การศึกษาเปรียบเทียบประสิทธิผลของการนวดไทยแบบราชสำนัก
กับไดโคฟีแนกเจลต่อการใช้งานของไหล่และความสามารถของแขนในผู้ป่วยไหล่ติด
32

วารสารพยาบาลทหารบก
Journal of The Royal Thai Army Nurses

การศึกษาเปรียบเทียบประสิทธิผลของการนวดไทยแบบราชสำนัก กับไดโคฟีแนกเจลต่อการใช้งานของไหล่และความสามารถของแขน ในผู้ป่วยไหล่ติด

A Comparative Study of Court-Type Traditional Thai Massage Versus Diclofenac Gel on Function of Shoulder and Ability of Arm in Patients with Frozen Shoulder: A Randomized, Controlled Trial

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บทคัดย่อ

การวิจัยเรื่องนี้มีวัตถุประสงค์ เพื่อศึกษาเปรียบเทียบผลของการนวดไทยแบบราชสำนักกับไดโคฟีแนกเจล ต่อการใช้งาน
ของไหล่และความสามารถของแขนในผู้ป่วยไหล่ติด รูปแบบการวิจัยเชิงทดลองทางคลินิก เลือกประชากรโดยการสุ่มจำนวน 60 คน
แบ่งเป็นกลุ่มทดลอง 30 คน กลุ่มควบคุม 30 คน กลุ่มทดลองรักษาโดยการนวดแบบราชสำนักสัปดาห์ละ 2 ครั้งติดต่อกัน 6 สัปดาห์
กลุ่มควบคุมรักษาโดยการทาไดโคฟีแนกเจล ทาครั้งละ 5 กรัม 3 ครั้งต่อวัน ติดต่อกัน 6 สัปดาห์ ติดตามผลทั้งสองกลุ่มสัปดาห์ที่ 8
และ 10 ประเมินผลการรักษาโดยแบบประเมินความสามารถของแขนในการทำกิจกรรม (DASH) แบบประเมินการทำงานของไหล่
(Function of shoulder) ก่อนและหลังการทดลอง ผลการทดลองพบว่า ทั้งด้านการใช้งานของไหล่และความสามารถของแขนก่อน
และหลังการทดลองภายในกลุ่มของทั้งกลุ่มทดลองและกลุ่มควบคุมมีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ (p < 0.0001)
แต่เมื่อเปรียบเทียบระหว่างกลุ่มพบว่ามีความแตกต่างแต่ไม่มีนัยสำคัญทางสถิติ สรุปได้ว่าการนวดไทยแบบราชสำนักและ
ไดโคฟีแนกเจลต่างก็ให้ผลดีในการรักษาไหล่ติด เห็นได้จากผลของระดับการใช้งานของไหล่และความสามารถของแขนในการ
ทำกิจกรรมในผู้ป่วยไหล่ติดได้ผลดีขึ้นเหมือนกัน

คำสำคัญ : นวดไทยแบบราชสำนัก ไหล่ติด การใช้งานของไหล่ ความสามารถของแขน ไดโคฟีแนกเจล

Abstract

The objectives was to determine the effectiveness of court-type traditional Thai massage (CTTM) and
diclofenac gel (DG) on function of shoulder and ability of arm in patients with frozen shoulder. The study
design was a randomized, single-blind. Sixty woman with frozen shoulder were recruits. Subjects were
randomly assigned to receive CTTM (treatment group, n = 30) and DG (control group, n = 30). CTTM was
performed for 12 sessions during a 1–6 week period, with followed up at week 8th, 10th. DG was administered
5 g three times a day for 6 weeks, and followed up at week 8th, 10th. Subjects were assessed function of

shoulder and ability of arm at initial and week 10th by visual analog scale (VAS) and Disabilities of the Arm, Shoulder and Hand (DASH) respectively. The results within group comparison were showed that DASH and VAS score significantly decreases after treatment (p < 0.0001). In addition, the scores between CTTM and DG groups after treatment were not significantly different. Both CTTM and DG were capable to heal frozen shoulder and demonstrated a positive effect on arm's ability and function of shoulder.

Keywords : court-type traditional Thai massage, frozen shoulder, function assessment, ability of arm, diclofenac gel

Introduction

Frozen shoulder affects up to 5% of the population. The incidence of frozen shoulder is to be 2.4 per 1,000 population in 2016 in England[1]. From the epidemiology data of muscle disease, the prevalence of neck and shoulder ache in Thailand was found to be 38.5 %. Women were at greater risk than men. Disease presented typically between the ages of 50 – 60 years. About two-thirds of the patients with shoulder ache from shoulder joint inflammation could become frozen shoulder. The data from Thai Traditional Medicine Services Center has shown that in 2015, there have been 274,188 and 88,871 patients with neck and shoulder pain and frozen shoulder respectively.

Many factors are associated with frozen shoulder including female gender, trauma, immobilization, diabetes, thyroid disease, stroke, myocardial infarction and the presence of autoimmune[2].

Frozen shoulder treatment involves non-medicinal and medicinal approaches to reduce pain and increase range of motion such as acupuncture, stretching massage, physiotherapy, non-steroidal anti-inflammatory drugs (NSAIDs), intra-articular injections with steroids and manipulate under anesthetics[3].

NSAIDs are medications, used to reduce pain and inflammation in the joints. NSAIDs has been proven to be highly effective in controlling the symptoms and signs of frozen shoulder. Diclofenac is used for musculoskeletal complaints, especially arthritis, rheumatoid arthritis, polymyositis, dermatomyositis, steoarthritis, dental pain, spondylarthritis, ankylosing spondylitis, gout attacks and pain management in cases of kidney stones and gallstones but the NSAIDs have side effects, including irritation of the stomach or the intestine [4].

Topical diclofenac significantly reduces pain and inflammation in acute and chronic conditions compared to oral NSAIDs (diclofenac, ibuprofen, naproxen) and other topical NSAIDs. Improvements have also been observed in patients' functional capacity and mobility. Topical diclofenac is well tolerated, resulting mostly in mild, easily resolved local skin irritation, and is associated with fewer side-effects than other topical NSAIDs and a lower rate of gastrointestinal complications than oral NSAIDs (diclofenac, ibuprofen, naproxen) [5, 6].

Traditional Thai massage (TTM) is an alternative treatment for musculoskeletal illnesses and relaxation. There are two types of TTM i.e. general TTM or Cha luei sak massage and the court-type traditional Thai massage (CTTM) or Ratcha samnak massage. CTTM is a therapeutic massage which is promoted in health care [7].

The important to study in this research due to there has never been reported the effectiveness of CTTM in treating frozen shoulder in clinical trials research in Thailand. Therefore, the researcher aimed

34 การศึกษาเปรียบเทียบประสิทธิผลของการนวดไทยแบบราชสำนัก
กับไดโคฟีแนกเจลต่อการใช้งานของไหล่และความสามารถของแขนในผู้ป่วยไหล่ติด

วารสารพยาบาลทหารบก
Journal of The Royal Thai Army Nurses

to conduct a randomized controlled trial to assess the effectiveness of CTTM compared to DG for treating frozen shoulder.

General Objectives

To comparative study of CTTM and DG in treating patients suffering from frozen shoulder.

Hypothesis

1. The CTTM can improve the function of shoulder in patients with frozen shoulder.

2. The CTTM can improve ability of arm in patients with frozen shoulder.

3. The CTTM is as effective as DG in treating patients with frozen shoulder.

METHODOLOGY

Sample size

The sample size was calculated using range of motion improvement rate from a previous study. The different level of flexion range of motion degree measured by the Patient Specific Functional Disability Measure was found to be 18.50 with a standard deviation of 2.0 ($\sigma 2$). The sample size at the significant level of lower than 0.05 (Z α = 1.96) and a power of test at 80 % Zβ = 0.84) was used. After adjusting for a 20 % drop out, 30 participants per group (60 for total) were suggested to be an appropriate sample size.

Trial design

In this single-blind randomized controlled trial, 60 patients were assigned into the treatment group and the control group by simple random sampling method using a pre-generated random assignment scheme enclosed in envelopes.

Ethical considerations

This research was approved by the Ethical Committee of the Department for Thai Traditional and Alternative Medicine of the Ministry of Public Health (Number10-2559 Date of approval October 27, 2016 – October 27, 2017).

Participants

The patients were those who have idiopathic frozen shoulder diagnosed at the Thai Traditional Medical Service Center, Sukhothai Thammatirat University, Nonthaburi province. Subjects for inclusion in the study were primarily selected by the licensed of Applied Thai traditional medicine practitioner and diagnosed by the orthopedic doctor. Baseline data were collected from all eligible individuals who responded to the announcements.

Inclusion and exclusion criteria

The inclusion criteria of this study are as follows: idiopathic frozen shoulder, ages more than or equal 40-65 years only female gender, level of pain greater than or equal to 4 of 10 scores, duration of frozen shoulder for 4 to 12 months (phase 2 of frozen shoulder), having a limited ≥25% loss of shoulder motion in all planes at least two in four position (abduction, forward flexion, internal rotation, and external rotation), blood pressure not over 140/90 mmHg and informed written consent

The exclusion criteria of this study are as follows: having a history of rotator cuff tears, rheumatoid arthritis, osteoarthritis and malignancies in the shoulder region , pregnancy, patient of breast cancer surgery, using steroidal or other drugs for treating frozen shoulder

Independent variable

Treatment of frozen shoulder consist of pharmacologic treatments (DG) and non-pharmacologic treatments (CTTM).

Dependent variables

Effectiveness of the CTTM on shoulder function and ability of arm.

Effectiveness of the DG on shoulder function and ability of arm.

Treatment of frozen shoulder

Treatment of frozen shoulder were the CTTM and DG assigned to the treatment group and the control group respectively.

Treatment group patients were treated for 45 minutes per CTTM session, 2 sessions a week for 6 weeks, stretching by pulling the arm after massage, follow up at week 8 and 10.

Control group patients were received 5 g of DG applied on the average surface of 10 ×14 cm, three times a day for 6 weeks and followed up at week 8th and 10th [8].

Outcome instruments

The function assessment of shoulder was evaluated by the patient using a 10-mm visual analog scale (VAS) with the descriptors "usually available" on the left end and "unworkable" on the right end. The ability of arm was evaluated by the patient using Disabilities of the Arm, Shoulder and Hand questionnaires (DASH) [9]. The questionnaire included 2 domains of total 30 items that indicated patient's ability to do activities and severity of symptoms of frozen shoulder and work module (optional) 4 items including the questions about the impact of arm, shoulder or hand problem on ability to work.

The reliability of DASH were tested in thirty patients with frozen shoulder at Sangkha hospital, Surin province. The intraclass correlation coefficient (ICC) was showed a high degree of correlation (ICC = 0.93).

Data analysis

Data were analyzed with the STATA version[10] software (licensed for College of Public Health Sciences, Chulalongkorn University). Mean median and standard deviations were calculated for each response variable. Paired t-tests were used to compare the outcome variables before and after the treatment period within each respective group. Student t-test,

Wilcoxon rank sum test were used to compare the difference in post-test values between groups.

Results

Sixty patients were screened for eligibility for the study. Thirty patients were randomly allocated to receive CTTM and thirty participants received DG. Demographic data and baseline clinical characteristics of the patients were presented in Table 1. The majority of baseline characteristics were equally balanced between the two groups.

The ability of arm was measured using DASH questionnaires. Table 2 showed the scores before and after receiving CTTM and DG.

The score of DASH in part 1 indicated patient's ability to do activities (100 scores represent higher degree of disabilities). Both CTTM and DG groups significantly showed the improvement of the ability of arm with the scores decreased from 75.00 to 28.55 (p-value <0.0001), and 72.92 to 37.30 (p-value<0.0001) respectively.

The score of DASH part 2 indicated the severity of symptoms. Both CTTM and DG groups significantly showed the reduction of the severity of symptoms with the scores decreased from 73.75 to 36.87 (p-value <0.0001), and 75.00 to 36.60 (p-value<0.0001) respectively.

Table 3 showed the scores before and after treatment between CTTM and DG groups. Before treatment, the scores of DASH in part 1 and part 2 of both CTTM and DG groups were not significantly different. In addition, the scores of DASH in part 1 between CTTM and DG groups after treatment were significantly different but part 2 not significantly different.

The function assessment was measured using VAS.

Table 4 showed the scores of VAS before and after receiving CTTM and DG. Within group, both CTTM and DG groups significantly showed the

36 การศึกษาเปรียบเทียบประสิทธิผลของการนวดไทยแบบราชสำนัก
กับไดโคฟีแนกเจลต่อการใช้งานของไหล่และความสามารถของแขนในผู้ป่วยไหล่ติด

วารสารพยาบาลทหารบก
Journal of The Royal Thai Army Nurses

Table 1 Demographic characteristics of patients with frozen shoulder

Characteristics	Treatment group Mean ± SD (n = 30)	Control group Mean ± SD (n = 30)	P-value
Age (years)	53.93 ±4.76	53.33 ± 4.28	0.609*
Education			
Lower than bachelor	1 (3.33)	3 (10.00)	
Bachelor	27 (90.00)	25 (83.33)	
Higher than bachelor	2 (6.67)	2 (6.67)	
Occupation			
Civil servants	23 (76.67)	22 (73.33)	
Employees	1 (3.33)	7 (23.33)	
Merchant	4 (13.33)	1 (3.33)	
Other	2 (6.67)		
Duration of symptom			
4-6 months	18 (60)	13 (43.33)	
7-9 months	11 (36.67)	15 (50.00)	0.530*
10-12 months	1 (3.33)	2 (6.67)	
Side of hand			
Left	17 (56.67)	11 (36.67)	
Right	13 (43.33)	19 (63.33)	
Treatment			
Take a medicine	1 (3.33)		
See a doctor	20 (66.67)	25 (83.33)	
physical therapy	6 (20.00)	-	
Acupuncture	3 (10)	5 (16.67)	

* student t-test

improvement of function of shoulder with the scores decreased from 6.00 to 3.03 (p-value <0.0001), and 5.96 to 3.16 (p-value<0.0001) respectively. In addition, the scores between CTTM and DG groups after treatment were not significantly different.

Within group, both CTTM and DG groups significantly showed the improvement of the ability of arm with the scores decreased in both parts. After treatment, the scores of DASH in part 1 between CTTM and DG groups were significantly different but part 2 not significantly different.

Within group, both CTTM and DG groups significantly showed the improvement of function of shoulder with the scores decreased in both parts.

Discussion

The research revealed that CTTM and DG could be an effective treatment for frozen shoulder patients. CTTM could reduce severity of symptoms,

Table 2 The mean DASH score before and after treatment in within group

DASH	CTTM (n = 30)			DG (n = 30)		
	Mean±SD	ta	p-value	Mean±SD	ta	p-value
DASH: Part1						
Before	75.00±12.54			72.92±10.27		
treatment		28.55	0.0001**		18.72	0.0001**
After treatment	28.55±7.96			37.30±3.94		
DASH: Part2						
Before	73.75±11.76			75±12.39		
treatment		12.16	0.0001**		17.29	0.0001**
After treatment	36.87±13.26			36.60±5.12		

[a]Paired t-test ** significantly different

Table 3 The mean, median DASH score before and after treatment between groups

Before treatment	DASH Part1			DASH Part2		
	Mean±SD	t[a]	p-value	Median min-max	z[b]	p-value
CTTM (n = 30)	75.00±12.54			75		
		0.70	0.484*	37.50-100	0.620	0.535*
DG (n =30)	72.92±10.27			72.08		
				50.83-94.16		

After treatment	DASH Part1			DASH Part2		
	Median min-max	z[b]	p-value	Median min-max	z[b]	p-value
CTTM (n = 30)	25.83			28.12		
	18.33-50.00			25- 68.75		
DG (n = 30)	37.91	4.78	0.0001**	37.50	0.687	0.491*
	30.83-44.16			31.25-50.00		

[a]Student t-test, [b]Wilcoxon rank sum test * not significantly different ** significantly different

38 การศึกษาเปรียบเทียบประสิทธิผลของการนวดไทยแบบราชสำนัก
กับไดโคฟีแนกเจลต่อการใช้งานของไหล่และความสามารถของแขนในผู้ป่วยไหล่ติด

วารสารพยาบาลทหารบก
Journal of The Royal Thai Army Nurses

Table 4 The mean VAS score before and after treatment in CTTM and DG groups

Function assessment	Treatment group (n = 30)		Control group(n = 30)		Between group	
					t^b	p-value
	Mean±SD	95%CI	Mean±SD	95%CI		
VAS score						
Before treatment	6.00±0.74	5.72 6.27	5.96±0.76	5.68 6.25	-0.17	0.864*
After treatment	3.03±0.71	2.76-3.30	3.16±0.69	2.90-3.42	0.72	0.469*
Compare in within group	t = 15.72[a] p-value 0.0001**		t = 16.58[a] p-value 0.0001**			

[a]Paired t-test, [b]Student t-test

improve patient's ability to do activities and shoulder function. This might be explained in terms of physiological effects. Massage is used for therapy such as reducing pain, anxiety, depression, muscle tension and increase joint range of motion. Massage also calls up the body's natural painkillers because It can stimulate the release of endorphins, the morphine-like substances that the body manufactures, into the brain and nervous system. As the gate control theory, CTTM essentially involves the exertion of pressure on the skin and muscles, thereby stimulating pressure receptors and inhibiting the transmission of pain receptors at the spinal cord or the 'gate.' CTTM increases the rate of blood flow, improve the performance of fatigued muscle and deep massage, promotes venous return and increase cardiac stroke volume [10-13]. Sitikaipong was studied the effectiveness between CTTM and diclofenac to relief shoulder pain. The results indicated significant improvement of all parameters in CTTM arm i.e. pain intensity, pressure pain threshold, flexibility at neck and shoulder muscle (p < 0.05) [11]. Buttagat was conducted pilot study on the effects of traditional Thai massage (TTM)compare with physical therapy on pain, muscle tension and anxiety in patients with scapulocostal syndrome by a randomized single-blinded study. The results indicated significant improvement in all parameters in TTM arm i.e. pain intensity, pressure pain threshold, muscle tension and anxiety associated with scapulocostal syndrome (p < 0.05) [12].

Non-selective NSAIDs work by inhibit COX-1 and COX-2. They are very commonly prescribed to reduce pain, inflammation and fever. Examples of non-selective NSAIDs include aspirin, ibuprofen, naproxen and diclofenac.[13] DG could reduce severity of symptoms, improve patient's ability to do activities and shoulder function because DG have analgesic, anti-pyretic, and anti-inflammatory effects. DG, is commonly used for acute or chronic musculoskeletal pain. It is applied directly to the site of pain on the skin, back, or joint. The effectiveness of topical NSAIDs for prolonged treatment (8 weeks or more) of osteoarthritis were found to be as effective as oral NSAIDs for pain relief.[14] Adverse gastrointestinal side effects were less common with the topical than oral NSAIDs, and occurred at a rate comparable to placebo.[15, 16]

Conclusions

The findings in present study strongly suggested that CTTM could reduce muscle tension, pain intensity and increase joint range of motion. DG could reduce pain intensity and anti-inflammatory so that it will also increase joint range of motion. Both CTTM and TC were capable to heal frozen shoulder and demonstrated a positive effect on arm's ability and function of shoulder.

Recommendations for Further Study

Based on the present findings, the CTTM could serve as an alternative therapy for the treatment of frozen shoulder patients. This could be an appropriate therapy for the patients who suffer with adverse effects of medication. Further research should be study in diabetes patient who suffering from frozen shoulder.

Acknowledgements

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40 การศึกษาเปรียบเทียบประสิทธิผลของการนวดไทยแบบราชสำนัก
กับไดโคฟีแนกเจลต่อการใช้งานของไหล่และความสามารถของแขนในผู้ป่วยไหล่ติด

วารสารพยาบาลทหารบก
Journal of The Royal Thai Army Nurses

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