

EFFECTIVENESS OF ULTRASOUND-GUIDED MDs SHOULDER INJECTION IN THE TREATMENT OF SUPRASPINATUS TENDONITIS AT THAI BINH MEDICAL UNIVERSITY HOSPITAL

ABSTRACT

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Objective: To evaluate the results and safety of ultrasound-guided MDs shoulder injection in the treatment of supraspinatus tendonitis at Thai Binh Medical University Hospital.

Method: Descriptive, longitudinal, non-controlled study. Each patient received 2 ml of MDs Shoulder collagen (1 vial per session) injected into the subacromial bursa under ultrasound guidance, for a total of 5 consecutive injections, one week apart. The parameters to evaluate the effectiveness of MD Shoulder collagen injection therapy include improving pain levels on the VAS scale, improving shoulder joint motor function on the OSS scale, abduction angle of shoulder and ultrasound imaging. Parameters to evaluate the adverse effects of the therapy. Firstly, local manifestations include increased pain after injection, infection at the injection site, bleeding. Secondly, whole body manifestations include changing in pulse and blood pressure, headache, dizziness, nausea, vomiting, itching, shock. Assessment time points: pre-treatment (T⁰), 1-week post-treatment (T¹), 4 weeks post-treatment (T⁴), and 12 weeks post-treatment (T¹²).

Results: The therapy of ultrasound-guided MDs shoulder injection for supraspinatus tendonitis obtained the following results: the therapy improves VAS pain scores from week 4 and week 12, OSS function scores from week 4 and week 12, abduction angle of shoulder from week 1, week 4, and week 12; reduces hypoechoic rate on ultrasound by week 12. Regarding adverse effects, no whole-body adverse effects or serious complications were observed during the 3-month follow-up. Increased pain at the injection site occurred in 11.4% of cases.

Conclusion: The therapy of ultrasound-guided MDs shoulder injection for supraspinatus tendonitis obtained the following results: the therapy improves VAS pain scores from week 4 and week 12, OSS function scores from week 4 and week 12, abduction

angle of shoulder from week 1, week 4, and week 12; reduces hypoechoic rate on ultrasound by week 12. Regarding adverse effects, no whole-body adverse effects or serious complications were observed during the 3-month follow-up. Increased pain at the injection site occurred in 11.4% of cases.

Keywords: Effectiveness, MDs Shoulder, ultrasound-guided injection, supraspinatus tendonitis.

I. INTRODUCTION

Rotator cuff tendon pathology is common. The incidence of symptomatic or asymptomatic rotator cuff disease, identified by surgery or imaging, increases with age, from 9.7% in those under 20 to 62% in those over 80 [1]. In the general population, rotator cuff pathology is the most common cause of shoulder pain. Any rotator cuff tendon can be damaged, but the supraspinatus tendon is most frequently affected. The term "supraspinatus tendon pathology" refers to primary damage to the supraspinatus tendon, including inflammation or degeneration, also known as "supraspinatus tendonitis."

There are various treatment options for supraspinatus tendonitis. Local collagen injection has been increasingly used in recent years, particularly with ultrasound guidance. Under real-time imaging, ultrasound-guided injection allows for more accurate targeting of the damaged area and needle placement.

Worldwide, studies have evaluated the efficacy of ultrasound-guided collagen injection in the treatment of shoulder joint pathologies. In 2014, Nestorova R et al [2] published a clinical and ultrasound study on the efficacy of Guna MDs collagen injection in treating acute pericapsular shoulder inflammation. The results showed significant pain relief, which persisted after treatment ended. Shoulder function improved, with a statistically significant difference, and no adverse effects were recorded. Conclusion: GUNAMDs collagen reduces pain and inflammation significantly in patients with pericapsular shoulder syndrome, subacromial bursa inflammation, and improves shoulder function, thereby enhancing quality of life.

In Vietnam, a study by Dang Chi Hieu and Nguyen Vinh Ngoc [3] published in 2021 evaluated the

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results of MDs Shoulder collagen injection under ultrasound guidance in treating supraspinatus tendonitis. The results showed that the therapy reduced pain and improved shoulder function and range of motion after 12 weeks. MDs Shoulder injections were as effective as Depo-Medrol injections in pain reduction, but MDs Shoulder therapy improved shoulder function better from the 5th week, continuing to 12 weeks ($p < 0.05$).

At Thai Binh Medical University Hospital, patients with supraspinatus tendonitis are frequently diagnosed and treated with local collagen injections. Therefore, we conducted this study to evaluate the efficacy and safety of MDs Shoulder injection under ultrasound guidance.

II. SUBJECTS AND METHODS

2.1. Subject, location, and study period

Patients having examinations at Thai Binh Medical University Hospital from June 2023 to July 2024, who were diagnosed with supraspinatus tendonitis based on clinical and ultrasound findings, agreed to have collagen injection treatment and had no contraindications for local injection (e.g., poorly controlled diabetes, skin infection at the injection site, fungal infections).

2.2. Method

Study design: Descriptive, longitudinal, non-controlled study. Each patient received 2 ml of MDs Shoulder collagen (1 vial per session) injected into the subacromial bursa under ultrasound guidance, for a total of 5 consecutive injections, one week apart. The parameters to evaluate the effectiveness of MD Shoulder collagen injection therapy include improving pain levels on the VAS scale, improving shoulder joint motor function on the OSS scale, abduction angle of shoulder and ultrasound

imaging. The OSS is a 12-item questionnaire. Each question is scored from 1 to 5. Then the total score is calculated. The total score ranges from 12 (best) to 60 (worst). Parameters to evaluate the adverse effects of the therapy. Firstly, local manifestations include increased pain after injection, infection at the injection site, bleeding. Secondly, whole body manifestations include changing in pulse and blood pressure, headache, dizziness, nausea, vomiting, itching, shock. Assessment time points: pre-treatment (T^0), 1 week post-treatment (T^1), 4 weeks post-treatment (T^4), and 12 weeks post-treatment (T^{12}). In case of bilateral supraspinatus tendinitis, we counted the number of 2 shoulder joints. At time points T^1 , T^4 , T^{12} or any time during the study period, if the patient showed mild pain, we advised monitoring, if the patient had moderate-severe pain, we prescribed additional celecoxib 200mg, 1-2 tablets/day.

Sample size and selection method: Convenience sampling with all patients meeting the inclusion criteria and no exclusion criteria were selected. A total of 34 patients with 35 affected shoulders were included in the study.

Data analysis: Data were processed using SPSS 20.0.

2.3. Research Ethics

The study was approved by the Scientific Council of Thái Bình University of Medicine and Pharmacy. Collagen products, including MDs Shoulder, have been clinically tested abroad, proving their efficacy and safety in human patients. The product is approved for use in Vietnam by the Ministry of Health under Decision No. 3288/QĐ-BYT on August 21, 2023. Participants had the right to refuse participation.

III. RESULTS

Table 1. General characteristics of the research subject

Age/Gender	Male (Number of Patients, Percentage)	Female (Number of Patients, Percentage)	Total (Number of Patients, Percentage)
< 30	0 (0)	0 (0)	0 (0)
30 - <45	0 (0)	1 (2,9)	1 (2,9)
45-60	5 (14,7)	9 (26,5)	14 (41,2)
> 60	7 (20,6)	12 (35,3)	19 (55,9)
$\bar{X} \pm SD$	58,3 + 7,6	62,1 + 11,5	60.9 + 10.1

Table 2. Compare the average values of VAS scores and OSS scores between the evaluation time points (35 shoulder joints)

Scores		T ⁰	T ¹	T ⁴	T ¹²
VAS	$\bar{X} \pm SD$	7,7	7,4	3,5	1,0
	p	p ₍₁₋₀₎ > 0,05		p ₍₄₋₀₎ < 0,001	p ₍₁₂₋₀₎ < 0,001
OSS	$\bar{X} \pm SD$	46,7	46,4	25,7	16,8
	p	p ₍₁₋₀₎ > 0,05		p ₍₄₋₀₎ < 0,001	p ₍₁₂₋₀₎ < 0,001

After 1 week of treatment, the VAS score showed a trend of decreasing from 7.7 to 7.4, but the difference was not statistically significant (p > 0.05). After 4 weeks of injection, the VAS decreased from 7.7 to 3.5 (p < 0.001). After 12 weeks, the VAS score was very low at 1.0 (p < 0.001).

After 1 week of treatment, the OSS score changed but was not statistically significant (p > 0.05). After 4 weeks of injection, the OSS decreased from 46.7 to 25.7 (p < 0.001). After 12 weeks, the OSS score was low at 16.8 (p < 0.001).

Table 3. Comparison of shoulder movement angles between evaluation time points (35 shoulder joints)

Abduction Angle of shoulder (degrees)	T ⁰	T ¹	T ⁴	T ¹²
$\bar{X} \pm SD$	143	145	162	170
p	p ₍₁₋₀₎ < 0,01		p ₍₄₋₀₎ < 0,001	p ₍₁₂₋₀₎ < 0,001

The shoulder angle gradually increased at each evaluation point. After 1 week of injection, the shoulder angle increased from 143° to 145° (p < 0.01). After 4 weeks, it increased from 143° to 162° (p < 0.001). After 12 weeks of treatment, the shoulder movement angle reached 170° (p < 0.001).

Table 4. Compare the change in ultrasound images between T⁰ and T¹²(35 shoulder joints)

Ultrasound Image	T ⁰ Quantity, (percentage)	T ¹² Quantity, (percentage)	p
Hypoechoic	24 (68,6)	6 (17,1)	< 0,05
Loss of Continuity	3 (8,6) 2 (5,7)		> 0,05
Calcification	1 (2,9)	1 (2,9)	> 0,05
Tendon Thickness ($\bar{X} \pm SD$)	7,8	7,7	< 0,05

The hypoechoic tendon rate before treatment was 68.6%, and after 12 weeks of injection, it decreased to 17.1% (p < 0,05). The loss of continuity decreased from 8.6% to 5.7% (p > 0,05). The calcification image showed no change. After 12 weeks of treatment, the supraspinatus tendon thickness decreased from 7.8 mm to 7.7 mm (p < 0.05).

Table 5. Adverse effects and percentage of patients needing additional NSAID's after injection (34 study subjects)

Informations	Quantity	Percentage
Increased pain after injection	4	11,4
Bleeding at injection site	0	0
Infection at injection site	0	0
Changes in pulse and blood pressure	0	0

Informations		Quantity	Percentage
NSAID's supplement	T ¹	21	61,8
	T ⁴	0	0
	T ¹²	0	0

Four shoulder joints experienced increased pain after the injection, accounting for 11.4%. No cases of bleeding at the injection site, infection or changes in pulse and blood pressure were observed.

After 1 week of injection, 21 patients (22 shoulders) required additional celecoxib, accounting for 61.8%. At later points (4 weeks and 12 weeks), no patients required additional celecoxib.

IV. DISCUSSION

According to Table 1, after one week of treatment, the VAS score showed a downward trend from 7.7 to 7.4, but the difference was not statistically significant ($p > 0.05$). After 4 weeks of injection, the VAS score decreased from 7.7 to 3.5 ($p < 0.001$). After 12 weeks, the VAS score was very low at 1.0, with a statistically significant difference ($p < 0.001$). In 2014, Nestorova R et al [2] published a clinical and ultrasound study evaluating the effectiveness of Collagen Guna MDs injection in the treatment of acute peri-arthritis. The results showed a significant reduction in pain, which continued to be maintained after the treatment was discontinued. The study concluded that Collagen Guna MDs significantly reduced pain and inflammation in patients with shoulder peri-arthritis and subacromial bursa inflammation. Our study results are similar to those of authors Dang Chi Hieu and Nguyen Vinh Ngoc [3], where there was an improvement in pain levels after 12 weeks in the MD Shoulder injection group. Regarding motor function, according to Table 2, after 1 week of treatment, the OSS functional score did not show any statistically significant change ($p > 0.05$). After 4 weeks of injection, the OSS score decreased from 46.7 to 25.7 ($p < 0.001$). After 12 weeks, the OSS score was very low at 16.8 ($p < 0.001$). According to the research of Nestorova R et al [2] on the effectiveness of MD Shoulder and MD Matrix injections into the subacromial space, using the Shoulder Function Assessment (SFA) scale, the SFA score improved significantly, with a statistically significant difference, indicating improved shoulder function and overall quality of life. Collagen therapy helps repair and restructure inflamed tendons by injecting collagen locally, activating the mechanical function of fibroblasts to synthesize new collagen, stimulating self-repair and reorganization of damaged connective tissue. This process takes time, which likely explains the improvement in VAS pain scores and OSS functional scores after 4 weeks and 12 weeks. Table 3 shows the gradual

improvement in shoulder abduction angle at the various time points. After 1 week of injection, the abduction angle increased from 143° to 145° ($p < 0.01$). After 4 weeks, it increased from 143° to 162° ($p < 0.001$). After 12 weeks of treatment, the shoulder range of motion reached 170° ($p < 0.001$). The study by Dang Chi Hieu and Nguyen Vinh Ngoc [3] also reported an improvement in shoulder joint range of motion, from 114.8° at T⁰ to 146.3° at T⁵, 153.7° at T⁸, and 154.3° at T¹². Improvements in ultrasound imaging are shown in tables 4, 5, and 6. The rate of hypoechoic tendons before treatment was 68.6%, and after 12 weeks of injection, it decreased to 17.1%. The image of tendon continuity loss decreased from 8.6% to 5.7%. There was no change in calcification. Among the shoulder joints with hypoechoic images before treatment, 18 showed no hypoechoic images after 12 weeks of treatment. In contrast, no shoulder joints that were initially non-hypoechoic showed any hypoechoic images after 12 weeks, with a statistically significant difference ($p < 0.001$). After 12 weeks of treatment, the thickness of the supraspinatus tendon decreased from 7.8 mm to 7.7 mm ($p < 0.05$). MD-Shoulder provides collagen in the form of tropocollagen, which is the basic unit of collagen fibers in tendons, muscles, and cartilage. After MD-Shoulder injection into the damaged area, newly synthesized collagen fibers accumulate in the damaged area, significantly improving the mechanical properties of the damaged tissue, promoting tissue repair and tendon healing. Our study results show both clinical and ultrasound imaging improvements. Regarding post-injection adverse events, the results are shown in tables 7 and 8. After injection, there were no cases of changes in pulse rate or blood pressure. Four shoulder joints experienced increased pain after injection, accounting for 11.4%. No cases of shock, allergic rash, local bleeding, or infection

were observed. These results suggest that MD Shoulder injections are a safe method with very rare unwanted effects. The study by Dang Chi Hieu and Nguyen Vinh Ngoc [3] also showed similar results, with 13.3% of patients in the intervention group experiencing increased pain after injection. After one week of follow-up, no adverse reactions were observed. In the study by Nestorova R et al [2] on 20 patients with acute periartthritis, no side effects were reported. After 1 week of injection, 21 patients (22 shoulders) required additional celecoxib, accounting for 61.8%. At later time points (after 4 weeks and 12 weeks), no patients needed additional celecoxib. In our study, after one week of MD Shoulder injection, the pain level showed little improvement, with minimal reduction in VAS pain scores and many patients still in severe pain categories. These patients were given additional oral celecoxib at doses of 200-400 mg/24 hours for 5-10 days. After 4 and 12 weeks of treatment, the pain levels significantly improved, with no patients reporting severe pain. Therefore, we did not prescribe celecoxib at these two time points. The use of celecoxib could impact the effectiveness of collagen injection therapy, specifically pain reduction, which could lead to increased shoulder range of motion and improved shoulder function. However, this effect is short-lived, as the half-life of the drug in plasma is 11 hours.

V. CONCLUSION

MD Shoulder collagen injection therapy under ultrasound guidance in the treatment of supraspinatus tendinopathy has the following effects and safety profile: improvement in VAS pain scores at the 4th and 12th weeks; improvement in OSS functional scores at the 4th and 12th weeks; improvement in shoulder abduction angle at the 1st, 4th, and 12th weeks; improvement in the hypoechoic ratio on ultrasound at the 12th week; no systemic adverse effects or serious complications observed during the 3-month follow-up; increased pain at the injection site occurred in 11.4% of patients; 61.8% of patients required additional celecoxib after the first week of injection.

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