นิพนธ์ต้นฉบับ

การศึกษาเปรียบเทียบประสิทธิผลของยาสเตียรอยด์สองขนาดในการฉีดสารน้ำเพื่อขยายเยื่อหุ้มข้อไหล่ โดยใช้เครื่องอัลตราซาวด์นำในผู้ป่วยไหล่ติด การทดลองแบบสุ่มและมีกลุ่มควบคุมแบบอำพรางสามฝ่ายที่แสดงความไม่ด้อยกว่า

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บทคัดย่อ

ที่มาของปัญหา: การฉีดสารน้ำเพื่อขยายเยื่อหุ้มข้อไหล่เป็นหนึ่งในวิธีการรักษาโรคไหล่ติดที่ใช้กันอย่างแพร่หลาย สารน้ำที่นิยมฉีดเข้าไปประกอบด้วย น้ำเกลือ ยาชาเฉพาะที่ และสเตียรอยด์ ขนาดของ triamcinolone acetonide (TA) ที่นิยมใช้ผสมสารน้ำคือ 20-40 มก. แต่การฉีดสเตียรอยด์เข้าในข้ออาจทำให้เกิดผลข้างเคียงได้ทั้งกับตัวข้อและกับร่างกาย

วัตถุประสงค์: เพื่อเปรียบเทียบประสิทธิผลของ TA 10 มก. กับ TA 40 มก. ที่ผสมในสารน้ำที่ฉีดเพื่อขยายเยื่อหุ้มข้อไหล่ในผู้ป่วยไหล่ติด

วิธีการศึกษา: การทดลองแบบสุ่มและมีกลุ่มควบคุมแบบอำพรางสามฝ่ายที่แสดงความไม่ด้อยกว่า อาสาสมัคร 42 คน ที่ได้รับการวินิจฉัยว่าเป็นโรคไหล่ติด แบ่งเป็นกลุ่มละ 21 คน กลุ่ม TA 10 มก. ได้รับการฉีดสารน้ำเพื่อขยายเยื่อหุ้มข้อไหล่โดยใช้อัลตราซาวด์นำด้วยสารน้ำที่ประกอบด้วย TA 10 มก. 1 มล., 1% lidocaine 5 มล. และน้ำเกลือ 14 มล. กลุ่ม TA 40 มก. ใช้สารน้ำที่ประกอบด้วย TA 40 มก. 1 มล., 1% lidocaine 5 มล. และน้ำเกลือ 14 มล. ผลลัพธ์หลักของการวิจัยคือ Shoulder Pain and Disability Index (SPADI) ผลลัพธ์รองคือ passive range of motion และ visual analogue scale ที่ 4 สัปดาห์ หลังการฉีด

ผลการศึกษา: ค่าเฉลี่ยของ SPADI ที่ 4 สัปดาห์ หลังการฉีด เท่ากับ 27.5±12 ในกลุ่ม TA 10 มก. และ 24.5 ±13 ในกลุ่ม TA 40 มก. ค่าสูงสุดของ 95% CI ของกลุ่ม TA 10 มก. (33.0) ไม่มากกว่าค่าต่ำสุดของ 95% CI ของกลุ่ม TA 40 มก. (18.6) บวกกับ 15 ซึ่งเป็นค่า non-inferiority margin (33.6) ผลลัพธ์รองที่ 4 สัปดาห์ ไม่มีความแตกต่างอย่างมีนัยสำคัญทางสถิติระหว่าง 2 กลุ่ม ยกเว้น passive external rotation

สรุป: การใช้ TA 10 มก. ผสมในสารน้ำที่ฉีดเพื่อขยายเยื่อหุ้มข้อไหล่ ไม่ด้อยกว่าการใช้ TA 40 มก. ในการเพิ่มสมรรถภาพของข้อไหล่ในโรคไหล่ติดระยะที่ 2 และ 3 การใช้ TA ขนาด 10 มก. น่าจะเป็นทางเลือกที่เหมาะสมเพื่อหลีกเลี่ยงผลข้างเคียงที่อาจเกิดจากสเตียรอยด์

คำสำคัญ: ข้อไหล่, สเตียรอยด์, อัลตราซาวด์, ไหล่ติด

Thaiclinicaltrials.org number, TCTR20201125003

ORIGINAL ARTICLE

Comparison of the Effectiveness of Two Corticosteroid Dosages in Ultrasound–guided Capsular Hydrodilatation in Patients with Adhesive Capsulitis: A Randomized, Triple–blind, Non–inferiority Study

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ABSTRACT

BACKGROUND: Hydrodilatation is one of the common treatments for adhesive capsulitis (AC) and aims to achieve physical distension of the shoulder joint capsule by injecting a considerable amount of fluid that contains normal saline, corticosteroids, and local anesthetics into the joint. The dosage of triamcinolone acetonide (TA) commonly used in hydrodilatation fluid is 20-40 mg. Intra-articular corticosteroids have many potential complications.

OBJECTIVES: To compare the effectiveness of two corticosteroid dosages (10 mg VS 40 mg TA) in ultrasound-guided capsular hydrodilatation in patients with AC

METHODS: A randomized, triple-blind, non-inferiority study. Forty-two participants who had been diagnosed with AC were randomly divided into 2 groups. Both groups received ultrasound-guided hydrodilatation. Hydrodilatation fluid in the 10 mg TA group contained 1 mL of 10 mg TA, 5 mL of 1% lidocaine, and 14 mL of normal saline solution, while in the 40 mg TA group contained 1 mL of 40 mg TA, 5 mL of 1% lidocaine, and 14 mL of normal saline solution. Outcome measures include the Shoulder Pain and Disability Index (SPADI) as primary outcome, passive range of motion, and visual analogue scale at 4 weeks.

RESULTS: The mean SPADI at 4 weeks were 27.5±12 in 10 mg TA group and 24.5±13 in 40 mg TA group. The upper bound of the 95% CI of 10 mg group (33.0) lay below the lower bound of the 95% CI of 40 mg TA group (18.6) plus non-inferiority margin of 15 (33.6). There was also no significant difference between the two groups at 4 weeks for all secondary outcome measurements except passive external rotation of the shoulder.

CONCLUSIONS: Using 10 mg of TA in hydrodilatation fluid was similar to using 40 mg of TA in terms of function improvement in patients with stage 2 and 3 of AC. For patients with AC, hydrodilatation with a low dose of corticosteroids may be the optimal treatment option.

KEYWORDS: shoulder, steroids, ultrasonography, bursitis

INTRODUCTION

Adhesive capsulitis (AC) or frozen shoulder is a condition of unknown etiology that results in the development of restriction of active and passive shoulder motion. Approximately 2% to 5% of the general population is affected by AC. AC is 2-4 times more common in females than males and most frequently seen in people between the ages of 40 and 60.[1] Although AC is self-limiting, it can affect daily life. In the long term, 41% of patients reported some ongoing symptoms.[2]

The common treatment for AC includes range of motion (ROM) exercise, physical therapy, intra-articular corticosteroid injections, hydrodilatation, manipulation under general anesthesia and arthroscopic lysis of adhesion. Hydrodilatation aims to achieve physical distension of the shoulder joint capsule by injecting a considerable amount of fluid that contains normal saline, corticosteroids, and local anesthetics into the joint.[3-5] Ultrasound-guided hydrodilatation increased the accuracy of the injections and prevented the adverse effects associated with extra-articular leakage and damage to adjacent structures. It can be performed as an outpatient procedure with no exposure to radiation. Although hydrodilatation's long-term efficacy is similar to that of all other treatments[3-4], it provides short-term benefits in the treatment of AC.[3-6] This should allow patients to return to their daily activities faster, and will not need to come to the hospital frequently, thus reducing congestion in the hospital. Previous studies have compared the clinical outcomes of capsule-preserved hydrodilatation against those of capsule-ruptured hydrodilatation. The result showed that greater improvements in pain and ROM were observed in the capsule-preserved group than in the ruptured group.[7] The dosage of corticosteroids in the hydrodilatation fluid in each study varies. The dosage of triamcinolone acetonide (TA) commonly used in hydrodilatation fluid is 20-40 mg.[3-5] Some studies compared two corticosteroid dosages for intra-articular corticosteroid injection in the treatment of AC. In a study that compared the symptom relief provided by 10 mg and 40 mg of intra-articular TA, 40 mg of intra-articular TA was found to provide greater symptom relief than 10 mg, whereas another study revealed that there were no statistically significant differences between the 40 mg and 20 mg TA groups.[8-9]

Corticosteroids were mixed in hydrodilatation fluid in order to reduce inflammation. Corticosteroid injections may cause various side effects, such as increased blood sugar in a diabetic patient, atrophy of subcutaneous fat tissue, and depigmentation of the skin.[10-11] Intra-articular corticosteroids may impair the structure and function of the articular cartilage. It is commonly known that corticosteroids, by the dose, have a negative effect on articular cartilages in a time-dependent manner.[12-14] Therefore, it is widely recommended to use the smallest dose possible, although dose-dependent efficacy in hydrodilatation has rarely been studied. The aim of this study is to compare the effectiveness of two corticosteroid dosages (10 mg VS 40 mg TA) in ultrasound-guided capsular hydrodilatation in patients with AC. We hypothesized that a 10 mg TA regimen would not be inferior to a 40 mg TA regimen with regard to improvement of shoulder function, shoulder pain, and ROM.

METHODS

Study design

A triple-blind (operator, participants and outcome assessor), non-inferiority, randomized controlled trial design will be used to compare the effect of 10 mg of TA in hydrodilatation fluid (10 mg TA group) and 40 mg of TA in hydrodilatation fluid (40 mg TA group) for treatment of AC. This study was conducted at Lerdsin hospital in Bangkok, Thailand from January 2021 to December 2022. The trial protocol was approved by the Lerdsin Hospital Ethics Committee (Number LH631053) and was

registered in the Thai Clinical Trials Registry (TCTR20201125003).

Participants

Study participants were adults (age ≥ 18 years) who had been diagnosed with AC and had restriction of passive motion greater than 30° in two or more planes of movement.[6] Exclusion criteria were fibromyalgia; rheumatoid arthritis; ankylosing spondylitis; myositis; myopathy; cancer; coagulopathy; secondary AC; history of trauma to shoulder joint; rotator cuff lesion on ultrasonographic examinations; previous corticosteroids injection at the affected shoulder; allergy to local anesthetic, corticosteroids or normal saline solution. All participants provided written informed consent.

Sample size

The sample size estimation was based on our previous pilot study revealing a mean difference of post-intervention SPADI scores between the two groups: 4.76 with a standard deviation of 12.36. Assuming α=0.05 and β=0.2 we estimate that 38 participants (19 per group) will be required to test for comparative efficacy between the two treatments with a non-inferiority margin of 15 points in SPADI scores. With an estimated drop-out rate of 10%, the target sample size was 42 participants (21 participants per group). Selection of the non-inferiority margin is based on SPADI's test properties. There is no minimal clinically important change (MCIC) of SPADI score in patients with AC. Previous study presented estimates of the MCIC of SPADI in patients with rotator cuff disease who received corticosteroid injection in the subacromial bursa or systemic corticosteroid injection.[15] MCIC were 15.4 at 2 weeks and 23.1 at 6 weeks for SPADI. Our study also aims to compare the effectiveness of two corticosteroid dosages in patients with shoulder problem that is comparable to this study. Therefore, the non-inferiority margin is set to 15 points.

Randomization

The primary researcher (Siriwadee N.) randomized and allocated participants in a 1 to 1 ratio, with random permuted blocks of size two and four, to 10 mg TA group and 40 mg TA group, using Stata's ralloc procedure. The allocation sequence was concealed from the operator.

Intervention

All hydrodilations were performed by the same board-certified physiatrist who has 5 years' experience in musculoskeletal ultrasound with ultrasound equipment (using SONIMAGE HS1, Konica Minolta Inc., Japan) 4- to 18-MHz linear array transducers. Participants were side lying on the unaffected side. Using an aseptic technique, a 22-gauge spinal needle was inserted into the glenohumeral joint from the posterior aspect of the shoulder. Hydrodilatation fluid was prepared by the primary researcher using an opaque syringe, thus the participants, operator, and assessor, remained blind to group allocation. For the 10 mg TA group, hydrodilatation fluid was 20 mL of a solution comprising 1 mL of 10 mg TA, 5 mL of lidocaine hydrochloride 1% and 14 mL of normal saline. For the 40 mg TA group, hydrodilatation fluid was 20 mL of a solution comprising 1 mL of 40 mg TA, 5 mL of lidocaine hydrochloride 1% and 14 mL of normal saline. The expansion of the joint capsule was observed via ultrasound while injecting fluid. After hydrodilatation, the participants were asked to wait 20 minutes to observe any acute adverse reactions. All participants received exercise instructions to do at home. Physical therapy and other interventions were prohibited throughout the study. Analgesic and anti-inflammatory drugs were prescribed as needed.

Outcome measurements

Treatment efficacy was evaluated at baseline and 4 weeks after the injection. The primary outcome measure was the Thai version of the Shoulder Pain and Disability Index (Thai SPADI).[16] The SPADI is a self-administered index consisting of 13 items divided into two subscales: pain and disability, which required 5-10 minutes to complete. The SPADI scores

range from 0-100 with higher scores indicating greater impairment.[17] Secondary outcome measures included a 10-cm visual analogue scale (VAS) for global shoulder pain and shoulder passive ROM. A 10-cm VAS with 0 cm representing “no pain” and 10 cm representing “the worst pain possible”. The passive ROM was measured by the assessor who was blinded to the treatment groups using goniometer, forward flexion, abduction, external and internal rotation in sitting position.

Statistical analysis

The analysis was performed according to the intention to treat principle. Categorical data were presented as frequency and percentages, whereas continuous data were presented in terms of mean, median, and standard deviations (SD). To compare demographic and baseline characteristic data among groups, the researchers used the Fisher's exact test for categorical data and the Unpaired t-test (or the Mann-Whitney U test in case of non-normal distribution) for continuous data.

The primary outcome (SPADI at 4 weeks) was analyzed using the Unpaired t-test (or the Mann-Whitney U test in case of non-normal distribution). The 95% confidence interval (CI) for mean SPADI score at 4 weeks of two groups was calculated. Non-inferiority of 10 mg TA group over 40 mg TA group was accepted if the upper bound of the 95% CI of 10 mg TA group lay below the lower bound of the 95% CI of 40 mg TA group plus non-inferiority margin of 15. The secondary outcomes were analyzed using the conventional t-test/ the chi-square test. Statistical significance was accepted at *p*-value less than 0.05. The data were analyzed using Stata version 15.

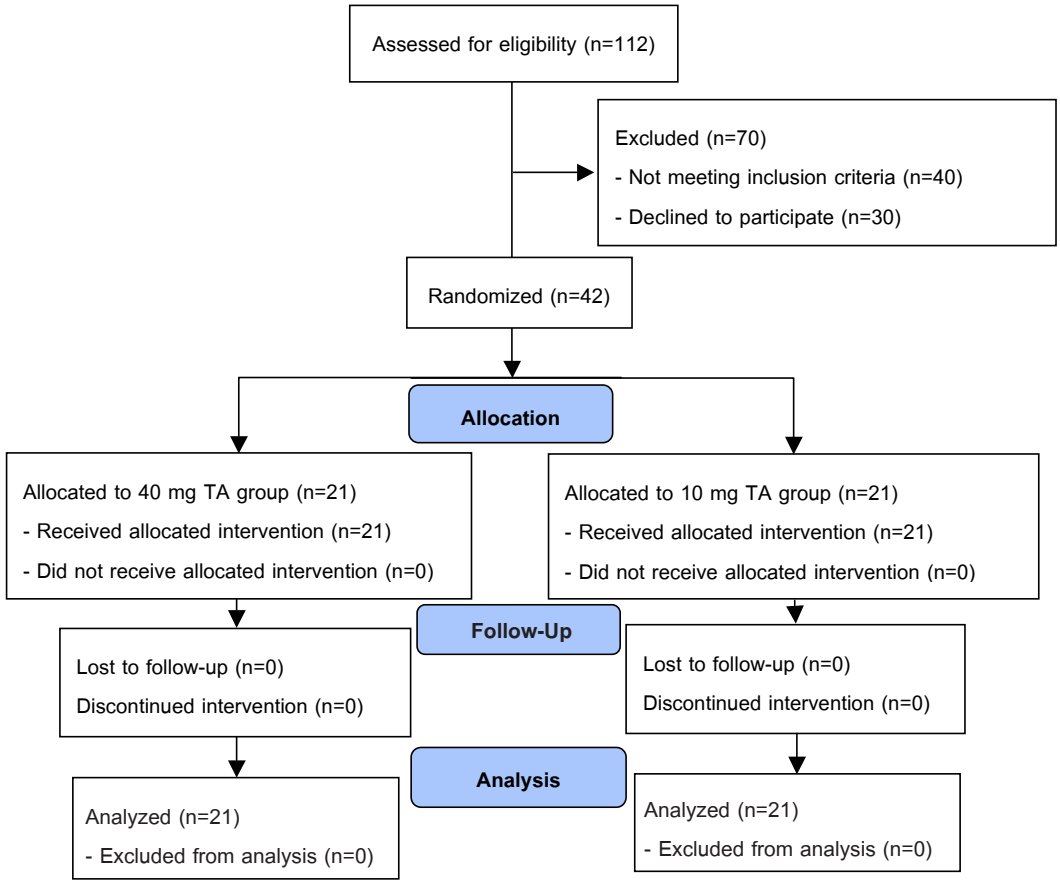

Figure 1 Participant flow chart

RESULTS

Between January 2021 and December 2022, 112 potential participants were screened and 42 were recruited, with 21 participants randomly assigned to each group. The reasons for exclusion were restriction of passive motion less than 30° (n=13), secondary frozen shoulder (n=25), previous corticosteroid injection at the affected shoulder (n=1), taking warfarin (n=1), or declined to participate (n=30). There was no drop out from the study. The flow of the study is shown (Figure 1). There was no significant difference in baseline characteristics and clinical variables between 2 groups including age, sex, presence of DM, duration of symptoms, affected side, and all outcomes at baseline (Table 1). The mean SPADI at 4 weeks were 27.5±12 in 10 mg TA group and 24.5±13 in 40 mg TA group (Table 2). The upper bound of the 95% CI of 10 mg TA group (33.0) lay below the lower bound of the 95% CI of 40 mg TA group (18.6) plus non-inferiority margin of 15 (33.6) (Figure 2). There was also no significant difference between the two groups at 4 weeks for all secondary outcome measurements except passive external rotation of the shoulder (Table 2). There was only one minor side effect: a bruise at the injection site was reported (n=2) in both groups. The majority of both groups performed regular shoulder exercises. There is no significant difference in the use of analgesic medication between the two groups.

Table 1 Baseline demographic and clinical characteristics of participants

Characteristics	10 mg TA group n (%)	40 mg TA group n (%)	*p*-value
Sex; female: n (%)	16 (76)	15 (71)	0.99
Age: mean±SD	50.9±7.8	50.5±6.5	0.88
Diabetes mellitus: n (%)	9 (43)	10 (48)	0.99
Duration; month: median (IQR)	5 (4-9)	5 (4-8)	0.98
Side; right: n (%)	8 (38)	7 (33)	0.99
SPADI: mean±SD	56.4±16.3	56.6±11	0.97
VAS: median (IQR)	3 (2-3)	5 (4-7)	0.66
Forward flexion; degree: mean±SD	121±11.7	120.2±10.5	0.84
Abduction; degree: mean±SD	98.3±19.3	98.3±15.8	0.36
External rotation; degree: mean±SD	59.8±15.6	64.3±11.2	0.29
Internal rotation; degree: mean±SD	27.9±10.2	31.2±11.1	0.32

Table 2 Change of outcome measurement 4 weeks after hydrodilatation

Outcomes	10 mg TA group	40 mg TA group	95%CI	*p*-value
SPADI: mean±SD	27.5±12	24.5±13	-4.7-10.9	0.43
VAS: median (IQR)	3 (2-3)	2 (1-3)	NA	0.16
Forward flexion; degree: mean±SD	134.3±12.9	137.4±12.3	-11-4.8	0.43
Abduction; degree: mean±SD	105.7±20.2	115.5±20.4	-22.4-2.9	0.13
External rotation; degree: mean±SD	67.9±12.2	75±8.7	-13.7-0.54	0.03
Internal rotation; degree: mean±SD	39±9.8	39±10.9	-6.5-6.5	0.99

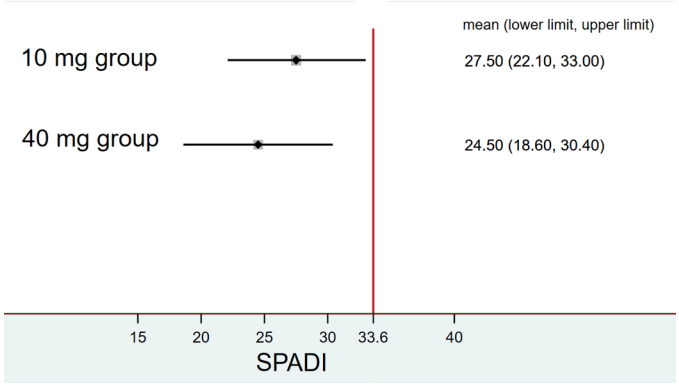

Figure 2 95% confidence intervals for mean SPADI score at 4 weeks

DISCUSSION

This prospective triple-blind randomized, controlled trial showed that the 10 mg TA group was not inferior to the 40 mg TA group with regard to SPADI at 4 weeks. In addition, the secondary outcomes including VAS and passive ROM revealed no significant difference between the two groups except for passive external rotation of the shoulder. These may result from the main effect of hydrodilatation being a physical distention of the shoulder joint capsule. Moreover, the participants in this study already had restriction of shoulder motion in which inflammation had decreased, so the dosage of corticosteroids is not an important factor influencing the treatment outcome. This result is similar to the current double-blind, randomized, controlled trial, in which hydrodilatation with 40 mg TA was compared to hydrodilatation with 10 mg TA in patients with AC.[18] In this trial, the patient demographics are comparable to our study in terms of gender preference, age, and duration of symptom. All outcome measurements, including SPADI, VAS, and ROM at 6 and 12 weeks after injection, were not significantly different between the two groups. Whereas, our study assessed the same outcomes at 4 weeks because we expected that triamcinolone acetonide would be completely absorbed from the joint within a period of 2 to 3 weeks.[19] Based on this knowledge, we determined that a four-week follow-up would be sufficient. Hence, our study is triple-blind, which can minimize possible bias. The passive external rotation ROM at 4 weeks was significantly better in the 40 mg TA group. This result could be due to intra-observer variability. Previous study investigated intra-observer reproducibility of measurements of passive ROM in patients with AC. Data has shown that the estimated smallest detectable difference (SDD) for passive external ROM of the affected side was 13°, while in our study the mean difference of passive external ROM at 4 weeks was 7.1°.[20] Although the passive external rotation ROM at 4 weeks was significantly better in the 40 mg TA group, in both groups, they were still within the functional ROM for daily activities.[21]

The guidance of an optimal dose of corticosteroids in hydrodilatation fluid has not been established, usually being based on the physician's experience. We suggest using the minimum dose of corticosteroids to avoid possible side effects. A previous study compared the effects of hydrodilatation without corticosteroids versus corticosteroids alone in primary idiopathic AC.[22] The results revealed that there was no significant difference in all outcomes between the two groups, and in both groups, there was a significant improvement in ROM and pain. It would be beneficial if a future study compared the efficacy of hydrodilatation without corticosteroids and hydrodilatation with low dose corticosteroids in AC.

The volume of fluid injected during hydrodilatation varied among previous studies. It was reported

that the mean capsule-preserving volume of hydraulic distension in patients with adhesive capsulitis was 25.1±6.9 mL; therefore, in our study, we implied that joint capsules were preserved in the majority of the participants after injections of 20 mL of fluid.[23]

Our study has several limitations. First, although we calculated the sample size based on the results of a previous pilot study, 21 participants per group may be a relatively small sample size. Future studies with larger sample sizes are necessary to further validate our findings. Second, we selected participants who already had restrictions of passive motion which were in the freezing stage (stage 2) and frozen stage (stage 3) according to Hannafin and Chiaia stage. It is possible that the effects of corticosteroids are different in the inflammatory phase (stage 1) or in participants with more severe pain. Lastly, since our diagnoses were based on physical examination and ultrasonography, some participants with minor rotator cuff tears or labral lesions may had been included in the study.

Despite these limitations, there are some positive aspects to this study. First, to ensure the accuracy of the AC diagnosis, each participants was evaluated clinically by the same physician. Second, all ultrasonography and injections were performed by a single experienced physician using sonographic guidance to ensure the injectate was administered within the shoulder joint.

According to the findings of our study, using 10 mg of TA in hydrodilatation fluid was similar to using 40 mg of TA in terms of function improvement in patients with stage 2 and 3 of AC according to Hannafin and Chiaia stage. For patients with stage 2 and 3 of AC, hydrodilatation with a low dose of corticosteroids may be the optimal treatment option.

Conflicts of Interest: None

Financial Support: None

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