Subacromial corticosteroid injection versus subcutaneous 5% dextrose in patients with chronic rotator cuff tendinopathy: A short-term randomized clinical trial

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Abstract: *Aim:* The aim of this study is to compare subcutaneous 5% dextrose versus subacromial corticosteroid injection for the treatment of chronic rotator cuff tendinopathy. *Methods:* We carried out a randomized clinical trial with two parallel groups at a university hospital. Overall, 57 (32 women) were included in two groups of corticosteroid ($n = 29$) and dextrose ($n = 28$). The mean pain score was 6.6 (1.0). We used a visual analog scale for pain and goniometry for the range of motion. The measurements were repeated 1 month after the interventions. For corticosteroid, a single injection of triamcinolone and 1% lidocaine, and for dextrose, a mixture of 5% dextrose and 2% lidocaine three times weekly were prescribed. *Results:* Both interventions were effective in decreasing pain compared to the baseline (both $p < 0.001$). The difference in pain between the two groups was nearly significant 1-month post-intervention ($p = 0.052$). The comparison of the two groups in considerable pain reduction (≥2.8) was in favor of dextrose ($p = 0.046$). The differences in the range of motion were not conclusive. None of the participants reported an important adverse effect. *Conclusion:* The 5% dextrose treatment is at least as effective as corticosteroid for reducing pain in patients with rotator cuff tendinopathy.

Keywords: corticosteroid injection, dextrose, prolotherapy, rotator cuff tendinopathy, shoulder, joint

Introduction

In general population, one out of three individuals eventually experiences shoulder pain [1]. Shoulder pain is a frequent chief complaint of patients presenting to daily practice. Rotator cuff tendinopathy is the most common cause of shoulder pain particularly in older people [2]. In addition to pain, rotator cuff disorders lead to disability and affect the patient's daily activity and well-being. Old patients are at greater risk of age-related degenerative tendinopathy, whereas young patients are more prone to trauma [3].

Patients with rotator cuff tendinopathy are commonly treated with conservative methods. The goals of treatment are to decrease pain and restore function, and the methods are mainly selected according to physicians' experience and habit [4]. Physicians often instruct patients to modify their shoulder activity and to perform exercises for strengthening muscles and increasing range of motion. Non-steroidal anti-inflammatory drugs and corticosteroid injection to the site of pain are usual therapeutic measures for the treatment of rotator cuff tendinopathy [5]. Inadequate therapy increases the probability of recurrent and refractory form of the disease and the patient may need surgical intervention.

In spite of the frequent use of corticosteroid injections as standard therapy, there is still much controversy about its efficacy, indications, and adverse effects [6, 7]. Even systematic reviews were not consistent in their conclusions [4, 8, 9]. A recent meta-analysis showed that the efficacy of corticosteroid injection in reducing pain is similar to placebo. The study indicated that only small

temporary pain relief could be expected between 4 and 8 weeks of treatment [4]. In addition, there is no benefit in multiple corticosteroid injections compared with a single injection [4] or xylocaine alone [10]. However, some researchers prefer to use corticosteroid combined with or as an alternative to other treatment options [11, 12]. A retrospective study showed that preoperative corticosteroid injection would be beneficial in patients undergoing arthroscopic repair of partial-thickness rotator cuff tears [13].

Despite the high prevalence of rotator cuff tendinopathy, there is no established guideline for different treatment modalities, even for physiotherapy and exercise [2, 14, 15]. At present, health services are paying more attention to new and sometimes unproven methods in order to develop inexpensive and practical treatments for rotator cuff disorders [2, 11, 12, 16, 17]. Among the different new methods, prolotherapy with hypertonic dextrose has been used for the treatment of some musculoskeletal conditions [18, 19]. The mechanism of action of near isotonic (5%) dextrose is not known, although there are indications of an analgesic effect [20–22]. However, there is growing evidence regarding the healing effect of hypertonic dextrose [23–25]. In a clinical trial, prolotherapy showed a better outcome than exercise alone for treatment of chronic rotator cuff lesions [23]. In another trial, prolotherapy was better than saline injection for rotator cuff tendinopathy [24]. However, among a few studies on prolotherapy, there is no recently published research for comparing dextrose prolotherapy and corticosteroid injection in the treatment of chronic rotator cuff tendinopathy.

We conducted a trial to compare two treatments for chronic rotator cuff tendinopathy, dextrose prolotherapy versus local corticosteroid injection in the short term. Our hypothesis was that the two treatments would differ regarding pain relief and range of motion in the shoulder joint.

Materials and Methods

Design and setting

From February 2017 to 1 year, we performed a randomized trial with two parallel groups. The study was conducted in the outpatient clinic of the Department of Physical Medicine and Rehabilitation at the Baqiyatallah University Hospital. The hospital is a large referral and subspecialty center in Tehran, Iran.

Recruitment

We recruited patients who had come to the clinic because of shoulder pain. Eligibility was assessed by a resident of physical medicine and rehabilitation who interviewed and examined patients. At first, a form on past medical history and the risk factors of rotator cuff tendinopathy was filled in. Then, general physical examinations were performed and finally detailed shoulder examinations were conducted on the two sides. Measurement of pain with a visual analog scale and assessment of the range of motion for shoulder joints were carried out. Laboratory tests including differential blood cell count, erythrocyte sedimentation rate, and C-reactive protein assessment were ordered. Next, participants with the primary clinical diagnosis of tendinopathy were referred to medical imaging ward to obtain magnetic resonance imaging scan. One radiologist blinded to the study question read all scans. Then, participants were presented to one of the authors who confirmed the diagnoses. For several participants with equivocal manifestations, a consensus committee of the authors decided for diagnosis. Participants who met the eligibility criteria were invited to participate in the study. Enrolled patients who gave consent were immediately allocated randomly to one of the treatment groups.

Eligibility criteria

We included patients if they had chronic rotator cuff tendinopathy. The inclusion criteria were small rotator cuff tear or tendinopathy documented on a magnetic resonance imaging scan, undergoing at least 1-year follow-up because of rotator cuff tendinopathy, and refractory pain in spite of conservative therapy for at least 1 month. We excluded patients if they had large or full thickness rotator cuff tear, history of major trauma at the shoulder, or current adhesive capsulitis. Furthermore, they should have no history of high blood pressure, rheumatoid arthritis, and diabetes mellitus. Patients with previous surgery on the shoulder, corticosteroid injection at the affected site, or cervical spine damages such as discopathies are excluded from the study. Patients were also excluded if they were unwilling or unable to provide informed consent. We confined our analytical sample to participants who completed follow-up assessments.

Study intervention

A physical therapist educated all participants to carry out a home exercise program. In addition, each patient received a detailed written guide including illustrations of the program. The program consisted of flexibility and strengthening exercises of the shoulder and rotator cuff to increase the range of motion. Two of the authors performed corticosteroid and dextrose injections.

Local corticosteroid injection

Each patient in group corticosteroid received one injection. Patients were instructed to sit upright and place their arms on their backs. Shoulders were extended and internally rotated. Under the guidance of real-time ultrasound, a 23-gauge needle of 6-cm length was inserted into the bursa from the posterior side of the shoulder. Then, a mixture of 20 mg (10 mg/ml) triamcinolone, 2 ml of acetonide, and 1% of 2 ml lidocaine was injected to the affected side. We had participants under close observation at the clinic for at least 30 min and noticed if there was any possible side effect, such as hypersensitivity or bleeding. Before leaving the hospital, patients were provided with an information leaflet about the long-term adverse effects, such as increase in pain, skin depigmentation, and flushing. They were instructed not to use analgesic medications except for acetaminophen if needed. We also checked for the presence of any complication at the follow-up examination.

Subcutaneous dextrose

Subcutaneous injection of dextrose has been used previously for some musculoskeletal painful problems [20]. For subcutaneous 5% dextrose, we prepared 4 ml of a mixture including 3 ml of 5% dextrose and 2 ml of 2% lidocaine. The mixture was injected subcutaneously with the use of a 23-gauge needle to the anterior, posterior, and lateral sides of the shoulder, and also to tender points. For the supraspinatus tendon, the arm was positioned at the patient's side with the elbow flexed to 90°, and the humerus rotated internally until the hand crossed behind the back. The needle was directed toward the insertion site of the tendon and the injection was carried out. For subscapularis and pectoralis major, the hand was placed on the thigh, and the needle was directed anteriorly on the proximal humerus below the humeral head and the solution was injected. Next, injections were done into the structures near the coracoids process, and into the anterior, lateral, and posterior aspects of the acromion. For the infraspinatus tendon and teres minor, the upper arm was flexed and the elbow bent to 90°, and along the posterior humerus, the solution was injected. For each participant, injections were repeated three times at 1-week intervals. Patients were instructed to limit shoulder movement for several days, restrain heavy lifting, and not to use analgesics except for acetaminophen, if needed. They were also provided with an information leaflet about the possible adverse effects, such as increase in pain, bleeding, infection, etc. Any side effect was noticed at each follow-up examination.

Outcome measures

Anthropometric features were recorded for all participants. We used a 10-cm visual analog scale to measure subjective pain rated from 0 (*no pain*) to 10 (*most severe pain*). In addition, we measured the percent of participants achieving pain reduction ≥2.8 in visual analog scale [24]. The range of motion in abduction, flexion, and external rotation was compared between the two groups using goniometry. We performed the measurements before and 1 month after interventions.

Ethical considerations

The study protocol was carried out in compliance with the Declaration of Helsinki. Ethics approval was obtained from the University of Baqiyatallah review boards. All participants signed written consents. They received verbal and written explanations of the nature and purpose of the study. In addition, they were informed sufficiently regarding possible complications of the treatments. Patients were free to withdraw from the study at any time.

Sample size, randomization, and statistical analyses

Based on the power of 80% and a two-tailed p value of less than 0.05 as statistically significant, we considered 30 participants in each group to find Cohen's moderate standardized effect size ≈0.5. We used blocked randomization to provide two samples of equal size. Random numbers were generated by a computer. Data are presented as the mean and standard deviation for continuous and as numbers and proportions for categorical variables. Kolmogorov–Smirnov test was used for the assessment of normality. Either a χ^2 test or Fisher's exact test was used for testing differences among the study groups for categorical variables. All data analyses were performed with IBM SPSS for Windows (IBM Corp., Armonk, NY, USA).

Results

Overall, for the analytic sample, we had 57 participants with chronic rotator cuff tendinopathy in two groups of local corticosteroid injection and dextrose prolotherapy, who completed the steps of the study. *Figure 1* shows the patients' flow through the study steps. In total, we had 32 women and 25 men in our sample. Mean (SD) age was 58 (9.9) years, and the mean pain score was 6.6 (1.0) in the visual analog scale. In addition, the mean range of motion for flexion, abduction, and external rotation was 109.1 (6.7), 86.1 (6.7), and 44.3 (5.4) degrees, respectively.

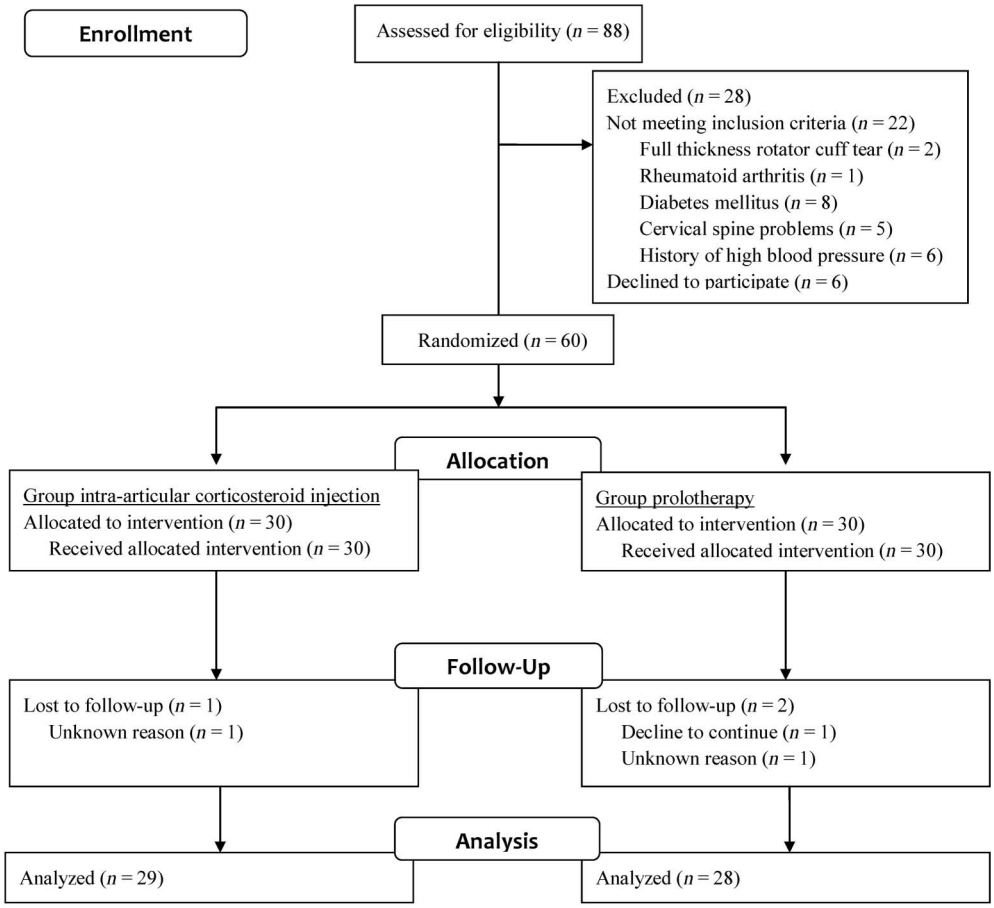

Fig. 1. Patients' flow diagram

Table I Baseline characteristics of the study groups (both groups, $n = 30$)

Characteristic		Corticosteroid	Dextrose	p value
Female [n (%)]		17 (59)	15 (54)	0.907
Age [years; mean (SD)]		56.3 (8.3)	59.4 (9.2)	0.197
Pain duration [month; mean (SD)]		61.5 (36.1)	50.4 (22.8)	0.229
Right side [n (%)]		16 (53)	14 (46)	0.796
Current cigarette smoker [n (%)]		10 (33)	11 (37)	1.000
Current alcohol use [n (%)]		6 (20)	5 (17)	1.000
Pain (visual analog scale)		6.7 (0.9)	6.5 (1.1)	0.684
Range of motion (degrees)	Flexion	111.4 (5.1)	106.9 (7.7)	0.279
	Abduction	86.9 (10.3)	85.4 (10.3)	0.721
	External rotation	45.1 (5.3)	43.5 (5.6)	0.645

Table I shows the characteristics of the groups at the baseline. There was no significant difference between the two groups regarding sex ratio and mean age between the two groups. *Table II* shows outcome measurements for pain throughout the study.

Within-group analyses showed that both interventions were successful in decreasing pain compared to the baseline (both comparisons $p < 0.001$). However, between-group analysis indicated that there was no significant difference between corticosteroid injection and dextrose

Table II Within- and between-group analyses for mean (SD) change in pain and the range of motion in groups corticosteroid and dextrose at the baseline ($n = 30$ and 30) and 1-month post-intervention ($n = 29$ and 28, respectively)

Variable	Assessment	Intervention		p value
		Corticosteroid	Dextrose	
Pain [mean (SD) (visual analog scale)]	Baseline	6.7 (0.9)	6.5 (1.1)	0.684
	One month	4.2 (1.3)	3.0 (1.2)	0.052
	p value	<0.001	<0.001	
Clinically significant pain reduction at 1 month [n (%)]		11 (38)	19 (68)	0.046

Table III Mean (SD) change in the range of motion in groups corticosteroid and dextrose at the baseline ($n = 30$ and 30) and 1-month post-intervention ($n = 29$ and 28, respectively)

Variable		Assessment	Intervention	
			Corticosteroid	Dextrose
Range of motion (degrees)	Flexion	Baseline	111.4 (5.1)	106.9 (7.7)
		One month	145.1 (8.8)	130.9 (9.3)
	Abduction	Baseline	86.9 (10.3)	85.4 (10.3)
		One month	136.9 (10.6)	106.6 (6.6)
	External rotation	Baseline	45.1 (5.3)	43.5 (5.6)
		One month	59.7 (6.2)	53.5 (8.0)

with respect to pain reduction at the end of the follow-up period ($p = 0.052$) *(Table II)*.

We also observed differences in the range of motion within and between the two groups *(Table III)*. Both interventions were advantageous in increasing ranges of motion. However, we did not analyze the results because the data are not normal, and they are heading opposite directions, which make the results non-convincing. None of the participants reported an important adverse effect from corticosteroid or dextrose.

Discussion

We conducted a trial to compare subcutaneous 5% dextrose and local corticosteroid injection for the short-term treatment of chronic rotator cuff tendinopathy. Pain and range of motion were measured as the outcomes of the study. This study showed that while the two interventions are beneficial, their efficacies are different in several aspects. Both treatments are effective with respect to pain control. The analyses of mean (SD) pain score showed that the difference between the two groups is not significant 1-month post-intervention ($p = 0.052$). It is well-documented that steroid injection has benefit at 1 month for the management of rotator cuff tendinopathy. On the other hand, the comparison of the two groups in pain reduction (≥ 2.8) indicated that the difference is significant in favor of dextrose ($p = 0.046$). Overall, we believe that the difference in mean (SD) is approaching significance and that maybe the study is underpowered for detecting a difference in efficacy for pain control. Therefore, this study implied that the dextrose treatment is at least as effective as corticosteroid for reducing pain in patients with rotator cuff tendinopathy. The differences in the range of motion were not conclusive. There are some similarities between our results and those of published studies.

In a recent meta-analysis on the effect of corticosteroid on pain reduction for patients with rotator cuff tendinopathy, studies with at least 10 adults were included [4]. For 11 studies, numbers needed to treat at assessment points less than 1 month, 1–2 months, and 2–3 months were calculated. That study showed that the efficacy of corticosteroid at 3 months is similar to placebo. However, analyses of studies with assessment times less than 2 months indicated small pain relief. It seems that corticosteroid would relieve pain in the short term. Our results showed that, within 1-month, corticosteroid is beneficial in pain relief. It should be noticed that prior or concurrent treatments and age range of patients were different in the enrolled studies. Changes in the range of motion were not investigated in the meta-analysis, too. In addition, the meta-analysis has been critiqued by other researchers from different aspects [8]. According to our results, we still believe that corticosteroid would alleviate pain, at least in the short term.

In a longitudinal comparison study, the efficacy of subacromial corticosteroid injection was studied in patients with rotator cuff disease [5]. The aim was to find if there were correlations between subacromial bursitis on ultrasonography and its response to subacromial

corticosteroid injection. Patients ($n = 69$) were randomly allocated to three groups of ultrasonography findings: normative bursa ($n = 23$), bursa thickening ($n = 22$) with a thickness of more than 2 mm plus effusion, and bursa effusion. All three groups received single triamcinolone injection. The first two groups showed a significant reduction in pain and an increase in the abduction. The third group showed better outcomes in internal and external rotations. The implication was that subacromial corticosteroid injection would be beneficial in patients with subacromial bursitis. This study indicated that corticosteroid injection improves outcome in pain reduction and increases the range of motion.

In another study, the effects of intra-articular corticosteroid and transcutaneous electrical nerve stimulator were compared in 1, 4, and 12 weeks for treatment of rotator cuff tendinopathy [26]. The study showed that the outcomes were favorable with regard to pain reduction and range of motion in all the weeks. Even in decreasing pain at night, pain in movement, and pain at rest corticosteroid were more effective. It was reported that both treatments are effective, and corticosteroid is especially more favorable in the first week regarding pain and range of motion.

We found several studies on the effects of subcutaneous dextrose on rotator cuff lesions. In a randomized comparative trial for the treatment of chronic rotator cuff lesions, researchers used 25% dextrose prolotherapy to reduce pain and improve function [23]. Overall, 101 patients with symptoms persisting longer than 6 months were allocated to groups exercise ($n = 44$) and prolotherapy ($n = 57$). The eligibility criteria were almost similar to ours. Patients were examined at baseline, and at 3, 6, and 12 months (comparisons $p < 0.001$). Within-group analyses showed that at 3 weeks of injection significant, improvement has been taken place in group prolotherapy regarding pain and range of motion. They found more favorable outcomes for prolotherapy during the follow-up period with regard to pain, shoulder abduction, flexion, and internal rotation. External rotation was similar between the two groups. The study showed that participants were apparently more satisfied with prolotherapy. It was concluded that prolotherapy should be considered in the treatment of chronic rotator cuff lesions. In this study, treatment with prolotherapy was also successful in reducing pain and increasing range of motion for flexion, abduction, and external rotation. Similarly, with respect to the external rotation, we did not find a significant difference between the corticosteroid and prolotherapy.

In another trial, researchers compared the effect of 25% dextrose prolotherapy and placebo injections on pain [24]. Overall, 73 participants with chronic rotator cuff tendinopathy of 7 (2.0) years duration were allocated randomly to three groups and were followed for 9 months. In group prolotherapy, better outcomes were documented. They concluded that dextrose prolotherapy may improve the standard care of painful rotator cuff tendinopathy for certain patients. Certainly, they had full-thickness tears in their inclusion criteria and also their exclusion criteria were less restrictive than ours. In addition, we used 5% dextrose for prolotherapy.

The effect of prolotherapy has been evaluated on refractory rotator cuff lesions, retrospectively [25]. In a case–control study, patients with persistent symptoms for 3 months were allocated to two groups of 16.5% dextrose prolotherapy ($n = 57$) and conservative treatment ($n = 53$). The study showed that the effect of treatment on pain and active range of motion were significantly better for prolotherapy. Flexion, abduction, and external rotation improved in the treatment groups. While the implications of the study are similar to ours, its method is not comparable to our prospective randomized clinical trial.

To our knowledge, there is no published study comparable to ours regarding the comparison of corticosteroid and subcutaneous 5% dextrose for treatment of rotator cuff tendinopathy. Our research team was expert, the analyses were straightforward, and the sample was sufficiently large to detect important differences. However, we did not investigate the clinical efficacy of dextrose in the long term. Therefore, further long-term longitudinal research with a larger sample size is demanding to find the place of subcutaneous 5% dextrose in treating patients with rotator cuff tendinopathy.

We did not observe any important adverse effect on both treatments. However, intra-articular injection demands higher experience and precision. Corticosteroid has some known side effects, such as tendon rupture, pain after injection, and skin pigmentation. These adverse effects are in contrast to patients' expectations, and the resultant decrease of compliance will reduce the efficacy of other complementary treatment modalities, such as physiotherapy.

Conclusions

In conclusion, both corticosteroid and subcutaneous 5% dextrose would be beneficial for treating rotator cuff tendinopathy in the short term. This study implied that the dextrose treatment is at least as effective as corticosteroid for reducing pain in patients with rotator cuff tendinopathy. In addition, subcutaneous 5% dextrose is less invasive than subacromial corticosteroid injection. We use dextrose prolotherapy as an efficient alternative to corticosteroid.

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Authors' contribution: AA contributed to the study idea and literature review and recruited patients. MA designed the study and helped in the

development of the protocols, and programmed the intervention, and analyzed the data. SEH participated in the literature review, planning the study, and interviewing patients. All the authors critically reviewed and approved the final version of this manuscript.

Conflict of interest: The authors declare no competing interests.

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