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Background : *Myofascial pain syndrome is one of the most frequent causes of pain in the musculoskeletal system. There are many treatments to relieve pain of the involved muscles such as dry needling and ultrasound. More recent publications indicate a possibility of using radial extracorporeal shock wave therapy (rESWT) to treat myofascial pain syndrome, which is non invasive, effective, and has less complication.*

Objectives : *To determine the effectiveness of radial extracorporeal shock wave therapy and ultrasound in chronic myofascial pain syndrome in the infraspinatus muscle.*

Methods : *Patients with chronic myofascial pain syndrome duration more than 3 months. Forty-six patients were randomly divided into two groups: group 1 received the treatment with rESWT 1 time/week, and group 2 received the treatment with ultrasound 5 times/week. Pressure pain threshold by algometer (PPT), pain intensity by visual analogue scale (VAS), and range of motion of shoulder (ROM) were assessed before starting the treatment and every week for 6 weeks after treatment. Satisfactions were evaluated by the patients after the last treatment.*

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Results : *There was no statistical difference between two groups in demographic data. There was statistical significance of pain reduction at the first week and subside from pain at 3-4 weeks after received the treatment in both groups. The comparison of pressure pain threshold by algometer (PPT), pain intensity by visual analogue scale (VAS), and range of motion of shoulder (ROM) before and after treatment were significantly improved in both groups (P < 0.01). Therefore, PPT significantly improved the patients in group 1 more than in group 2 (P < 0.01) but there was no significant improvement of VAS, and ROM of shoulder between the groups. At the end of the study, the satisfaction score in group 1 were significant higher than that of group 2 (P < 0.01).*

Conclusions : *The rESWT is more effective than ultrasound for pain reduction in the infraspinatus muscle in chronic myofascial pain syndrome.*

Keywords : *ESWT, shock wave, ultrasound, myofascial pain syndrome.*

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เหตุผลของการทำวิจัย : *กลุ่มอาการปวดกล้ามเนื้อและเนื้อเยื่อพังผืด (myofascial pain syndrome) เป็นสาเหตุของอาการปวดที่พบบ่อย และมีวิธีการรักษาหลายวิธี เช่น การคลายจุดปวดด้วยเข็ม (dry needling) หรือการใช้คลื่นความถี่สูง (ultrasound) เป็นต้น โดยในระยะหลังมีการศึกษาถึงการใช้คลื่นกระแทก (radial extracorporeal shock wave therapy) ในการรักษากลุ่มอาการปวดชนิดนี้มากขึ้น พบว่าได้ผลดีและไม่มีภาวะแทรกซ้อนที่รุนแรง*

วัตถุประสงค์ : *เพื่อเปรียบเทียบประสิทธิภาพของการใช้คลื่นกระแทก และการใช้คลื่นความถี่สูงในการรักษาผู้ป่วยกลุ่มอาการปวดกล้ามเนื้อและเนื้อเยื่อพังผืดระยะเรื้อรังบริเวณกล้ามเนื้อสะบัก*

วิธีการทำวิจัย : *ผู้ป่วยนอกที่มีอาการปวดกล้ามเนื้อสะบัก ระยะเวลาตั้งแต่ 3 เดือนขึ้นไป ที่มารับการตรวจที่แผนกผู้ป่วยนอก ตึก ภปร. ชั้น 5 ฝ่ายเวชศาสตร์ฟื้นฟู โรงพยาบาลจุฬาลงกรณ์ แบ่งผู้ป่วย 46 ราย เป็น 2 กลุ่ม กลุ่มละ 23 ราย โดยวิธีการสุ่ม กลุ่มที่ 1 ได้รับการรักษาด้วยการใช้คลื่นกระแทก (rESWT) 1 ครั้ง/สัปดาห์ กลุ่มที่ 2 ได้รับการรักษาด้วยการใช้คลื่นความถี่สูง 5 ครั้ง/สัปดาห์ ทำการประเมิน pressure pain threshold (PPT) โดยใช้ algometer ประเมินระดับความปวดโดยใช้ visual analogue scale (VAS) (0 - 100) และค่าพิสัยการเคลื่อนไหวของข้อไหล่ประเมินก่อนและหลังการรักษาทุก 1 สัปดาห์ เป็นเวลา 6 สัปดาห์ แต่สามารถหยุดการรักษาก่อนได้เมื่อ VAS = 0 และประเมินความพึงพอใจเมื่อสิ้นสุดการรักษา*

ผลการศึกษา : *ข้อมูลพื้นฐานของผู้ป่วยทั้ง 2 กลุ่มไม่มีความแตกต่างกันอย่างมีนัยสำคัญ หลังได้รับการรักษาพบว่าทั้ง 2 กลุ่ม ทำให้อาการปวดลดลงอย่างมีนัยสำคัญ (P < 0.01) ที่ 1 สัปดาห์หลังการรักษาและหายปวด (VAS = 0) ที่ 3 – 4 สัปดาห์หลังการรักษา เมื่อเปรียบเทียบก่อนรักษาและหลังรักษา 3 สัปดาห์ทั้ง 2 กลุ่มมีค่า PPT เพิ่มขึ้น VAS ลดลง และค่าพิสัยการเคลื่อนไหวของข้อไหล่เพิ่มขึ้นอย่างมีนัยสำคัญ (P < 0.01) และเมื่อเปรียบเทียบระหว่างกลุ่มพบว่ากลุ่มการใช้คลื่นกระแทก มีค่า PPT เพิ่มขึ้นมากกว่ากลุ่มการใช้คลื่นความถี่สูงอย่างมีนัยสำคัญ (P < 0.01) แต่ค่า VAS และค่าพิสัยการเคลื่อนไหวของข้อไหล่ไม่มีความแตกต่างกัน ส่วนความพึงพอใจทั้งในแง่ของการลดปวด ความสะดวกในการมารับการรักษาและจำนวนวันที่มารักษาต่อสัปดาห์ พบว่ากลุ่มการใช้คลื่นกระแทกมีความพึงพอใจมากกว่ากลุ่มการใช้คลื่นความถี่สูงอย่างมีนัยสำคัญ (P < 0.01)*

สรุป : *การใช้คลื่นกระแทกมีประสิทธิภาพในการบรรเทาอาการปวดได้ดีกว่าการใช้คลื่นความถี่สูงในการรักษาผู้ป่วยกลุ่มอาการปวดกล้ามเนื้อและเนื้อเยื่อพังผืดระยะเรื้อรังบริเวณกล้ามเนื้อสะบัก*

คำสำคัญ : *การรักษาด้วยคลื่นกระแทก, การรักษาด้วยคลื่นเสียงความถี่สูง, กลุ่มอาการปวดกล้ามเนื้อและเนื้อเยื่อพังผืด.*

Myofascial pain syndrome is considered one of the most frequent causes of pain in musculoskeletal system that commonly affects the working-age population.[1, 2]

Myofascial pain syndrome is characterized by myofascial trigger points (MTrPs), which are defined as hypersensitive spot in a taut band of skeletal muscle, which can cause referred pain, autonomic phenomenon, and local twitch response on compression or needling.[1, 2]

The treatment approaches are 2 steps: first is a specific treatment to relieve pain of the involved muscles, such as trigger point injection, ultrasound therapy, and massage etc. The second step is to correct the perpetuating factor that can cause recurrent of the symptoms.[2]

Therapeutic ultrasound is a suitable method in treatment of MTrP.[2,3] It is possible to heat the deeper muscle, increase vascular blood flow and micromassage, that can reduce pain and spasm at the MTrP.[3, 4]

More recent publications indicate a possibility of MTrP treatment by using radial extracorporeal shock wave therapy (rESWT), which is non invasive, effective, and has less complication.[5, 6] Luxembourg treated 184 patients with chronic pseudo sciatica pain (>12 months) and trigger points at gluteal muscles by radial shock waves (Masterpuls, Storz). The treatment with radial shockwaves resulted in a significant reduction of pain after 6 months from visual analogue scale (VAS) 7.3 to 1.9. in 84% of patients, and a relief of the referred pain in 69%.[7] Bauermeister treated active trigger points in neck, shoulder and lower back pain patients with radial shockwaves (Swiss dolorclast[®]) The VAS was significant reduction after the treatment in all 3 groups.[8]

There are a few literatures and randomized controlled trial study about radial shock wave therapy. The purpose of this study was to compare the effectiveness of pain reduction between radial shockwaves and conventional ultrasound in the treatment of chronic myofascial pain syndrome.

Materials and Methods

This experimental study was carried out at outpatient clinic of rehabilitation department, King Chulalongkorn Memorial Hospital, Bangkok, Thailand between December 2010 to August 2011. This study was approved by Ethics Committee of The Institutional Review Board of the Faculty of Medicine, Chulalongkorn University, Bangkok. (The protocol number 229/53).

Inclusion criteria

1. The patients who were diagnosed myofascial pain syndrome[1,2] for more than 3 months with active trigger point at infraspinatus muscle and visual analogue score of pain (VAS) more than 30 (VAS range from 0 - 100).
2. All patients consented to join in the protocol. Exclusion criteria: the patient who had one of the following criterias was excluded from the study
    1. Fibromyalgia (ACR1990)[9]
    2. Cervical radiculopathy, myelopathy or disease of shoulder joint
    3. Inflammatory joint disease, hypothyroidism, anemia, depressive disorder
    4. Using anticoagulant or aspirin
    5. Using NSAID within 2 weeks before enrollment to the study
    6. Received any treatment of myofascial trigger point at infraspinatus muscle within 1 month before

enrollment to the study

7. Cognitive impairment

8. Contraindication for using ultrasound[4] or shockwave therapy[6]

Sample size calculation: The sample size was calculated by using two independent group formula. [10] Calculate from the study of Srbely JZ.and Dickey JP. [11]

The CI was 95% (α = 0.05, β = 0.10)

Formula n/group = $2[\frac{(z_{\alpha/2} + z_{\beta})\sigma}{\Delta}]^2$

σ2 = 100.5, x_1 = 50.7, x_2 = 37.8, Δ = $x_1 - x_2$

n/group = 13

Demographic data, underlying disease, current medication, duration of pain, career and daily activity were recorded. All patients were evaluated about the active myofascial trigger point by using Travell and Simons criteria[1] , located the point of pain at the infraspinatus muscle and pain intensity by using 0 -100 mm visual analogue scale (VAS). The pain threshold were evaluated by Fisher's method[12] which patient lying in prone position and using pressure algometer pressed 90 degree on the skin over the active trigger point. Gradually increased the pressure with rate about 1kg/sec until the patient started to feel pain or discomfort, then recorded the pain threshold. Repeated the process for 3 times with rest 60 second between each time using the mean for statistic analysis. Shoulder range of motion were recorded in internal and external rotation by using goniometer. Repeated for 2 times with rest 30 second between each time. The mean was used for statistic analysis.

The patients were randomly allocated into two groups by computer generator randomization as the followings:

Group 1 received the treatment with rESWT by Swiss Dolorclast model which has pneumatic shock wave generator. The first 500 impulses were used at the active trigger point and another 2,000 – 2,500 impulses were used in the area of muscle spasm around the trigger point. The intensity of impulse was 1 - 3.5 bar and the frequency was 15 Hz.The patients were received the treatment 1 time/week for 6 weeks[13] by the same doctor. Only data from the patient who received treatment every week until the end of program would be analyzed.

Group 2 received the treatment with ultrasound by Sonopuls 590 ENRAF NONIUS model. The ultrasound probe was 5 cm^2, using stroking technique with treatment intensity was 0.5 - 2 watt/ cm^2 and the frequency was 1MHz in continuous mode. The patients were received treatment for 10 minutes each time, 5 times/week [14] for 6 weeks by the same therapist. Only data from the patient who received treatment at least 3 times/week would be analyzed.

In both groups, the patient could stop treatment prior to 6 weeks if their VAS score was 0. All patients received stretching exercise after each treatment, home exercise program and education about proper posture for daily activity. Between the treatment programs, the patient could take only acetaminophen (500 mg) for pain relief. Pain threshold, pain intensity, shoulder range of motion, amount of acetaminophen and adverse event would be recorded every week. At the end of treatment, satisfaction was evaluated by using numeric rating scale from 1 (not satisfied) to 5 (very satisfied).

Outcome measurement

Primary outcome

- Evaluation of pressure pain threshold by algometer (PPT) before and every week of treatment program until the end of treatment program.

Secondary outcome

- Evaluation of pain intensity by visual analogue scale (VAS 0 - 100) and range of motion of shoulder (ROM) before and every week of treatment program until the end of treatment program.

- Evaluation of satisfaction (numeric rating scale 0 - 5) after the end of treatment program.

Statistical Analysis

1. The quantitative data, pressure pain threshold by algometer (PPT), pain intensity by visual analogue scale (VAS), range of motion of shoulder (ROM) and the amount of acetaminophen were analyzed using mean and standard deviation, and using unpaired *t*-test compared between two groups.
2. The qualitative data were analyzed compared between two groups using chi-square test.
3. Comparing of pressure pain threshold, pain intensity, shoulder range of motion before and after treatment between two groups using repeated ANOVA.
4. Comparing of satisfaction between two groups using Mann Whitney U test.
5. The statistical significance was set at $P < 0.05$

Results

Forty-five patients participated in this study were 8 male and 37 female, average age was 43.8 ± 11.6 years (22 – 65 years), and the mean duration of pain was 10.75 ± 5.35 months (5 - 24 months). There were 25 patients in group 1 who received rESWT and 20 patients in group 2 who received ultrasound as shown in Figure 1. There was no statistical difference between the two groups in demographic data, duration of pain, side of pain, career, previous treatment and baseline data before starting this treatment program as shown in Table 1.

There was statistical significance of pain reduction > 20% at the first week after received the treatment in both groups. Most of the patients were subside from pain (VAS = 0) at 3 - 4 weeks of treatment program without statistical difference ($P = 0.59$) between the two groups as shown in Figure 2 and 3.

Comparing before and 3 weeks after treatment, there was statistical significance increase of pressure pain threshold (PPT), pain score reduction(VAS) and increase shoulder range of motion ($P < 0.01$) as shown in Table 2.

Comparing between two groups after treatment, there was statistical significance increase pressure pain threshold in group 1 more than group 2 ($P < 0.01$), but there was no statistical difference in VAS and shoulder range of motion as shown in Table 3.

There was statistical difference of satisfaction in pain reduction and compliance in group 1 more than group 2.

There was no major adverse event in this study, only 3 patients had muscle soreness for 1 - 2 days after received rESWT.

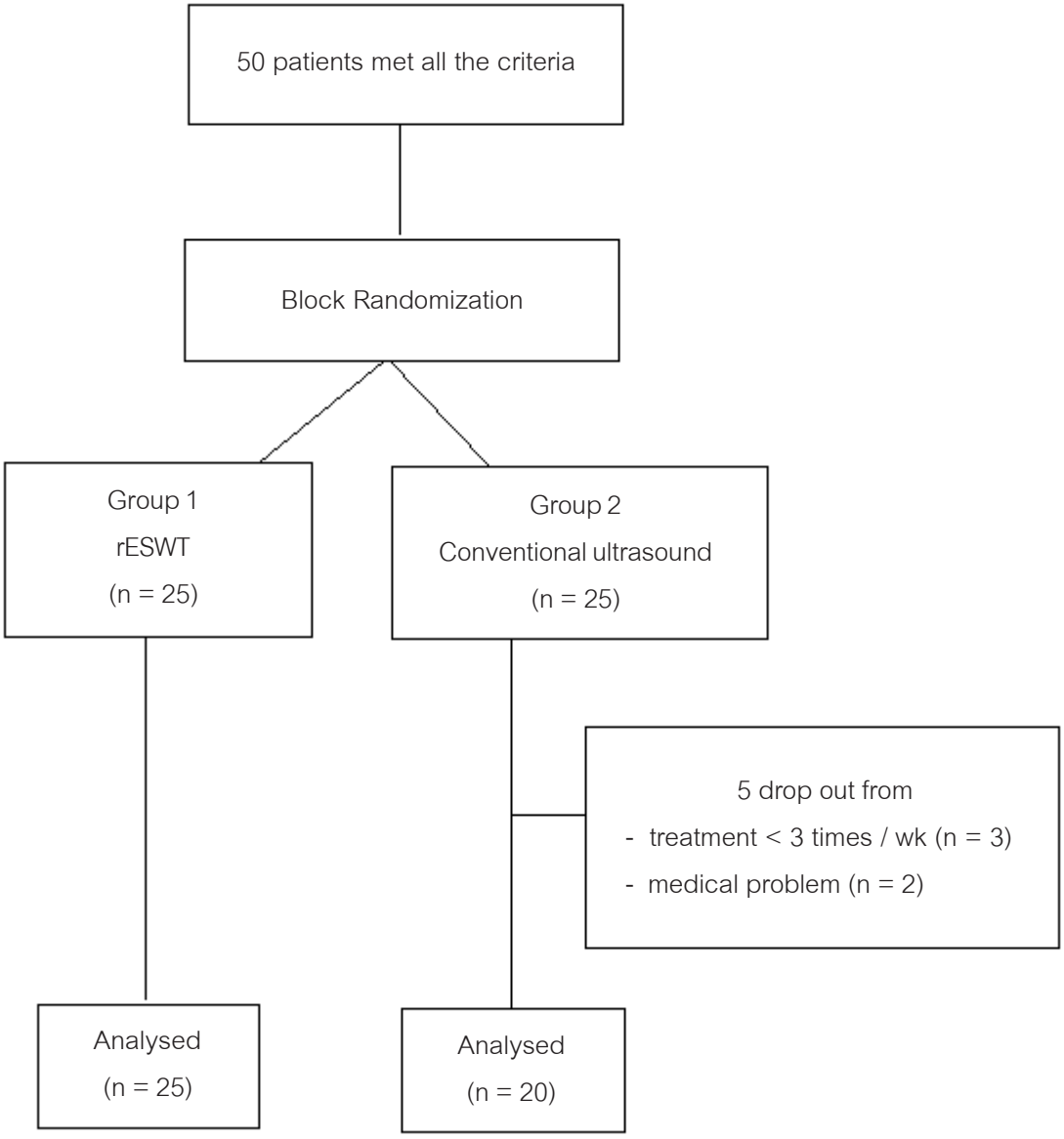

Figure 1. Randomization flow diagram.

Table 1. Baseline characteristics of patients with chronic myofascial pain syndrome.

Baseline data	**ESWT (N = 25) Mean (SD)**	**Ultrasound (N = 20) Mean (SD)**	***P*-value**
Gender - female : male	20 : 5 (4 : 1)	17 : 3 (5.6 :1)	0.66
Age (years)	42.88 (12.32)	44.95 (11.02)	0.55
Body mass index (kg/m^2)	22.19 (2.07)	23.21 (2.44)	0.14
Duration of pain (months)	11.72 (5.75)	9.55 (4.66)	0.17
Side - right	14 (56%)	15 (75%)	
- left	11 (44%)	5 (25%)	0.18

Table 1. (Con) Baseline characteristics of patients with chronic myofascial pain syndrome.

Baseline data		ESWT (N = 25) Mean (SD)	Ultrasound (N = 20) Mean (SD)	*P*-value
Career*	- heavy worker	2 (8%)	2 (10%)	
	- light worker	23 (92%)	18 (90%)	0.81
Previous treatment				
- no previous treatment		6	12	
- dry needling 1		1		
- xylocaine injection		3	2	
- ultrasound 8 3				
Evaluation before treatment				
- pain intensity (VAS)		77.32 (6.02)	77.12 (6.98)	0.92
- pressure pain threshold		2.15 (0.32)	2.22 (0.36)	0.5
- shoulder range of mention				
: internal rotation		71.4 (10.02)	75.95 (5.81)	0.06
: external rotation		76.7 (5.48)	79.65 (4.39)	0.05

* heavy worker : farmers , laborer, motor car mechanic etc.

* light worker : housekeeper , officer, business owner etc.

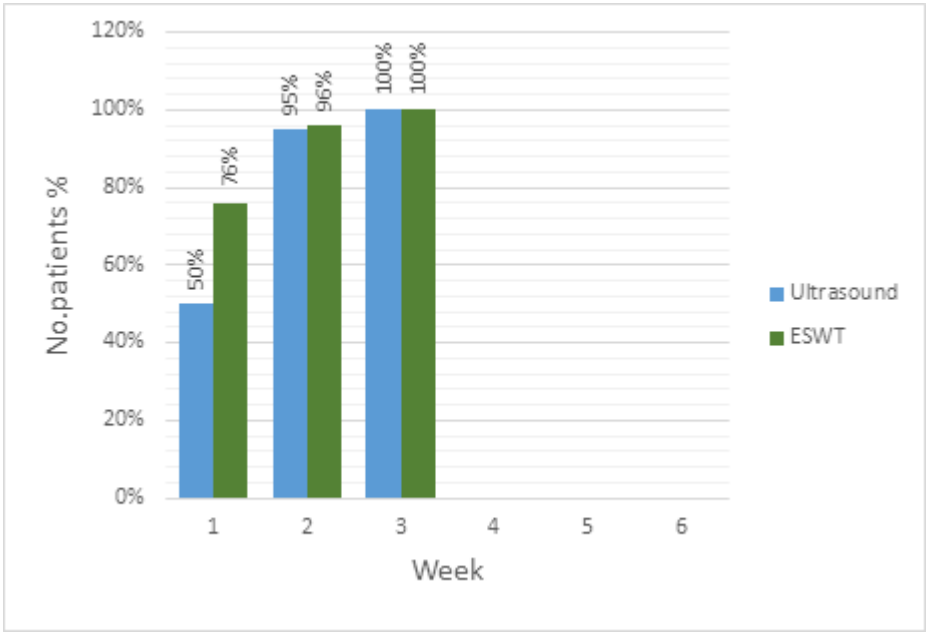

Figure 2. Percentage of patients and duration of pain reduction > 20% after treatment.

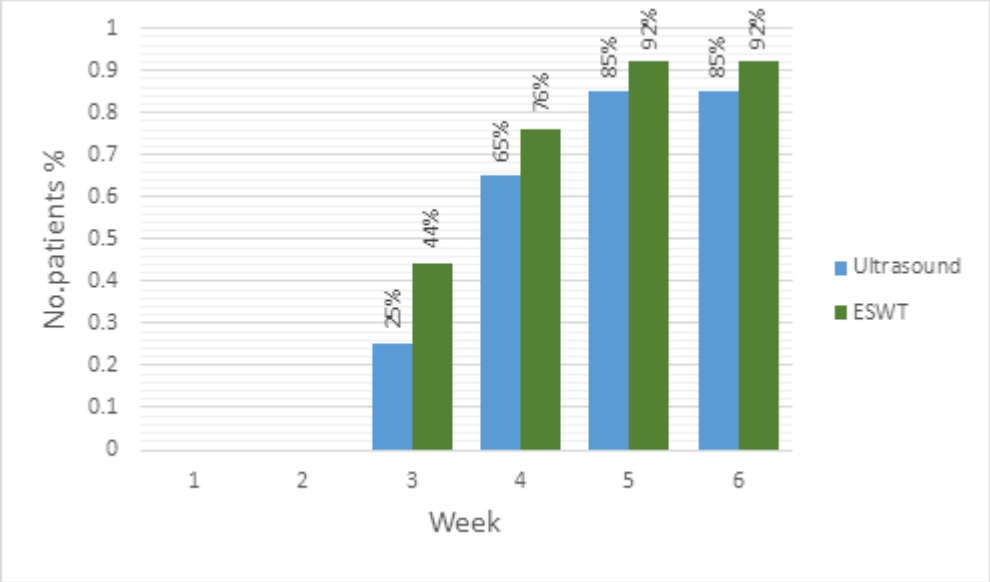

Figure 3. Percentage of patients and duration after treatment which subside from pain. (VAS = 0)

Table 2. Pressure pain threshold (PPT), pain intensity (VAS), shoulder ROM (IR: internal and ER: external rotation) of both groups before treatment and at 3 weeks after treatment.

		ESWT (N = 25)			**Ultrasound (N = 20)**		
		mean (SD)	***P* - value**	**95 % CI**	**mean (SD)**	***P* - value**	**95 % CI**
PPT	Week 0	2.17 (0.33)			2.25 (0.36)		
	Week 3	2.99 (0.50)	< 0.01 *	-0.9 to -0.6	2.61 (0.35)	< 0.01 *	-0.4 to -0.2
VAS	Week 0	76.89 (5.89)			76.38 (6.96)		
	Week 3	14.95 (16.60)	< 0.01 *	54.7 to 67.3	21.11 (16.51)	< 0.01 *	45.7 to 60.9
Shoulder ROM (IR)	Week 0	71.73 (10.37)		76.22 (6.06)			
	Week 3	87.84 (4.73)	< 0.01 *	-19.6 to -12.9	89.11 (2.30)	< 0.01 *	-15.3 to -10.7
Shoulder ROM(ER)	Week 0	77.06 (5.51)			80.16 (4.33)		
	Week 3	89.63 (1.15)	< 0.01 *	-15.1 to 10.8	90.00 (0.01)	< 0.01 *	-12.0 to 8.1

* Statistic significance $P < 0.05$ comparing within the group.

Table 3. Pressure pain threshold (PPT), pain intensity (VAS), shoulder ROM (IR: internal and ER: external rotation) comparing between both groups, before and at 3 weeks after treatment.

	ESWT (N = 25) mean (SD)	**Ultrasound (N = 20) mean (SD)**	***P* - value**	**95 % CI**
PPT				
Week 0	2.15 (0.32)	2.22 (0.36)	0.5	
Week 3	2.95 (0.49)	2.56 (0.37)	0.04 *	-0.6 to -0.1
Difference	0.33 (0.21)	0.80 (0.39)	< 0.01 *	-0.6 to -0.2
VAS				
Week 0	77.32 (6.02)	77.12 (6.98)	0.92	
Week 3	16.28 (16.54)	23.77 (17.89)	0.15	-3.0 to 17.9
Difference	61.04 (15.26)	53.35 (16.20)	0.11	-17.2 to 1.8
Shoulder ROM (IR)				
Week 0	71.4 (10.02)	75.95 (5.81)	0.06	
Week 3	87.74 (4.65)	89.00 (2.29)	0.24	-0.8 to 3.4
Difference	13.35 (5.01)	16.34 (8.1)	0.13	-6.9 to 0.9
Shoulder ROM (ER)				
Week 0	76.7 (5.48)	79.65 (4.39)	0.05	
Week 3	89.66 (1.10)	89.75 (1.11)	0.78	-0.5 to 0.7
Difference	10.4 (4.39)	12.96 (5.19)	0.08	-5.4 to 0.32

* Statistic significance $P < 0.05$ comparing between both groups.

Table 4. Comparing satisfaction scores between both groups at the end of treatment.

Satisfaction	**ESWT (N = 25) mean (SD)**	**Ultrasound (N = 20) mean (SD)**	***P* - value**
Pain reduction	4.84 (0.37)	4.10 (0.44)	<0.01
Convenience of treatment	4.80 (0.40)	3.75 (0.71)	<0.01
Compliance (treatment day/week)	4.92 (0.27)	3.65 (0.48)	<0.01

*Statistic significance $P < 0.05$ comparing between both groups.ik

Discussion

The result of this study revealed that, there were statistical significant increase of PPT, decrease VAS for pain and increase range of motion of shoulder after 3 weeks of rESWT treatment in chronic MPS at the infraspinatus muscle that was similar to Luxemberurg's and Bauermeister's studies.[5,8] Luxemberurg's study which treated 93 patients who had chronic MtrP at the neck using low to moderate energy shock wave with 1,000 – 4,000 shock impulses

once a week for 3 - 10 weeks (average 5 - 6 treatment sessions) and found that the pain was reduced for 80% and also improved the range of motion of the neck. In Bauermeister's study which treated active trigger point in chronic pain of the neck, lower back and shoulder with rESWT (Swiss dolorclast) and found that VAS after treatment were reduced in all groups.

The exact mechanism of shock wave therapy in treatment of MtrP remains unknown. We believed that direct mechanical force of shock wave to the muscle knot might release the MtrP and decrease the muscle tone[13] and the molecular effect might stimulate neovascularization and increase tissue growth factors that improve blood circulation and tissue regeneration. It may also have analgesic effect that can reduce pain.[15,16]

In this study, we compared the two groups at 3 weeks of treatment and found that there was more statistically significant increase of PPT in the rESWT group than that of the ultrasound group (P <0.01). The pressure algometer is a quantitative tool that has good sensitivity and specificity to evaluate myofascial trigger point sensitivity[12] similar to the study of Srbely JZ, et al[11] and Esenyel M, et al[17] that using PPT to follow up the result of the treatments of MPS. In this study, we also found that the rESWT group had more pain intensity reduction (VAS) than the ultrasound group but without statistical difference; this might came out from our too small sample sizes.

The duration of treatment with rESWT in this study showed that there was clinical significance in pain reduction (>20%) at 1 week of treatment; most patients were free from pain (VAS = 0) at 3 - 4 weeks of treatment program similar to Luxemberurg's study[13] which used rESWT 1 - 2 times/week for 6 - 8 times in the treatment of chronic MPS.

There was statistical difference in satisfaction score for pain reduction and convenience of treatment in rESWT group more than ultrasound group (P <0.01) because rESWT is non invasive, minimal adverse event and need only 1 treatment time/week which has better compliance more than ultrasound. In this study we found 20% drop out in the ultrasound group.

Conclusion

Radial extracorporeal shock wave therapy (rESWT) is more effective than the conventional ultrasound treatment for pain reduction in chronic myofascial pain syndrome at the infraspinatus muscle. The rESWT is safe without major adverse event and has such a good compliance that the patient needs receive the treatment only once a week. Therefore, rESWT is one of the effective treatments for chronic myofascial pain syndrome.

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