptive neurones.[23] Based on this explanation, suprascapular nerve block might be more effective in chronic hemiplegic shoulder pain than intra-articular steroid injection, although further study is needed.

In terms of shoulder PROM, all four planes showed significant improvement with time in both groups. The greatest improvement in PROM was in external rotation in the intra-articular steroid group at 13.4° (50.8%) compared to 5.9° (15%) in suprascapular nerve group. Limitations of shoulder external rotation played an important role in shoulder pain post stroke.[24] The significant improvement of external rotation in the intra-articular steroid group leads to reduction of pain as shown by the lower average NRS at one hour which was maintained at one month and three months, unlike in suprascapular nerve block group where the average NRS increased at one month.

Improvement of PROM is important for enabling patients to perform activities of daily living. Functional shoulder range of motion for activities of daily living are 120° for forward flexion, 45° for extension, 130° for abduction, 60° for external rotation and 102° for internal rotation.[25] To be completed, most tasks require humeral elevation which, in turn, requires shoulder abduction and flexion.

In this study, both groups had achieved improvement in PROM of forward flexion at three months to greater than the functional range of motion of 120°, reaching 120.6° for the intra-articular steroid group and 132.2° for the suprascapular nerve block group. However, improvement in PROM of abduction in both groups at three months fell short of the functional range of motion of 130°. Although the shoulder range of motion improvement observed in this study was passive, it is still important in enabling the patient to perform activities of daily living after neurological recovery.

Functional outcome measurements of SPADI were made in this study. Both groups showed improvement with time in outcome measures of SPADI, SPADI-pain and SPADI-disability. However, no significant differences between the two groups were observed at any point in any of the measurements. An improvement of SPADI of 10 has been demonstrated to represent significant clinical improvement.[26] In this study, the improvement of SPADI from pre-injection to three months was significant in both groups, where the scores improved by 18.6 (28.1%) in the intra-articular steroid group and 21.7 (35.1%) in suprascapular nerve block group.

Similar improvements were observed in SPADI-Pain and SPADI-Disability. For SPADI-Pain, improvement from pre-injection to three months was 29.5 (53.2%) in the intra-articular steroid group and 23.8 (46.1%) in the suprascapular nerve block group. It is interesting to note that the improvements in SPADI-pain were greater than in SPADI-disability.

These findings are similar to a randomized control trial of the efficacy of a suprascapular nerve block for chronic shoulder pain.[20] This is likely due to the fact that participants recruited in both groups were mostly chronic stroke patients with an average duration from onset of stroke to intervention of more than 15 months. These patients are less likely to have neurological recovery of the upper limb that can be translated into improvement of function and reduction of disability.

Our study showed that neither of the two injection techniques is superior in terms of pain reduction, either PROM or SPADI. However, the intra-articular steroid group had an earlier onset of the analgesic effect (at one month) compared to the other group (at three months). SPADI-Pain showed more improvement with time in both groups compared to both total SPADI and to SPADI-Disability.

A study limitation was the inadequately small sample size. Our initial sample size calculated from the effect size of a previous study was 86. However, we were only able to recruit 35 patients, of whom four were lost to follow-up. The recruitment period was interrupted from the middle of March until the end of June 2020 due to a movement control order enacted by the Malaysian government as well as to the closure of the Rehabilitation Medicine Clinic as our hospital focused its resources on managing COVID-19 patients.

It was also difficult to ensure that participants received adequate physiotherapy sessions due to the service interruptions during the pandemic. Another aspect that we were not able to control was the quantity and type of analgesics taken by patients during the study which might have influenced pain control results.

For future research, we suggest a larger sample size to more accurately demonstrate any significant differences between the two groups. It would also be interesting to include selection of participants based on the chronicity of their stroke to investigate the efficacy of intervention in both post-acute and chronic stroke and also to lengthen the follow-up to six months. We further suggest stratification of patients based on shoulder ultrasound findings.

Conclusions

This preliminary study found that neither the suprascapular nerve block nor the intra-articular steroid injection technique is superior in terms of pain reduction, passive range of motion and shoulder pain and disability index. This finding is likely due to the small sample size of only 35 patients rather than the planned 86. However, the intra-articular steroid group did show an earlier analgesic effect at one month than the suprascapular nerve block group.

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Original Article

Peripheral Arterial Disease in Coronary Artery Bypass Graft Candidates: Prevalence, Risk Factors and Functional Mobility

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ABSTRACT

Objectives: To determine the prevalence of peripheral arterial disease (PAD) among coronary artery bypass graft (CABG) candidates during the preoperative period of their surgical admission using the ankle brachial index (ABI) screening method and to evaluate risk factors, quality of life, and functional mobility.

Study design: Cross-sectional study.

Setting: Siriraj Hospital.

Subjects: Coronary artery bypass candidates.

Methods: Ankle brachial index (ABI) ≤ 0.9 was used to diagnose PAD. The four-meter walk test (4MWT) was used to evaluate functional mobility and the 36-Item Short Form Survey (SF-36) was used to evaluate quality of life.

Results: Of 192 candidates, 143 (74.5%) were male and 49 (25.5%) were female. Mean age was 64 years (SD 10). The prevalence of PAD identified by ABI screening was 12.5%. However, only 4.2% had a history of PAD. Age was the only risk factor significantly correlated with coexisting PAD in the CABG candidates. PAD risk was higher in patients of advanced age. There were no statistically significant differences between the PAD and non-PAD groups in calf pain or claudication symptoms, congestive heart failure, foot ulcers, end-stage renal disease (ESRD) or osteoarthritis of knee (OA knee). However, left ventricular ejection fraction (LVEF) was lower in the PAD group (mean 46.0, SD 20.9) than the non-PAD group (mean 55.95, SD 17.19) (p = 0.031). Time needed to complete the 4MWT was significantly higher in the PAD group (mean 6.6, SD 2.6 seconds) than non-PAD group (mean 4.9, SD 1.8 seconds) (p = 0.01). SF-36 revealed that the PAD group had a lower quality of life in the physical domain (p = 0.007).

Conclusions: PAD was identified in 12.5% of the CABG candidates. However, most cases were unrecognized. The PAD group had lower LVEF, functional mobility, physical health domain of quality of life than the non-PAD group.

Keywords: prevalence, peripheral arterial disease (PAD), coronary artery bypass, ankle brachial index (ABI), mobility, quality of life

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Introduction

Atherosclerosis is a common pathological condition of blood vessels that expresses in many important diseases such as coronary artery disease (CAD), peripheral arterial disease (PAD), and stroke[1] which share links to many of the same predisposing risk factors, e.g., age, smoking, diabetes and dyslipidemia. CAD and PAD can occur independently or can coexist in the same patient. The PARTNERS study suggested that 16% of outpatients at moderate risk of atherosclerosis have both PAD and cardiovascular disease.[2] CAD is the leading cause of death worldwide, including Thailand.[3,4] Treatments include education, lifestyle modification, medication, percutaneous coronary intervention, surgical correction and cardiac rehabilitation. Coronary artery bypass graft (CABG) is the surgical procedure used with CAD patients to relieve clinical symptoms and to increase longevity.

Cardiac rehabilitation is one of the treatments for CAD patients. Walking is an easy exercise/activity recommended for cardiac rehabilitation. However, the main clinical symptom of PAD is intermittent claudication that can limit walking or make walking difficult due to calf pain or claudication symptoms. CAD patients usually have impaired cardiac function leading to limited activity, including walking which can obfuscate a clinical diagnosis of PAD. However, PAD can now be diagnosed by non-invasive ankle brachial index (ABI) measurement.[5] Prevalence of PAD in the middle-class urban Thai population as measured by ABI was 5.2%.[6] The prevalence was much higher in patients with previous coronary or cerebrovascular events[7] as well as in hospitalized CAD patients.[8]

Hospital rehabilitation departments usually provide rehabilitation programs to improve the functional outcome of cardiac patients. A recent study of PAD patients undergoing outpatient cardiac rehabilitation had similar benefit but higher dropout rates than other patients.[9] Additionally, PAD has been demonstrated to be an independent predictor of poor long-term survival among patients undergoing CABG surgery[10]

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and was identified as an independent risk factor only for late mortality in patients undergoing isolated CABG surgery.[11] This finding emphasizes the importance of coexisting PAD. However, the prevalence of PAD in CABG candidates in Thailand has never been determined. To fill that void, we performed a cross-sectional study to determine the prevalence of PAD among CABG candidates during the preoperative period of their surgical admission using the ankle brachial index (ABI) screening method to explore the size of the population with a coexisting PAD condition. Potential risk factors and their correlation with functional mobility were also evaluated.

Methods

This cross-sectional descriptive study was conducted at Siriraj Hospital, a university-based hospital in Bangkok, Thailand. The protocol for this study was approved by the Siriraj Institutional Review Board (SIRB), Faculty of Medicine Siriraj Hospital, Mahidol University (553/2551(EC1)).

Participants

Inpatient coronary bypass candidates were invited to participate in the study during their preoperative period. All participants provided informed consent before joining the study which was conducted between January 2009 and December 2011. Patients with severe systemic illness that would have hindered assessment, those unable to communicate or unable to walk and patients who were blind were excluded.

Basic demographic and other characteristics were collected. All subjects underwent ABI screening using a non-invasive automatic device (Colin VP-2000). A diagnosis of PAD was made when ABI was ≤ 0.9.[5] Calf pain or claudication symptoms defined by the Edinburgh claudication questionnaire (ECQ)[12] were used to detect PAD. The four meter-walk test (4MWT) was performed to evaluate functional mobility. The test was performed by having patients walk at their usual pace using gait aids if needed. The better of two trials was used for analysis. Rate of perceived exertion (RPE) on a scale of 6-20 was also recorded. The self-reported short form 36-item health questionnaire (SF-36)[13] was used to evaluate quality of life.

Sample size was calculated based on the 16% PAD prevalence reported in the Hirsch AT study[2] with a 95% confidence interval and 5.5% allowable error. The calculated sample size was 171, with a 5% oversample of 180. The actual sample size in the study was 192.

Statistical analysis

PASW Statistics version 18 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Descriptive statistics were used for subject characteristics. The independent t-test was used to compare quantitative data, e.g., age and body mass index. The Chi-square test was used to compare qualitative data, e.g., gender and specific disease(s). Time for the 4MWT (in seconds) between the PAD and non-PAD group was analysed for cut-off values using the Receiver Operating Characteristic (ROC) curve. Statistical significance was accepted at $p < 0.05$.

Results

Table 1 shows the characteristics of the participants. A total of 192 participants were evaluated. The average age was 63.7 years (SD 10.2, range 27-87). There were 143 males (74.5%) and 49 females (25.5%). The prevalence of PAD determined by ABI screening (≤ 0.9) was 12.5% (95% CI, 8.5% to 17.9%). Only 4.2% of the patients had a previous history of PAD. The risk factors studied were age, sex, body mass index (BMI), smoking, diabetes mellitus, dyslipidemia, and family history of CAD. Age was the only risk factor found to be significantly correlated with coexisting PAD in the CABG candidates. PAD risk was higher in patients of advanced age (Table 2). The odds ratio in the age group over 70 years was 5.33 (95% CI, 1.62 to 17.51).

There were no statistically significant differences between PAD and non-PAD groups in congestive heart failure, foot ulcer, end-stage renal disease (ESRD) and osteoarthritis of knee (OA knee). However, the PAD group was found to have lower LVEF (mean 46.0, SD 20.9) than the non-PAD group (mean 55.95, SD 17.19) ($p = 0.031$).

Regarding calf pain or claudication as defined by ECQ, there was no statistically significant difference between the PAD and non-PAD groups. The concordance between ECQ and ABI in PAD screening was poor at only 0.163. As to functional mobility, 180 participants (93.75%) completed the 4MWT (Table 3). The mean RPE for the 4MWT of the PAD and non-PAD groups were 11.2 (SD1.4) and 10.9 (SD 1.0), respectively. There was no statistically significant difference in RPE between the groups ($p = 0.209$). During the 4MWT, the PAD group walked significantly slower (mean 6.6, SD 2.6 seconds) than the non-PAD group (mean 4.9, SD 1.8 seconds) ($p = 0.01$). Receiver operating characteristic (ROC) curve analysis revealed that the cut-off point of 6 seconds gave an odds ratio (OR) of 4.33 (95% CI, 1.62 to 11.53). However, when combined with age-adjusted analysis, the OR decreased to 3.2.

Quality of life studied using the self-reporting SF-36 revealed that the PAD group had a lower physical health domain ($p = 0.007$) but there was no significant difference in the mental health domain ($p = 0.928$) (Table1).

Discussion

The prevalence of PAD in CABG candidates was 12.5% which is similar to the prevalence of PAD in patients undergoing percutaneous coronary intervention[14] and those undergoing isolated CABG,[11] but higher than in the general population.[6,15,16] The prevalence was within the 6-14.4% range reported in diabetic patients.[17,18] Although there was relatively high prevalence of PAD identified by ABI screening, only 4.2% of the patients had been diagnosed as PAD. This sug-

Table 1. Characteristics of participants

Characteristics	Total (n = 192)	PAD (n = 24)	non-PAD (n = 168)	*p*-value
Gender[1]				
• Male	143 (74.5)	16 (66.7)	127 (75.6)	0.491
• Female	49 (25.5)	8 (25.5)	41 (24.4)	
Age (years)[2]	63.7 (10.2)	69.3 (9.8)	62.9 (10.1)	0.004*
Body mass index (kg/m^2)[2]	25.2 (4.0)	25.0 (3.8)	25.2 (4.0)	0.768
Left ventricular ejection fraction (%)[2,#]	54.8 (17.9)	46.0 (20.9)	56.0 (17.2)	0.031*
Parameters				
• History of smoking[1]	99 (51.6)	12 (50)	87 (51.8)	0.950
• Family history of CAD[1]	46 (24)	5 (20.8)	41 (24.4)	0.898
• Known history of PAD[1]	1 (0.5)	1 (4.2)	0 (0)	0.125
• Diabetes mellitus[1]	78 (40.6)	13 (54.2)	65 (38.7)	0.222
• Hypertension[1]	143 (74.5)	20 (83.3)	123 (73.2)	0.416
• Dyslipidemia[1]	162 (84.4)	22 (91.7)	140 (83.3)	0.381
• Congestive heart failure[1]	25 (13)	3 (12.5)	22 (13.1)	1.000
• Foot ulcer[1]	4 (2.1)	1 (4.2)	3 (1.8)	0.416
• End-stage renal disease[1]	2 (1)	0 (0)	2 (1.2)	1.000
• Osteoarthritis knee[1]	18 (9.4)	4 (16.7)	14 (8.3)	0.251
Claudication detected by ECQ				
• Yes[1]	26 (13.5)	6 (25.0)	20 (11.9)	0.105
• No[1]	166 (86.5)	18 (75.0)	148 (88.1)	
SF-36				
• Physical health[2]	55.6 (23.1)	43.7 (23.6)	57.2 (22.6)	0.007*
• Mental health[2]	71.3 (20.7)	70.9 (21.5)	71.3 (20.6)	0.928

[1]Number (%); [2]mean (SD); *$p < 0.05$ indicates statistical significance; #, missing data (n = 149/17/132)

CAD, coronary artery disease; PAD, peripheral arterial disease; ECQ, Edinburgh claudication questionnaire; SF-36, short form 36-health questionnaire

Table 2. Age and odds ratios of peripheral arterial disease (PAD) and non-PAD groups

Age (years)	PAD (n = 24)	non-PAD (n = 168)	Odds Ratio	*p*-value
≤ 60	4 (5.9)	64 (94.1)	1	0.002*
60-70	7 (9.7)	65 (90.3)	1.72 (0.48-6.17)	
> 70	13 (25)	39 (75)	5.33 (1.62-17.51)	

Number (%), *$p < 0.05$ indicates statistical significance

Table 3. Four meter walk test (4MWT) and rate of perceived exertion between PAD and non-PAD group (n = 180)[#]

Characteristics	Total (n = 180)	PAD (n = 20)	non-PAD (n = 160)	*p*-value
RPE	10.9 (1.1)	11.2 (1.4)	10.9 (1.0)	0.209
Time spent (seconds)	5.1 (1.9)	6.6 (2.6)	4.9 (1.8)	0.010*

[#]only 180 subjects completed test; Mean (SD); *$p < 0.05$ indicates statistical significance

gests that PAD had been previously overlooked in this group of patients.[2] The study also found no statistically significant difference in claudication pain based on ECQ between patients with PAD and the non-PAD patients. The concordance between ECQ and ABI in PAD screening was poor. This may be due to asymptomatic PAD or to some patients having low functional mobility or being unable to walk, making it difficult to accurately evaluate symptoms. ECQ has been previously reported to be insufficiently sensitive in detecting PAD.[19,20] Therefore, diagnoses that rely primarily on history taking, especially claudication pain, might fail to detect the presence of PAD. The majority of individuals seen in the cardiac rehabilitation unit were post-CABG patients.[21] These findings suggest that early PAD detection screening should be provided in cardiac rehabilitation programs to achieve better outcomes.

Age was the only risk factor found to be related to the coexistence of PAD with CAD, a situation which might be due to CAD and PAD having the same risk factors. Age is one of the non-modifiable risk factors of PAD and advanced age was found to be associated with increased risk of PAD. The prevalence of PAD increased with age.[15,22] In this study, the risk increased every decade beginning at age 60. This should remind health care providers to look for PAD in advanced age patients.

Lower LVEF, which might suggest greater cardiac impairment severity, was found in the PAD group. This is in concordance with a prior study which reported that concomitant PAD is associated with the angiographic severity of coronary atherosclerosis.[23]

Candidates who were able to perform the 4MWT reported an average RPE of about 11, which is described as fairly light, suggesting that the 4MWT can be performed safely by CABG candidates. The PAD group needed more time to complete 4MWT, an indication that they had less functional mobility. The effects of PAD or poor LVEF might be the reason for poorer 4MWT results because there were no significant differences in congestive heart failure, foot ulcer, end-stage renal disease and osteoarthritis of knee. However, the study did not collect data on other causes that could potentially impair functional mobility, e.g., peripheral neuropathy and lumbosacral radiculopathy. In cases where no ABI measurements are available, 4MWT may have a role in screening for PAD as well as monitoring for the development of PAD when times exceed 6 seconds. Abnormal 4MWT findings may also be used to help determine the need for further evaluation using other means of investigation to diagnose PAD. However, further study is needed to evaluate this suggestion.

Regarding quality of life, the PAD group had lower physical health QOL which might be due to impaired mobility. Considering the high dropout rate of PAD patients from rehabilitation programs in a previous report,[9] a focus on adherence to the program should be emphasized. The majority of patients appearing at our cardiac rehabilitation unit were in the post CABG patient group.[21] Attention should be paid to providing rehabilitation programs to improve the QOL of patients especially the ones with coexisting PAD.

This study has some limitations. As the duration of the preoperative period was limited, not all potential candidate patients could be invited to participate. Additionally, the study recruited only patients who were able to walk and to complete the self-report SF-36 and the validity and reliability of the ECQ used had not been previously evaluated. Other diseases which could potentially affect walking ability should be studied to identify additional factors related to functional mobility.

Conclusions

PAD coexisted in 12.5% of the CABG candidates. The prevalence of PAD increased with age, the only statistically significant coexistence-related risk factor. Significant issues identified included unrecognized diagnosis, lower LVEF, greater impairment in lower limb function and/or mobility and poorer physical domain of QOL. ABI screening and identification of PAD as well as methods of improving rehabilitation program adherence which could increase function and QOL in this group of patients are needed.

Disclosure

The authors report no conflicts of interest.

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Original Article

The Rate of Return to Driving after Traumatic Brain Injury in Malaysia and the Changes in Driving Behaviour

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ABSTRACT

Objectives: To examine the rate of return to driving among patients with traumatic brain injury (TBI) in Malaysia and its associated factors; and to identify the changes in their driving behavioural pattern.
Study design: A cross sectional study.
Setting: A tertiary hospital in an urban setting in Malaysia.
Subjects: TBI patients of more than six months duration with valid driving licenses, driving cars and/or riding motorcycles prior to the TBI and attended the outpatient clinic follow-up from December 2019 to June 2020
Methods: Personal and medical data were collected via face-to-face interview using a structured questionnaire and from the electronic medical record, respectively.
Results: A total of 52 patients were interviewed with the average age of 39.4 (12.7) years. The commonest cause of TBI was motor vehicle accident (MVA) (86.5%) with almost half (46.1%) of the patients returned to driving post-TBI within the range of 6 months to 17 years. Majority of the post-TBI drivers (70.8%) underwent a formal driver retraining program. This study found that both the cognitive status ($p < 0.05$, d= 0.1) and the functional status ($p < 0.05$, d = 0.1) were significantly associated with return to driving. Changes in driving behavioural pattern were reported in 70.8% of the drivers.
Conclusions: The rate of return to driving among patients with TBI is low. Hence there is a need to address the underlying barriers to return to drive in a comprehensive driving rehabilitation program post-TBI.

Keywords*:* driving, rehabilitation, traumatic brain injury, vehicle

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Introduction

Ability to drive is regarded as an instrument for a person's independence and mobility. By gaining the skills and capacities to drive, a person can participate in recreational, educational, and economical activities, return to employment, and indirectly achieve a better quality of life.[1] This statement is true across the population spectrum from the abled-body and the less-abled. Since majority of the traumatic brain injury (TBI) survivors are from the younger adult age group, ability to drive is crucial for a better community integration.[2,3] The ability to return to drive becomes increasingly important in countries like Malaysia, where the public transportation is not optimal for people with disabilities. According to a recent qualitative study, majority of the respondents from an urban area in Malaysia were not satisfied with the reliability, safety and accessibility of the public bus services available.[4]

Due to congested city roads and underdeveloped network of public transportation, the two preferred modes of transportation are compact cars and motorcycles. Between the two, motorcycle has been the most preferable, convenient, and affordable mode of transport. It is not surprising that motorcycle riders account for majority of the motor vehicle accident (MVA) victims and fifty eight percent of transport fatalities in Malaysia are from motorcycle accidents.[5] Therefore, to suit the local context, we defined return to driving as the ability to driving cars and/or riding motorcycles.

The ability to drive in persons with TBI is affected in many ways.[6] There are common complications post-TBI which are absolute contraindications to return to driving such as seizure and visual impairments, e.g., homonymous hemianopia and diplopia.[7,8] Relatively, persons with TBI can have some degree of cognitive deficit, balance impairments, paretic limbs and poor coordination[9] which hinder them from return to driving fully. Psychological and environmental factors such as fear, lack of confidence, post-traumatic stress disorder and denial by concerned family members to allow return to driving are also important reasons affecting their ability to return to drive.[2]

A previous study conducted in New Jersey, United States reported that as high as 85% of persons with TBI were able to return to driving.[3] There is no information available for the post-TBI drivers in Malaysia or its neighbouring countries. Therefore, the purpose of this study was to investigate the rate of return to driving in persons with TBI in Malaysia. We

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also wish to explore the associated factors of returning to drive and identify the driving behavior changes in TBI survivors.

Methods

The present study was approved by University Malaya Medical Center (UMMC) Medical Research Ethics Committee, identification number: 2019429-7366.

Participants

TBI patients who attended the outpatient specialist Brain Injury Rehabilitation clinic follow-up in UMMC, Malaysia from December 2019 to June 2020 were screened.

The inclusion criteria were age over 18 years old, history of TBI of more than 6 months, having a valid license and driving cars and/or riding motorcycles prior to TBI. The exclusion criteria were having concomitant physical disabilities other than TBI and acute ongoing medical illness.

Materials

The data was collected using a self-constructed questionnaire that was specifically designed based on the objectives of this study. The questionnaire has four sections: the first three sections consist of patients' demographic data, disease-specific characteristics and patients' driving exposure respectively, while the fourth part explores return to driving experience.

Study protocol

A pilot study using the questionnaire was conducted on 10 patients and necessary modifications were made after getting feedbacks from the patients. The principal investigator administered the questionnaire personally after consent was obtained via face-to-face interview with the patients. The average length of time for each interview was 10 minutes.

Each patient was informed of the objectives, confidentiality, and voluntary participation of this study. The patients' medical data was cross-checked with their Electronic Medical Record (EMR).

Statistical analysis

The descriptive analysis for categorical variables were expressed in frequencies and percentages. Post-TBI drivers and ex-drivers were assessed with regards to their demographic, biographical and medical characteristics using chi-square tests and independent sample t-tests. All statistically significant independent variables ($p < 0.05$) were evaluated to tease out collinearity. We then calculated the predictive power (effect Size) using Cohen's d formula using the univariate analysis.

Results

Seventy-one patients from the clinic were identified from Dec 2019 to June 2020. Nineteen patients were excluded because of these reasons: 16 did not fulfil the inclusion criteria, two have other concomitant physical disabilities other than TBI such as spinal cord injuries and traumatic amputations and one have an acute medical illness.

In total, 52 patients were recruited in this study. We were unable to proceed with the recruitment as planned earlier, due to the sudden national lockdown. The study centre was designated as one of the major covid-19 hospitals in the country and the time constraint to complete the study.

The mean age at the time of interview was 39.4 (12.7) years old. The youngest and oldest patients was 19 years old and 70 years old, respectively. The mean age at TBI was 35.9 (13.7) years old. The mean duration since TBI was 3.5 years (4.5) years. The male to female ratio was approximately 6:1 (45 males, 7 females). Slightly more than half (57.7%) of the patients were Malay and married (55.8%). The demographic and disease-specific characteristics are shown in Table 1.

Return to driving

All patients were driving/riding prior to TBI in which 21 of them (40.4%) rode motorcycles only, 14 (26.9%) drove cars

Table 1. Baseline demographic characteristics

Variables	N (%)
Sex	
Male	45 (86.5)
Female	7 (13.5)
Race	
Malay	30 (57.7)
Indian	13 (25.0)
Chinese	9 (17.3)
Marital status	
Married	29 (55.8)
Single	16 (30.8)
Separated	7 (13.5)
Educational level	
Tertiary	23 (44.2)
Secondary	19 (32.7)
Primary	10 (23.1)
Employment status	
Employed	39 (75.0)
Unemployed	9 (17.3)
Student	4 (7.7)
Etiology of injury	
MVA	45 (86.5)
Fall	4 (7.7)
Others	3 (5.8)
Severity of injury	
Severe	42 (80.8)
Moderate	6 (11.5)
Mild	4 (7.7)
Complications post-TBI	
Cognitive	41 (78.8)
Physical	35 (67.3)
Behaviour	22 (42.3)
Speech, language, hearing and taste	22 (42.3)
Vision	17 (32.7)
Others	6 (11.5)

MVA, motor vehicle accident; TBI, traumatic brain injury

Table 2. Factors associated with return to driving post-traumatic brain injury.

Variables	Drivers (n = 24)	Ex-drivers (n = 28)	*p*-value
Sex			
Male	20	25	0.690
Female	4	3	
Educational level			
Tertiary	13	10	0.162
Secondary	9	10	
Primary	2	8	
Employment status			
Employed	20	18	0.358
Unemployed	3	7	
Student	1	3	
Severity of injury			
Severe	18	24	0.519
Moderate	3	3	
Mild	3	1	
Length of coma			
Weeks	11	21	0.211
Days	5	3	
Hours	4	2	
NA	4	2	
Cognitive status (MoCA score)			
Normal (26-30)	18	11	0.002*
Mild impairment (18-25)	6	7	
Moderate/severe impairment (< 18)	0	10	
Functional Status (MBI score)			
Normal independency level (100)	19	11	0.002*
Minimal independency level (91-99)	4	5	
Moderate/severe independency level (< 91)	1	12	
Current age			
Mean (SD)	36.5 (9.9)	41.8 (14.5)	0.131
Age at TBI			
Mean (SD)	33.0 (10.2)	38.4 (15.9)	0.166
Age at license achievement			
Mean (SD)	20 (2.6)	22 (4.3)	0.056
Years of driving pre-TBI			
Mean (SD)	15 (10.4)	18.8 (14.5)	0.297
Years post-TBI			
Mean (SD)	3.5 (3.3)	3.6 (3.9)	0.970

NA, not applicable; MoCA, Montreal Cognitive Assessment; MBI, Modified Barthel Index; SD, standard deviation; MVA, motor vehicle accident; TBI, traumatic brain injury

*$p < 0.05$ is considered significant

only and another 17 (32.7%), both. The mean duration of driving pre-TBI was 17 (12.8) years and the mean age at driving license achievement was 21.1 (3.8) years old. Out of the 52 patients, 24 (46.2%) returned to driving after the TBI. However, one patient stopped driving recently due to newly diagnosed amnesia. From those who return to driving, 17 (70.8%) attended the formal driving retraining program prior to on-road driving.

From 24 patients with TBI who returned to driving (classified as drivers); 18 had severe TBI, three had moderate TBI and another 3 had mild TBI. From the 17 patients with normal cognitive status and returned to driving; 13 had severe TBI, four had moderate TBI and one had mild TBI. From the 19 patients who were functionally independent and returned to driving, 14 had severe TBI, three had moderate TBI and another two had mild TBI.

For those who were unable to return to driving (classified as ex-drivers); 24 had severe TBI, three had moderate TBI and one had mild TBI.

Factors influencing return to driving

Patients with TBI who achieved normal cognitive status (Montreal Cognitive Assessment (MoCA) score > 25) were significantly ($p < 0.05$) associated with return to driving as compared to those who had mild to severe cognitive status. Patients with TBI who were functionally independent (Modified

Barthel activity daily living Index (MBI) score of 100) were also significantly ($p < 0.05$) associated with return to driving as compared to those who needed some degree of assistance in their activities of daily living. The Cohen's effect size values for both MoCA score and MBI score suggested a small practical significance (d = 0.08 and d = 0.07 respectively). Other demographic descriptions were not significantly associated with return to driving as shown in Table 2.

Changes in driving behaviour

Majority of the patients (94.2%) were driving daily prior to TBI. Table 3 shows the driving behavioural changes for those who resumed driving. Only three drivers reported accidents post-TBI and these accidents were minor. The frequency of driving post-TBI were reduced with less than one third (26.9%) of drivers maintaining daily driving. More than two-thirds of the drivers reported changes in their driving behaviour post-TBI. Among those who reported changes in their driving behavioural pattern, almost one third (29.2%) of drivers reported avoidance from driving into cities, rush hour and unknown places whilst another quarter (25%) reported driving only during daytime post-TBI. Six out of the twenty-four drivers (25%) were unable to return to ride motorcycles and preferred to only drive cars, although they were able to ride motorcycles and drive cars before TBI.

Barriers to return to driving

Patients who did not return to driving (n = 28) were asked to state the most important barrier that prevented them from doing so. The most reported barrier by ex-drivers (67.9%) were permanent residual impairments post-TBI (including limb paresis, visual deficits, cognitive impairments, limb and seizure) followed with fear and phobia (17.9%) as well as denied by concerned family members (10.7%) as shown in Table 4. All the patients without permanent residual impairments have normal or only mild impairments in cognitive status and similarly, have normal or only minimal dependency function.

Table 3. Driving behaviour changes post-traumatic brain injury

Driving behaviour	n (%)
No changes	7 (29.2)
Avoidance of cities, rush hour, unknown places	7 (29.2)
Only drives during daytime	6 (25.0)
Stops riding a motorcycle and only drives a car	6 (25.0)
Driving more slowly	5 (20.8)
Others	1 (4.2)

Table 4. Barriers to return to driving

Reasons not returning to drive	Permanent residual impairments (n = 19)	Other barriers (n = 9)
Current age, mean (SD)	42.4 (13.9)	40.6 (16.4)
Age at TBI, mean (SD)	38.1 (15.7)	39.0 (12.3)
Severity of TBI, n (%)		
Severe	16 (57.1)	8 (28.6)
Moderate	2 (7.1)	1 (3.6)
Mild	1 (3.6)	0 (0)
Cognitive status (MoCA score), n (%)		
Normal (26-30)	4 (14.3)	7 (25.0)

TBI, traumatic brain injury; MoCA, Montreal Cognitive Assessment

Discussion

This is the first study in Malaysia examining the rate of return to driving after TBI, the factors associated with return to driving and exploring the driving behavioural changes. From the literature, the rate of return to driving post-TBI ranged between 36 to 85 percent.[2,3,10-12] In this study, we found a lower rate with 46% of persons with TBI returned to drive. This is similar to findings observed in Michigan, United States[2] and in Warwick, United Kingdom[11] which reported a rate of 39 and 36 percent, respectively. These studies have similar patients to ours with majority of them suffered moderate to severe TBI (74.5% and 89.2%). We expected that persons with more severe form of TBI to have less likelihood of returning to driving, especially if we examined them early after TBI. Thus, it is not surprising that the proportion of people with severe TBI who did not return to drive was higher compared to those who returned to drive (85% vs 75%).

TBI severity alone was not shown to consistently predict return to driving, especially in the longer follow-up period. Persons with mild TBI are known to return to driving earlier,[13] however Novack et al.[14] found that the severity of TBI was not a major factor to return to driving after 5 years. This study has shown that the ability to return to driving were significantly associated with normal cognitive status and being functionally independent in personal activity of daily living (ADL) despite the initial TBI severity. These findings are in line with other reports.[11,12,15] We measured the persons with TBI cognitive and functional statuses during outpatient clinic follow-up, with the mean duration of 3.5 years post-TBI. In the study by Cullen et al.,[12] persons with TBI cognitive and functional statuses were measured at rehabilitation admission around two months post-TBI and reported them to be significant predictors for return to driving. Other studies which examined the sociodemographic profiles and driving experiences pre- and post-TBI have found conflicting results with return to driving after TBI.[10,14,16,17]

Among the twenty-four drivers who returned to driving, seventeen (70.8%) underwent the driving assessment and passed. In Malaysia, the national guideline on the requirement of return to non-commercial driving after a disability (including TBI) includes assessment by a physician according to the Medical Examination Standards for Disable Driver's Licensing by the Ministry of Health Malaysia.[7] On-road driving assessment is not a formal procedure for driving assessment after TBI in Malaysia. To ensure the safety of the persons with TBI when they resume driving, we also advised for a full evaluation by the clinicians which include a set of cogni-

tive assessments related to driving and a driving simulator testing. In this study, we did not examine the association between the driving simulator test results and the driving behaviour pattern because of the small sample size.

Most of our drivers (70.8%) reported changes in driving behaviour pattern post-TBI. These patterns were also observed in another study.18 These changes are expected in persons with TBI who suffered some degrees of medical, cognition, physical and emotional complications as driving is a complex activity. It is interesting to highlight that six out of twenty-four drivers (25%) reported that they were unable to return to riding motorcycles and preferred to driving cars instead, although they were able to ride motorcycles before TBI.

We believe the reason for this preference is because riding a motorcycle is distinctly different than driving a car. A motorcycle rider needs to have a better balance and posture to control the vehicle as well as the passenger (pillion rider). Motorcycle rider is also viewed to have more exposure to driving hazards in contrast to a car driver. We believe that having a riding simulator in the country would have increased the confidence to return to riding among persons with TBI. However, there is no literature examining a riding simulator's role in return to riding motorcycles.

More than half (54%) of the persons with TBI in our study did not return to driving. Permanent residual impairments were identified as the most common barrier in this study. Permanent residual impairments reported include both absolute contraindications (post-traumatic seizure, visual deficit and cognitive impairment) and relative contraindications (limb paresis and imbalance). About thirty percent of the barriers reported were not directly related to impairments after TBI. These were reported in patients who have normal or mild impairment in cognition and function.

They were prevented from driving by concerned family members and significant others. Coleman et al.[17] have reported that the perceptions of driving fitness by significant others are only modestly related to actual driving ability. An education program and family reassurance may improve the likelihood of driving in certified drivers. Fear of driving was another barrier to driving. A formal screening to rule out post-traumatic stress disorder or excessive fear and anxiety is warranted in patients who did not return to drive despite no significant residual impairments. The screening can be conducted as part of the driving assessment by the clinicians mentioned earlier. These patients can be referred for the necessary treatment and intervention.

This study has its own limitation, it is a cross sectional study with a small sample size due to the sudden lockdown in the country. There is also a selection bias as this study was conducted in a single urban tertiary centre, which manages the more severe TBI population and has a driving rehabilitation unit, thus the result of this study needs to be carefully generalised. This study population may be more representative of the moderate to severe TBI population since we have a very small number of mild TBI survivors.

Prospective research can also compare the components of driving assessment results of both drivers and ex-drivers. Validated questionnaires can be utilized to explore driving behaviours, for example the Driving Behaviour Questionnaire,[19-21] and the barriers to driving for example, the Barriers to Driving Questionnaire.[2]

Conclusions

This study has shown that the rate of return to driving is relatively low among Malaysians with TBI. However, the rate is not different from previous study in other countries, and this could be largely attributed to the severity of the brain injury among the survivors and the severe complications that they have. Driving requires a seamless interaction of wide range cognitive skills. In addition, factors such as driving license regulation after brain injury, personal and familial risk perception, and professional and economic necessities need to be addressed to facilitate return to driving post TBI. A comprehensive driving rehabilitation program which addresses all the factors may improve the rate of returning to drive after TBI in each center.

Disclosure

The authors declare no conflict of interest of any kind.

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Original Article

Known-Group Validity and Inter-Rater Reliability of the Dynamic Loewenstein Occupational Therapy Cognitive Assessment (DLOTCA) - Thai Version

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ABSTRACT

Objectives: To investigate the known-group validity and inter-rater reliability of the Dynamic Loewenstein Occupational Therapy Cognitive Assessment (DLOTCA) - Thai version.

Study design: Descriptive cross-sectional design.

Setting: Four hospitals and four community rehabilitation centers in Chiang Mai province, Thailand.

Subjects: Thirty-seven patients with cognitive impairment and 37 healthy subjects were recruited by using the purposive sampling method.

Methods: The DLOTCA - Thai version was administered to the subjects. People with cognitive impairment were evaluated by two occupational therapists. The known-group validity was determined by using a comparative design between the groups with the Mann-Whitney U test and within the groups with the Wilcoxon signed-rank test. The reliability between the two raters was analyzed by using the intra-class correlation coefficient (ICC).

Results: The DLOTCA - Thai version successfully differentiated the pre-mediation scores between the two groups. People with cognitive impairment showed lower cognitive abilities and needed higher levels of mediation. Significant differences were found between the pre- and post-mediation scores within each group, which indicated high known-group validity of the DLOTCA - Thai version. The ICC between the two raters ranged from 0.914 to 1.000 that showed the high inter-rater reliability of the instrument.

Conclusions: From the results of the high degree of the known-group validity and inter-rater reliability, the DLOTCA - Thai version is an effective tool for identifying cognitive abilities in neurological dysfunction with cognitive impairment in clinical settings. This assessment tool also suggests potential change and provides an indication of the level of mediation that would benefit cognitive intervention.

Keywords: Dynamic Loewenstein Occupational Therapy Cognitive Assessment, cognitive impairment, psychometric property, neurological dysfunction, occupational therapy

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Introduction

Cognitive impairment is frequently found in people with brain damage; such as, stroke and traumatic brain injury (TBI).[1-3] This impairment leads to complications in the setting of the treatment goals, planning of intervention programs, and estimation of the rehabilitation outcomes.[4-6] Therefore, the early detection of cognitive impairment in patients with neurological dysfunction would benefit the therapists in setting suitable goals and appropriate intervention for their clients. In addition to physical assessment, cognitive evaluation is very important and requires an accurate and reliable assessment tool.[7]

The conventional cognitive assessment tools are static and provide information only about the clients' cognitive abilities and impairments, while dynamic cognitive assessment tools have been developed to address the learning potential and cues, which have helped therapists to improve the skills and intervention planning for their clients.[8-13]

The Dynamic Loewenstein Occupational Therapy Cognitive Assessment (DLOTCA) is one of the standardized cognitive functional assessment tools, which is popularly used in occupational therapy practice. The DLOTCA was developed from the Loewenstein Occupational Therapy Cognitive Assessment (LOTCA), a static assessment tool to become a dynamic one, in order to gather information about the quantity of a client's cognitive abilities and impairments. It is also used to identify the learning potential and recognize thinking strategies through the use of mediation. These strategies can help estimate the ability to learn or understand the type of information that a person requires for the optimal performance of a task and develop effective intervention planning.[8-13] The DLOTCA has been developed to assess individuals aged 18-69 years with neurological dysfunction, and has been studied for reliability and validity in various populations. The findings supported the construct validity, thus demonstrating the high efficiency to differentiate the responses between people with cognitive impairment and healthy people. In addition, the

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results showed excellent inter-rater reliability and moderate to excellent internal consistency.[10,14] The DLOTCA is a battery test that consists of 28 items in seven cognitive domains comprising Orientation, Awareness, Visual Perception, Spatial Perception, Praxis, Visuomotor Construction, and Thinking Operation. The DLOTCA can assess cognitive functions and cover more aspects than other dynamic assessment tools, e.g., Contextual Memory Test (CMT) and Toglia Category Assessment (TCA), where they can only evaluate the memory and categorization functions.[10,14-17]

The DLOTCA was initially developed in Israel and has since been translated into many languages in other countries like Denmark and Portugal in order to use this tool in different cultures and contexts, as well as to decrease any errors in the assessment process.[18,19] To the authors' knowledge, there is no standard test of the cognitive function in the Thai language. The authors, therefore, were interested in exploring the psychometric property of the DLOTCA - Thai version in terms of known-group validity and inter-rater reliability.

Methods

Subjects

The sample size in the present study was calculated by the G*power 3.1 program that configured the effect size = 0.8, error probability = 0.05, and power of the test = 0.95.[20] The effective numbers of the subjects were 74. The subjects were recruited by the purposive sampling method from eight settings in Chiang Mai province, Thailand: 1) Maharaj Nakorn Chiang Mai Hospital, 2) Chiang Mai Neurological Hospital, 3) McCormick Hospital, 4) Sarapeeborvonpattana Hospital, 5) Nong Pa Khrang Rehabilitation Center, 6) Nong Khwai Rehabilitation Center, 7) San Klang Rehabilitation Center, and 8) San Pong Rehabilitation Center. The 74 subjects were divided into two groups consisting of 37 healthy adults and 37 patients with cognitive impairment. Inclusion criteria for the subjects with cognitive impairment were: 1) been diagnosed with stroke or TBI, 2) aged 18 - 69 years, and 3) had cognitive impairment when assessed by the Mental State Examination T10 (MSET10). The inclusion criteria for the healthy adult group were to have a normal cognitive function when assessed by the MSET10. Both the healthy adults and cognitive impairment subjects could understand the Thai language and could follow three instructions. The exclusion criteria were: 1) had hearing loss or uncorrected visual problems by asking from their caregivers, 2) been diagnosed with psychosis or depression as seen from the patients' medical records or by asking from their caregivers, and 3) had drowsiness by observing their behavior during the screening phase.

Materials

1. *The DLOTCA - Thai version:*

Before the translation and adaptation process began, the authors sent an e-mail to Dr. Noomi Katz, the original DLOTCA' s author, to request permission for the process of translation. After receiving permission, the authors started the process of the translation and adaptation of the instrument proposed by the World Health Organization (WHO). This process consisted of forward translation, the expert panel, back-translation, expert panel discussion, and pretesting.[21] In the first process, the English version of the DLOTCA was translated to the initial Thai version by the translator, an occupational therapist who was knowledgeable in the English and Thai languages, and familiar with the DLOTCA battery. Next, the authors and the forward translator discussed solving the inconsistent expressions of the translation and concluded it to be a forward Thai version. In the back-translation step, the forward Thai version was translated into English by the back-translator, a psychologist who was knowledgeable in the Thai and English languages, but unfamiliar with the DLOTCA. For the expert panel discussion that included the authors and translators, the discrepancies between the back-translation version and the original version were solved for conceptual and semantic equivalence. In this step, some words and some sentences were changed for appropriateness with the Thai culture for clarity. This completed the DLOTCA pretesting Thai version. In the pretesting phase, 10 healthy adults and 10 patients with cognitive impairment were recruited. They were aged 18-69 years, able to understand the Thai language, and could also follow the three instructions. The first author administered the DLOTCA pretesting version to these respondents and asked them which words or instructions were unclear. In this process, only two sentences in the Visuomotor Construction and Thinking Operations domains needed to be altered. After these five steps, the final DLOTCA - Thai version was produced.[22]

The DLOTCA - Thai version was a battery of tests consisting of a test booklet and test kits. It was administrated for 45-90 minutes depending on the amount of mediation needed. In case subjects were unable to complete the assessment in one session, it was possible to administer this test in more than one session within a reasonable time.

The DLOTCA - Thai version contained 28 subtests in seven cognitive domains. The first one, Orientation (O), consisted of two subtests composed of four questions for Orientation to Place (OP) and four questions for Orientation to Time (OT). Each question had a score of 0-2. The second one, Awareness (A), comprised three questions to examine the reason for hospitalization, recognition of cognitive impairment before testing, and after testing. Each question had a score of 1-3. The Awareness domain was administered only to the cognitive impairment group and also calculated for inter-rater reliability. The third one, Visual Perception (VP), contained three tasks for recognizing familiar objects (Object Identification), overlapping objects (Figure-ground) and objects at a different angle (Object Constancy). Each task had a score of 1-4. The fourth one, Spatial Perception (SP), comprised three subtests composed of awareness of their own body (Direction on the Client's Body), recognizing the position of objects around them (Spatial Relations), and recognizing

the position of objects in a picture (Spatial Relationships in a Picture). Each question had a score of 0-1. The fifth one, Praxis (P), had three subtests consisting of imitating movements (Motor Imitation), demonstrating how to use familiar objects (Utilization of Objects), and gesturing to use an object (Symbolic Actions). Each instruction had a score of 0-2. The sixth domain, Visuomotor Construction (VC), was composed of seven subtests comprising copying geometric shapes (Copying Geometric Forms), rebuilding the design from the model (Reproduction of a Two-dimensional Model), reconstructing the pattern on the board with pegs (Pegboard Construction), rebuilding the design with color blocks (Colored Block Design), rebuilding the design with the plain blocks (Plain Block Design), rebuilding the puzzle design (Reproduction of a Puzzle), and filling the numbers on a clock face by pointing the hands to 11:10 (Drawing a Clock). Each subtest had a score of 1-5. The last one, Thinking Operations (TO), consisted of eight subtests of sorting 14 cards of objects into groups (Categorization), sorting 18 plastic pieces into groups (ROC Unstructured), arranging five pictures in the correct sequence (Pictorial Sequence A), arranging six pictures in the correct sequence (Pictorial Sequence B), drawing the correct geometric shapes in sequence (Geometrical Sequence A), drawing the correct number and position of arrows in a sequence (Geometrical Sequence B), four questions of calculation (Verbal Mathematical Questions), and arranging 18 plastic pieces into groups as shown in the example (ROC Structured). Each subtest had a score of 1-5, except the Verbal Mathematical Questions that had a score of 0-1.

Each subtest, except for Orientation and Awareness, had a set of structured mediations from general to specific cognitive strategies. There were detailed options for each level of mediation where the evaluator could select the best option for the client to improve their performance. The Visual Perception, Spatial Perception, and Motor Imitations subtests of the Praxis domains had a structure of four mediation options, while the rest had a structure of five mediation options. The ranges from one to five were: 1) General intervention; 2) general feedback; 3) specific feedback; 4) partial intervention; and 5) stimuli reduction.

The scoring consisted of three components for each subtest, except Orientation and Awareness. The first one was a basic pre-mediation score. This was a static score in which higher scores indicated better performance. The second one was a dynamic mediation score. This was given in the case of a participant needing some cognitive strategies to understand or to do the task correctly or completely. This score then indicated the level of information required. The last one, a post-mediation score, was given to test the participant's ability to repeat the original task after mediation. Higher scores indicated better performance. If a participant needed no mediation, the post-mediation score equaled the pre-mediation score.[10]

2. The Mental State Examination T10 (MSET10):

This instrument was recommended as a cognitive screening test. The sensitivity of the MSET10 was 100%, and its specificity ranged from 98.40% to 99.40%. It had ten subtests. The first subtest, Orientation to Time, contained five questions about time awareness. The second subtest, Orientation to Place, contained five questions about place awareness. The third area was Registration consisting of a question for repeating three words. For the fourth area, Attention and Calculation, an examiner chose only one of two questions depending on the person's ability to make a calculation or spell a word. The fifth area was Recall that the examiner asked the client to repeat the names of three things being heard beforehand. The sixth area, Naming, was about the recognition of two familiar objects. The seventh area was to test the ability to exactly repeat a sentence. The eighth area was to examine following three commands. The ninth area was to test following a reading command. The last one was writing, where the examinee was asked to write a sentence. The highest scores were 29. The cut-off scores for the interpretation of the MSET10 results were divided into three categories depending on the educational level of the examinee. Firstly, a score less than 15 indicated having an impaired cognitive function for no education or illiterate people. Secondly, a score less than 18 was considered as an impaired cognitive function for people who graduated from primary school. Lastly, a score less than or equal to 22 was considered as cognitive impairment for those who finished at a higher level than primary school.[23]

Study protocol

The multisite studies were ethically approved by three institution research boards comprising the Board of the Faculty of Associated Medical Sciences, Chiang Mai University, the Board of Maharaj Nakorn Chiang Mai Hospital, and the Board Chiang Mai Neurological Hospital. Before screening the subject, the first author gave the research project information to each subject and then requested them to sign the consent form. Next, the first author firstly recruited the patients with cognitive impairment, and then the healthy people according to the inclusion and exclusion criteria.

For studying the known-group method, the patients with cognitive impairment and the healthy people were individually assessed by the first author with the DLOTCA - Thai version. When the first author assessed the cognitive abilities of the patients with cognitive impairment, the research assistant, an occupational therapist with at least three years of experience working with neurological patients and who had received DLOTCA scoring training with the manual, gave a score to each subject separately from the first author to study the inter-rater reliability.[24,25]

Statistical analysis

The frequency and percentage of the demographic data were presented and tested for the homogeneity between

those of the cognitive impairment group and those of the healthy group by using the chi-square test. The mean, standard deviation, median, and interquartile range were calculated to express the cognitive performance and levels of mediation for each group in studying the known-group validity. This was because the cognitive scores were not distributed in a normal curve, the Mann-Whitney U test; thus, was used to analyze the difference of the domain scores between groups. Furthermore, the Wilcoxon-signed rank test was calculated to test the change from the pre- to post-mediation scores within the group in all domains, except on Orientation and Awareness. The ICC was used to analyze the inter-rater reliability.

Results

In the study of the known-group validity, 37 clients with cognitive impairment and 37 healthy adults were purposively recruited. Most of them were aged 60-69 years, had completed elementary education, and worked in commerce and service occupations. Moreover, the age, education level, and occupation type in both groups showed no differences (Table 1). In addition, only 37 clients with cognitive impairment were included for testing the inter-rater reliability.

Known-group validity

The mean, standard deviation, median, and interquartile range of the pre-mediation cognitive scores of each group are presented in Table 2. The comparison of the scores between the two groups by the Mann-Whitney U test revealed that there was a significant difference in the pre-mediation scores in all domains between the groups. In addition, the results revealed that healthy participants achieved maximum scores on Orientation, Spatial Perception, and Praxis. They also got a near maximum score on Visual Perception, Visuomotor Construction, and Thinking Operation. However, clients with cognitive impairment received maximum scores only on Spatial Perception. These scores indicated that clients with cognitive impairment had lower cognitive performance than healthy participants.

The mean, standard deviation, median, and interquartile range of the mediation scores in all domains are presented in Table 3. The mediation scores between the groups of clients with cognitive impairment and healthy adults who needed mediation displayed significant differences in all domains. The healthy adults needed low levels of mediation (general intervention and general feedback) in all domains except in Visual Perception and Verbal Mathematical Questions. For these two domains, the healthy adults needed higher levels of mediation (partial intervention). The clients with cognitive impairment needed the highest levels (partial intervention and reduced amount) of mediation in all domains.

Moreover, the mean, standard deviation, median, interquartile range and comparison of the pre- with the post-mediation cognitive scores within the groups of participants

Table 1. The demographic data of the age, education level, and occupation type of the people with cognitive impairment and healthy adults in the construct validity measurement (n = 74; 37 in each).

	Demographics	No. of persons (%)		*p*-value
		Cognitive impairment group	Healthy adults	
Age (years)	Less than 60	18 (48.60)	17 (45.90)	0.817
	60-69	19 (51.40)	20 (54.10)	
Education	Elementary level	24 (64.90)	24 (64.90)	1.000
	Secondary level or upper	13 (35.10)	13 (35.10)	
Occupation	Agriculture	4 (10.80)	4 (10.80)	1.000
	Commerce and services	32 (86.50)	32 (86.50)	
	Student	1 (2.70)	1 (2.70)	

*$p < 0.05$ by chi-square test

Table 2. Comparison of the pre-mediation cognitive scores between the cognitive impairment and healthy group (n = 74; 37 in each).

Cognitive domains[a]	Pre-mediation cognitive scores[b]								Z-score	*p*-value
	Cognitive impairment group				Healthy adults					
	M	SD	Me	IQR	M	SD	Me	IQR		
O (0-2)	1.28	0.47	1.25	1.69-1.06	2.00	0.00	2.00	2.00-2.00	-7.58	< 0.001*
VP (1-4)	2.72	0.67	3.00	3.17-2.33	3.61	0.15	3.67	3.67-3.67	-6.97	< 0.001*
SP (0-1)	0.62	0.21	1.00	1.00-0.86	0.94	0.05	1.00	1.00-1.00	-7.07	< 0.001*
P (0-2)	1.23	0.42	1.33	1.50-1.00	1.96	0.07	2.00	2.00-1.92	-7.21	< 0.001*
VC (1-5)	2.29	1.13	2.00	3.36-1.21	4.37	0.39	4.43	4.64-4.14	-6.72	< 0.001*
TO (1-5)	1.83	0.91	1.43	2.57-1.14	4.12	0.40	4.14	4.50-3.86	-7.19	< 0.001*
VQ (0-1)	0.05	0.15	0.00	0.00-0.00	0.51	0.35	0.50	0.86-0.25	-6.23	< 0.001*

[a]O, orientation; VP, visual perception; SP, spatial perception; P, praxis; VC, visuomotor construction; TO, thinking operations; VQ, verbal mathematical questions; [b]M, mean; SD, standard deviation; Me, median; IQR, interquartile range; *$p < 0.05$ by the Mann-Whitney U test (1-tailed).

revealed significant differences in the cognitive scores between the post- and pre-mediation in all domains (Tables 4 and 5). These scores indicated that cognitive abilities could be improved through the mediation process.

Inter-rater reliability

In an inter-rater reliability study, the intra-class correlation coefficient (ICC) was calculated for a subsample of 37 clients with cognitive impairment. As shown in Table 6, the correlations of the pre- and post-mediation scores and level of medication given by the two raters were between .914 to 1.000. These scores addressed the consistency of the implementation of the rating system.

Discussion

The known-group validity analysis of the DLOTCA - Thai version revealed that the pre-mediation scores between the groups had statistically significant differences on all domains at the level of 0.05. This supported the construct validity by discriminating between the groups of healthy adults and those of the cognitive impairment clients. This also strengthened the fact that this assessment tool was designed for identifying both the basic and higher cognitive abilities and limitations of a client suffering from neurological dysfunction in clinical practice.[10,14] In addition, clients with cognitive impairment received lower scores than healthy adults in all domains. These scores confirmed that the cognitive impairment clients had lower cognitive abilities than healthy people. The results

Table 3. Comparison of the mediation scores between clients of the cognitive impairment group and healthy group who needed mediation

Domains[a]	Mediation Scores[b]										Z-score	*p*-value
	Cognitive impairment group					Healthy adults						
	N	M	SD	Me	IQR	N	M	SD	Me	IQR		
VP	37	3.48	0.58	4.00	4.00-3.00	36	3.88	0.37	4.00	4.00-4.00	-3.38	0.001*
SP	36	3.24	0.95	3.76	4.00-2.50	22	1.86	0.71	2.00	2.00-1.00	-4.62	< 0.001*
P	36	3.34	0.92	3.41	4.11-2.61	12	1.99	0.76	2.00	2.83-1.13	-3.79	< 0.001*
VC	37	4.18	0.96	4.57	5.00-3.69	35	2.07	0.64	2.00	2.60-1.60	-6.42	< 0.001*
TO	37	4.43	0.57	4.57	5.00-4.07	37	2.53	0.55	2.50	3.00-2.00	-7.28	< 0.001*
VQ	37	4.64	0.53	5.00	5.00-4.25	28	3.43	1.15	4.00	4.33-2.63	-4.93	< 0.001*

[a] VP, visual perception; SP, spatial perception; P, praxis; VC, visuomotor construction; TO, thinking operations; VQ, verbal mathematical questions; [b]M, mean; SD, standard deviation; Me, median; IQR , interquartile range; *$p < 0.05$ by the Mann-Whitney U test (2 tailed).

Table 4. Comparison of the post-mediation cognitive scores with the pre-mediation cognitive scores in the cognitive impairment group (n = 37).

Domains[a]	Cognitive scores[b]								Z-score	*p*-value
	Pre-mediation				Post-mediation					
	M	SD	Me	IQR	M	SD	Me	IQR		
VP	3.14	0.71	3.33	3.67-3.00	3.68	0.05	3.67	3.67-3.67	-4.46	< 0.001*
SP	0.78	0.18	0.75	0.92-0.67	0.99	0.03	1.00	1.00-1.00	-4.70	< 0.001*
P	1.70	0.39	1.83	2.00-1.63	2.00	0.00	2.00	2.00-2.00	-5.23	< 0.001*
VC	3.06	1.38	3.43	4.29-1.71	5.00	0.00	5.00	5.00-5.00	-4.79	< 0.001*
TO	2.68	1.16	3.00	3.64-1.43	4.99	0.47	5.00	5.00-5.00	-4.79	< 0.001*
VQ	0.05	0.15	0.00	0.00-0.00	0.57	0.46	0.75	1.00-1.00	-4.47	< 0.001*

[a]VP, visual perception; SP, spatial perception; P, praxis; VC, visuomotor construction; TO, thinking operations; VQ, verbal mathematical questions; [b]M, mean; SD, standard deviation; Me, median; IQR, interquartile range; *$p < 0.05$ by the the Wilcoxon signed-rank test (2 tailed).

Table 5. Comparison of the pre-mediation cognitive scores between the cognitive impairment and healthy group (n = 74; 37 in each).

Cognitive domains[a]	Cognitive scores[b]								Z-score	*p*-value
	Pre-mediation				Post-mediation					
	M	SD	Me	IQR	M	SD	Me	IQR		
VP (1-4)	3.61	0.15	3.67	3.67-3.67	3.68	0.05	3.67	3.67-3.67	-2.65	0.008*
SP (0-1)	0.94	0.05	0.92	1.00-0.92	1.00	0.03	1.00	1.00-1.00	-4.41	< .001*
P (0-2)	1.95	0.07	2.00	2.00-1.92	2.00	0.00	2.00	2.00-2.00	-3.17	0.002*
VC (1-5)	4.37	0.39	4.43	4.64-4.14	5.00	0.00	5.00	5.00-5.00	-5.17	< .001*
TO (1-5)	4.12	0.40	4.14	4.50-3.86	4.99	0.05	5.00	5.00-5.00	-5.32	< .001*
VQ (0-1)	0.51	0.35	0.50	0.86-0.25	0.97	0.16	1.00	1.00-1.00	-4.61	< .001*

[a]VP, visual perception; SP, spatial perception; P, praxis; VC, visuomotor construction; TO, thinking operations; VQ, verbal mathematical questions; [b]M, mean; SD, standard deviation; Me, median; IQR, interquartile range; *$p < 0.05$ by the Wilcoxon signed-rank test (1 tailed).

Table 6. The inter-rater reliability of the DLOTCA - Thai version (n = 37) with intra-class correlation coefficient.

Cognitive domains	Examiner A		Examiner B		Intra-class correlation coefficient	Reliability level
	M	SD	M	SD		
Orientation	1.283	0.470	1.307	0.486	0.993	Excellent
Awareness	2.297	0.435	2.198	0.523	0.914	Excellent
Visual perception						
Pre-mediation	2.720	0.673	2.720	0.664	0.997	Excellent
Mediation	3.477	0.576	3.477	0.576	1.000	Excellent
Post-mediation	3.144	0.705	3.153	0.705	0.995	Excellent
Spatial perception						
Pre-mediation	0.621	0.214	0.621	0.214	1.000	Excellent
Mediation	3.242	0.952	3.305	0.872	0.956	Excellent
Post-mediation	0.779	0.175	0.772	0.171	0.992	Excellent
Praxis						
Pre-mediation	1.229	0.415	1.234	0.415	0.997	Excellent
Mediation	3.337	0.924	3.351	0.906	0.998	Excellent
Post-mediation	1.700	0.392	1.709	0.393	0.998	Excellent
Visuomotor construction						
Pre-mediation	2.293	1.126	2.293	1.127	0.998	Excellent
Mediation	4.180	0.957	4.180	0.957	1.000	Excellent
Post-mediation	3.061	1.381	3.054	1.380	1.000	Excellent
Thinking operations						
Pre-mediation	1.183	0.911	1.183	0.912	1.000	Excellent
Mediation	4.429	0.565	4.429	0.565	1.000	Excellent
Post-mediation	2.687	1.160	2.683	1.165	1.000	Excellent

M, mean; SD, standard deviation.

in this present study were different from the study of the original version of the DLOTCA. In the study of the DLOTCA - English version, the comparison of healthy people and stroke patients found a significant difference in pre-mediation in the Orientation, Visual Perception, Spatial Perception, and Praxis domains between the groups. There was no difference in the scores on the Visuomotor Construction and Thinking Operation domains between the groups. This might be a result of the influence of education on cognitive function. In that study, healthy participants had less years of education than the stroke patients.[10] Contrary to this present study, healthy people and clients with cognitive impairment were a similar age, education level, and occupation.

In addition, the results revealed that clients with cognitive impairment needed a higher level of mediation than the healthy group. This was consistent with the literature review where Radomski and Morrison[26] stated that people with brain damage would have a change of input data and cognitive processes resulting in cognitive impairment. The results also demonstrated the significant differences of the pre- and post-mediation cognitive scores in a group of clients with cognitive impairment who had a high level of mediation; mostly partial intervention and reduced stimuli. These scores suggested that through the structure of the mediation process the potential for change in cognitive abilities would benefit in the intervention. This was consistent with the literature review of Haywood and Tzuriel[12] that the teaching or mediation process could measure strategies for thinking, perception, learning, problem-solving, and also improve cognitive function. It also supported the hierarchy of the cognitive abilities that were the foundation for the LOTCA development[10,27] and the notion of higher cognitive demands; therefore, more mediation would be required to improve the skills. The DLOTCA - Thai version thus has been in line with those of previous studies and theories and supported the premise of a new method of evaluation that has led directly to intervention planning for the clients.[8-14,28]

The results also showed that the healthy participants received maximum scores on the basic cognitive skills, except on the Visual Perception domain. This might be because of the difference in culture. The DLOTCA was developed in Western culture and some objects used in Visual Perception would be unfamiliar in the Thai culture resulting in not recognizing the objects. For higher cognitive skills; such as, Visuomotor Construction, Thinking Operations, and Verbal Mathematical Questions, even healthy adults did not reach the maximum scores. They then needed mediation to perform the subtests. These results indicated that healthy people had some difficulties too, probably due to their education and experience, as well as terms of complexity and unfamiliarity with the task.[10,14,29]

In the study of inter-rater reliability, the results revealed that the scoring of the pre- and post-mediation, as well as the level of mediation process on all cognitive domains were at an excellent level. This indicated that the DLOTCA - Thai version used clear words and language, as well as guiding to consistently implement the rating system. This was because of the standardized translation and adaptation of the instruments process that followed the WHO guidelines[21] where there was a translation, back-translation, and verification of semantic and conceptual equality between the original assessment tool and translated version by a panel of experts. There were corrections followed by the advice of experts and the use of concise and clear words.[21,30] Another impact may have been the result of the training before the implementation of the tool. This was consistent with the literature review that training is a necessary process to help practitioners gain knowledge, understanding, and skills to perform accurately and effectively. Moreover, this would help to increase the potential of the practitioners as well.[31] The results confirmed the advantage of this tool for practitioners and researchers in occupational therapy. The good psychometric properties in terms of construct validity and inter-rater reliability of the DLOTCA - Thai version were suitable for assessment in Thai clients. However, there were no cut-off points for each domain. Further research is recommended for sensitivity and specificity studies.

Conclusions

The DLOTCA - Thai version has passed the study of the psychometric properties of known-group validity and inter-rater reliability that could be used as a cognitive assessment tool in the Thai context. Therapists could use the data that were derived from the DLOTCA - Thai version for planning and cognitive rehabilitation that would be appropriate with competence and impairments, learning potential, and the conceptual strategies of an individual. Lastly, the therapists could use mediation in cognitive intervention.

Disclosure

The authors have no conflict of interest to declare.

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Original Article

Purple Urine Bag Syndrome in a Paraplegic Woman with a Long-Term Indwelling Catheter and Asymptomatic Urinary Tract Infection: A Case Report

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ABSTRACT

Objectives: To report on points of concern in a paraplegic patient with a neurogenic bladder who presented with purple urine in a urine bag.

Study design: A case report.

Setting: Department of Rehabilitation Medicine, Maharat Nakhon Ratchasima Hospital, Thailand.

Subjects: A 32-year-old paraplegic woman with long-term use of an indwelling catheter.

Methods: The patient's medical record, including demographic data, clinical presentation and laboratory results as well as urologic ultrasonography, treatment, and outcome were reviewed.

Results: A patient with an indwelling transurethral catheter presented with a second episode of smelly purple urine for three days. She had no fever. She remained in bed due to an undiagnosed right hip fracture, a pressure ulcer, and chronic osteomyelitis of the right greater trochanter. A urine strip showed positive nitrite and a culture showed the presence of *E. coli*. Ultrasonography showed no renal or bladder stones. After three days of intravenous antibiotic treatment, the purple urine completely resolved.

Conclusions: Paraplegic patients with a long-term indwelling catheter, asymptomatic urinary tract infection with purple urine should receive prompt and appropriate antibiotic therapy.

Keywords: purple urine, urinary tract infection, urinary catheter, indwelling catheter, paraplegia

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Introduction

Purple urine bag syndrome (PUBS) is an occasional phenomenon characterized by discoloration of urine. The condition was firstly described by Barlow and Dickson in 1978.[1] The prevalence of PUBS has been variously reported in different series, ranging from 8.3 to 42.1% of patients with an indwelling cathater.[2] Purple urine results from an accumulation of indigo and indirubin from bacteria-mediated tryptophan conversion.[3] PUBS is commonly associated with urinary tract infection (UTI) caused by enzymatic degradation of urinary indoxyl sulfate by Providencia stuartii and Klebsiella pneumoniae bacteria which produce indigo and indirubin, particularly in alkaline urine.[4-7] Reported risk factors for this syndrome include advanced age, female gender, constipation, dementia, a bedridden situation, institutionalization or hospitalization, end-stage renal disease, dehydration, chronic urinary catheterization, use of a polyvinyl chloride urinary catheter and/or urine bag, recurrent UTI, high urinary bacterial counts, and alkaline urine.[6] Abnormal color of urine in the urine bag might be a source of worry for the patient as well as healthcare providers, although it appears to be a benign condition.[6,8] There has been one case report of PUBS in a patient with spinal cord injury (SCI), incomplete tetraplegia and five years of use of a suprapubic catheter,[9] but there have been no reports of this syndrome among patients with SCI in Thailand.

The objective of reporting this case was to raise awareness that atypical urine color related to asymptomatic UTI requires appropriate antibiotic therapy to cure the underlying infection and to prevent serious complications.

Case presentation

The patient was a 32-year-old female who presented with a complete T10 vertebral injury and flaccid paraplegia, the result of a traffic accident in 2006. After rehabilitation, she was a wheelchair user but also practiced therapeutic walking with bilateral knee-ankle-foot orthoses (KAFO) for 20 minutes twice daily. Although her spinal cord injury lesion was complete, including flaccid paralysis of both legs, the bulbocavernosus reflex was positive indicating a neurogenic bladder with supra-sacral lesion. She was able to void 200-300 mL of urine with a post-void residual of less than 50 ml and reported no incontinence. She performed manual evacuation for

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bowel care every other day. Six months after the injury, vesicoureteral reflux (VUR) was detected and treated with oxybutynin (5 mg) 2 tablets twice daily and an indwelling catheter. In 2007 the VUR resolved at which time she removed the catheter and continued voluntary voiding.

In 2013, an ulcer appeared at the right greater trochanter which was suspected to have been caused by a pressure injury from the upper thigh band of the KAFO. In 2016, the pressure ulcer still persisted, and she started having chronic low-grade fever of unknown origin (FUO), forcing her to rest in bed. Initial investigation could not find the cause of the fever, delaying diagnosis of osteomyelitis at the undiagnosed broken right hip, the same side as the pressure ulcer. After the osteomyelitis was diagnosed, the right femoral head was removed (Figure 1), a colostomy was performed, and an indwelling catheter was inserted to prevent contamination from diapers.

In May 2020, this patient reported two episodes of purplish discoloration of the urine in the urine bag within a month (Figure 2). The first episode resolved after a few days of oral antibiotics prescribed by a district hospital doctor. She noticed that initially the urine in the bag contained crumbled sediment with a consistency of coarse sand. Later, the sediment changed color, starting from a light purple color and becoming a dark purple, and the urine smelled like ammonia. She usually drank less than 2 liters of water per day. The Foley catheter and urine bag were changed every month. Her regular medication was oxybutynin but not amitriptyline. When the second episode of purple urine occurred, she again went to the district hospital, but this time the doctor started an intravenous antibiotic therapy with ceftriaxone (third-generation cephalosporin). Due to concern about the recurrence of purple urine, she consulted the author, a physiatrist, who treated her neurogenic bladder.

After completing a 3-day intravenous antibiotic therapy, she was afebrile with mild dehydration. Her heart rate was 112 beats per minute, she complained of thirst and her body weight was down from 45 kg to 43 kg. Her urine was yellowish and clear in the urine bag tube, but the urine bag itself was stained purple (Figure 2). Investigation revealed a hemoglobin level of 11.5 g/dL with 9,000 WBCs per micro-liter. Her blood urea was 34 mg/dL and serum creatinine was 0.9 mg/

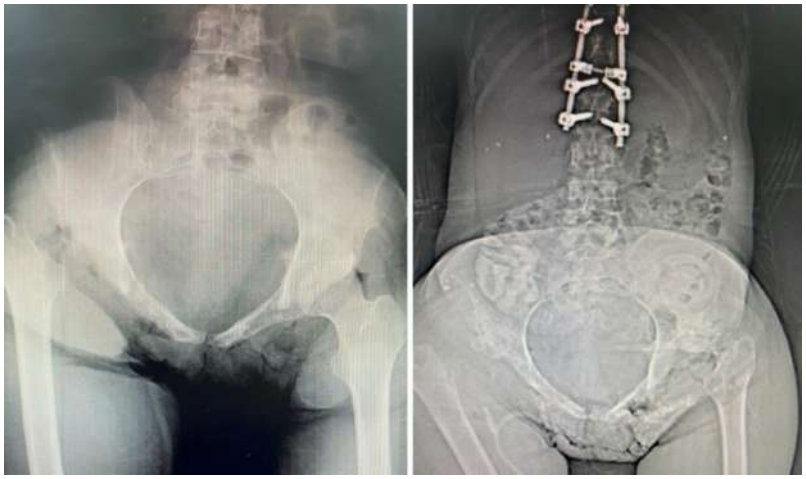

Figure 1. X-ray films of pelvis and hip in anteroposterior view. Left: the undiagnosed right hip fracture. Right: the hip after the right femoral head resection and colostomy.

Figure 2. The urine bag was stained purple, but the urine in the urine bag tube changed to a light yellow color following 3 days of intravenous antibiotic therapy

dL. The urine strip showed a pH of 7.0, a specific gravity of 1.020, and was positive for nitrite. Urine microscopy revealed 4-6 leucocytes per high power field and 3-5 red blood cells per high power field with triple phosphate crystals. Ultrasonography detected no hydronephrosis and no kidney or bladder stones. A urine culture was done before initiating intravenous antibiotic therapy. The culture grew greater than 105 colony-forming units of Escherichia coli which were sensitive to ceftriaxone. The author then prescribed 10 days of oral ciprofloxacin after which she had no recurrence of purple urine.

Discussion

The present case was a middle-aged woman with chronic flaccid paraplegia and suprasacral neurogenic bladder and bowel resulting from a traumatic spinal cord injury. Initially, she voided voluntarily with low post-void residue, but later used indwelling transurethral catheters for 4 years to prevent contamination of a chronic unhealed pressure ulcer at the right greater trochanter and osteomyelitis of an undiagnosed fracture of the right hip. These complications caused her to become less physically active. She reported no fever during two recent episodes within one month of purple and smelly urine in the urine bag. The second episode was immediately treated with a 3-day intravenous antibiotic course. Urine culture later confirmed significant bacteriuria, but her clinical presentation was asymptomatic UTI.

It should be noted that discoloration of urine can be the result of various factors such as orange color caused by rifampicin, blue green caused by indomethacin, amitriptyline and Psuedomonas, and tea color caused by hemolysis.[5] Purple urine is an atypical occurrence. Interestingly, PUBS was firstly reported in the nineteenth century; a famous historical figure (the English King George III who reigned from 1760 to 1820) was believed to have had this condition.[1] Urine bags turning purple or blue have been commonly reported in individuals with long-term use of an indwelling urinary catheter.[3] It is believed that bacterial enzymes such as sulfatase and phosphatase, especially in alkaline urine, form two pigments, indirubin (red) and indigo (blue), and that the mixture of these pigments is responsible for converting the urine to a purple color.[3] Additionally, renal failure is associated with a decrease in indoxyl sulfate clearance which causes bacteria present in the urinary bladder to produce more indigo and indirubin.[2,3,7]

UTI presenting with purple urine can be easily detected but is often neglected because most cases are asymptomatic.[5] According to a previous report, only 11.8% of cases present with fever or hypotension.[4] In the present case, the patient had asymptomatic UTI with purple urine which completely resolved after a short course of intravenous antibiotic therapy. Using the Cockcroft-Gault equation, her estimated creatinine clearance was 61 mg/dL, indicating a mild decrease in renal function.[10] Delayed treatment of UTI can result in serious complications and even death: the overall mortality rate in patients with PUBS has been reported to be 6.8%.[4] Significant risk factors for mortality following PUBS include female gender, diabetes, leukocytosis, uremia, and shock.[2,4]

Presently, long-term use of an indwelling catheter is not recommended in patients with chronic SCI and neurogenic bladder.[11] However, in Thailand many patients with chronic SCI chose indwelling catheters because of the convenience.[12] Antibiotic therapy is considered only for SCI patients with symptomatic UTI.[11] Asymptomatic UTI should initially managed by drinking more fluids and more frequent changes of the catheter and urine bag. In the case of this patient, drinking less than 2 liters of fluids daily and changing the Foley catheter and urine bag only monthly increased the risk of UTI. To prevent recurrent UTI, patients should be encouraged to have the catheter and urine bag changed more frequently, perhaps every two weeks, and to increase their intake of liquids to to help keep the urine color clear as well as to facilitate defecation.

In SCI patients, constipation is usually due to prolonged colonic transit time and rectal sphincter dyssynergia.[13] A study of Thai patients with chronic SCI revealed that constipation was common and that drinking less than 2 liters of liquid per day was significantly related to hard and lumpy stools.[14] In the present case, although the patient had had a colostomy to eliminate contamination of a chronic pressure ulcer, the urine still became infected with *E. coli*, an organism commonly found in the large bowel. It has been demonstrated that the common microbial organisms *E. coli* as well as *Enterobacters* and *Proteus* spp. can cause catheter-associated UTI and PUBS.[4] Additionally, chronic constipation can lead to bacterial overgrowth resulting from reduced gut motility and prolonged transit time. Prolonged tryptophan transit and the resulting increase in the level of indoxyl sulfate in the urine have been hypothesized to be the mechanism of action.[4]

In addition to long-term use of an indwelling catheter and constipation, immobilization and being a female are also risk factors for PUBS.[2,3,7,8] The present case was a paraplegic who had become less active following an undiagnosed hip fracture and resulting chronic pressure ulcer. Being female is considered to be a risk factor for UTI because of a relatively short urethra.[2] However, a systematic review of PUBS reported between 1980 and 2016 found that of 116 patients, the number of male cases was almost equal to that of female cases.[4]

Conclusions

Reporting this first case of a Thai SCI patient with long-term indwelling catheter and PUBS should increase awareness of healthcare providers in Thailand and other countries regarding the importance of prompt and proper antibiotic

treatment of patients with asymptomatic UTI who have purple urine as a means of preventing serious life-threatening complications. Patients with long-term use of a transurethral indwelling catheter should be periodically reminded to properly care for the catheter and the urine bag to prevent chronic or recurrent UTI.

Disclosure

The author declares no potential conflicts of interest.

Acknowledgements

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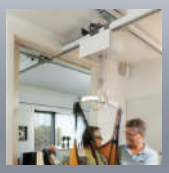

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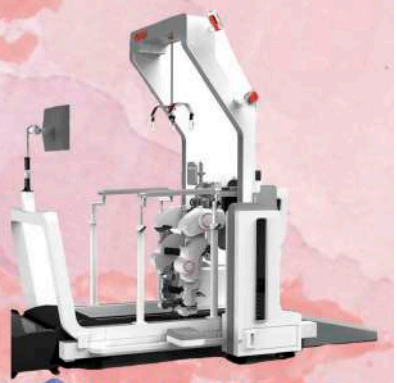

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