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Original Research Articles

Effects of Corticosteroids Injection in Rotator Cuff Tears

Bernardo Gialanella, MD, and Paola Prometti, MD

Unità Operativa di Recupero e Rieducazione Funzionale, Fondazione Salvatore Maugeri IRCCS, Lumezzane (BS), Italy

Reprint requests to: Bernardo Gialanella, Fondazione Salvatore Maugeri, IRCCS, Unità Operativa di Recupero e Rieducazione Funzionale, Via Giuseppe Mazzini 129-25066 Lumezzane (BS), Italy. Tel: 39-030-82-53-170; Fax: 39-030-89-20-262; E-mail: bernardo.gialanella@fsm.it.

Abstract

Objective. The aim of this study was to evaluate the effect of intraarticular injections of corticosteroids (triamcinolone) in patients with symptomatic rotator cuff tears (RCT).

Design. Randomized controlled study.

Setting. Rehabilitation unit.

Patients. Sixty patients with full-thickness RCT were enrolled in the study. Patients were randomly divided into three equal groups of 20 patients. The first group received single intraarticular injection of 40 mg triamcinolone, the second group received two injections of 40 mg triamcinolone at 21-day interval, and the third group received no treatment (control group). All patients underwent rehabilitation sessions. Outcome measures were pain, evaluated using a visual analog scale, and shoulder functional status, evaluated by Constant–Murley score.

Measures. Outcome measures were pain, evaluated using a visual analog scale, and shoulder functional status, evaluated by Constant-Murley score.

Results. Pain at night score of both groups who received triamcinolone was lower than that of Control Group at 1 month ($P < 0.05$ and $P < 0.01$ in first and second groups, respectively) and at 3 months ($P < 0.05$ and $P < 0.01$ in the first and second groups, respectively). Similarly, activity pain score of groups treated with triamcinolone was lower than that of the control group at 1 month ($P < 0.001$ in both groups) and at 3 months ($P < 0.001$ in both groups). There was no statistically significant difference in pain at night between the first and second groups at 1 and at 3 months. There was no statistically significant difference among groups at 3 and 6 months in Constant–Murley scores.

Conclusions. Our study indicates that intraarticular injection of triamcinolone improves pain relief for 3 months in RCT and its action is not prolonged or potentiated by two injections of the drug done at 21-day intervals.

Key Words. Rotator Cuff Tears; Triamcinolone; Pain; Intraarticular Injections

Introduction

Rotator cuff tears (RCT) are a common source of shoulder pain with incidence ranging from 5% to 40% [1]. The incidence of rotator cuff damage increases with age and is most frequently caused by degeneration of the tendon, rather than injury from sports or trauma [2].

Although RCT are common, many patients remain asymptomatic [3]. The clinical manifestation of RCT has a wide spectrum: some patients may experience only mild discomfort and transient weakness, whereas others have incapacitating pain and loss of function of the arm [2].

The treatment of massive RCT remains a challenge [4,5]. The best method of treatment varies for every patient. The decision on how to treat RCT is based on the patient's severity of symptoms, functional requirements, and presence of concomitant diseases that may complicate treatment.

Treatment recommendations vary from conservative treatment to surgical repair of the torn tendon. Conservative treatment is often adopted because reasonable results cannot be guaranteed with surgical intervention. Conservative treatment is based on nonsteroidal anti-inflammatory drugs (NSAIDs) [2], rehabilitative therapy [6,7], activity modification [8], and corticosteroid injections [2,5,9,10].

Corticosteroid injection is one of the most frequently used approaches in RCT. However, data on the effects of corticosteroids in RCT are scanty and provide conflicting and not definitive data [2,5,9,10].

Bokor et al. [2] and Koubâa et al. [9] showed positive results in patients with RCT treated with combinations of rehabilitation, anti-inflammatory agents, and local corticosteroids injections.

Yamada et al. [5] found improvement in pain relief, muscle strength and range of motion (ROM) in RCT patients treated with conservative treatment, including injections of lidocaine and dexamethasone sodium phosphate into the subacromial bursa.

Shibata et al. [10] showed pain relief in patients with RCT treated with corticosteroids but no significant difference in improvement of pain and efficacy between patients treated with sodium hyaluronate and those receiving dexamethasone. Conversely, Darlington and Coomes showed that in supraspinatus tears, local corticosteroids resulted in some relief of pain but did not improve the ROM and painful arc and concluded that there was no objective evidence that local corticosteroids might improve the condition [11].

The aim of this randomized controlled study was to evaluate the effect of intraarticular injection of triamcinolone acetonide (TA) in patients with symptomatic RCT.

Patients and Methods

Patients

We enrolled 60 RCT patients diagnosed by history, clinical examination, conventional radiography, ultrasound examination, and/or magnetic resonance imaging (MRI).

RCT patients had to meet the following inclusion criteria:

- positive imaging diagnosis of full-thickness RCT;
- surgery not considered the first treatment of choice;
- age older than 75 years; and
- willingness to sign the informed consent form.

Exclusion criteria were inflammatory rheumatic diseases, history of fracture or operations around the shoulder region, neurological diseases that may lead to shoulder pain, infections or tumors, hypersensitivity to TA, pregnancy, diabetes, coagulation diseases, and intraarticular injections in the involved shoulder within the last 12 months.

The Ethics Committee of our institution approved the study protocol and all patients gave their written informed consent to participate. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patients were randomly divided into three groups of 20 patients each, according to the following treatment assigned:

- Group TA1: single intraarticular injection of 40 mg TA;
- Group TA2: two injections of 40 mg TA, the first injection after baseline evaluations and the second injection 21 days after; and
- Control Group: no treatment.

The intraarticular injection was performed through a posterior approach and without local anesthesia. In addition, all patients underwent 15 sessions of 20 minutes each of passive gleno-humeral joint mobilization, taking into account the limit imposed by pain and cuff strengthening exercises [7].

The patients were followed for 6 months. RCT size was classified as small, medium, or massive (<3 cm, from 3 to 5 cm, or >5 cm, respectively) on the basis of greatest size [12]. NSAIDs request during the study period was classified as either "none," "occasional," or "frequent."

Osteoarthritis (OA) was assessed by X-ray and graded according to the Samilson and Prieto classification criteria [13].

Outcome Evaluations

Outcome tests (*Pain and Functional Status of the Shoulder*) were conducted at baseline and repeated after 3 and 6 months during the treatment period, by the same physician who performed the intraarticular injections. Pain was also evaluated at 1 month through a telephone contact.

Pain

Pain (both around shoulder during rest and movements, and pain causing sleep disturbance) was evaluated by a 10-point visual analog scale (VAS) [14] (from 0 [*no pain*] to 10 [*intolerable pain*]).

Functional Status of the Shoulder

The functional status of the shoulder joint was evaluated by the total Constant–Murley scale [15] and its subsectional parameters. This scale evaluates overall shoulder function in 100 points: shoulder pain was evaluated in 15 points, activities of daily living (ADLs) in 20 points, active ROM in 40 points, and strength in 25 points. In the current study, we did not assess strength because of difficulty of patient to perform this test.

Statistical Analysis

Data were analyzed statistically using the software application Statistica Version 6 (StatSoft, Tulsa, OK, USA). Statistical analysis was performed using descriptive statistic tests (mathematical mean, standard deviations), parametric tests (Student's *t*-test, analysis of variance followed by post hoc analysis with Scheffé correction), and nonparametric statistical tests (Wilcoxon rank test, χ^2 tests, Kruskal–Wallis, Mann–Whitney's *U*-test). A *P*-value <0.05 was considered statistically significant.

Results

Patients

All 60 patients completed the study. Table 1 shows the baseline characteristics of patient population. No significant baseline difference was found among the three groups for age, gender, affected shoulder, symptom

Table 1 Demographical characteristics of patient population

	Group TA1: (20 Patients)	Group TA2 (20 Patients)	Control Group (20 Patients)	*P* Value
Age	78.7 ± 6.6	77.3 ± 4.9	79.4 ± 4.5	0.464
Gender				0.573
Male	2	1	2	
Female	18	19	18	
Affected shoulder				0.255
Right	16	12	16	
Left	4	8	4	
Symptom duration	6.6 ± 5.2	4.4 ± 2.7	5.2 ± 2.6	0.179
NSAID request				0.906
None	0	0	0	
Occasional	15	16	16	
Frequent	5	4	4	
Tear size				0.386
Small	10	9	12	
Medium	4	8	6	
Massive	6	3	2	
Degree of osteoarthritis				0.952
Grade I	16	16	15	
Grade II	3	2	3	
Grade III	1	2	2	

Comparison among groups was performed by analysis of variance (age, symptom duration) and χ^2 (gender, affected shoulder, NSAID request, tear size). Data are shown as mean ± standard deviation, or number.
TA1, group of patients who received a single injection of triamcinolone; TA2, group of patients who received two injections of triamcinolone at 21-day intervals; NSAIDs, nonsteroidal anti-inflammatory drugs.

duration, RCT size, and severity of OA. No adverse events were reported during the study.

Before starting the study, all patient used NSAIDs and there was no difference in NSAIDs request among the groups at baseline ($P = 0.906$). Groups TA1 and TA2 reduced NSAIDs request and used NSAIDs less frequently than the Control Group at 1 month ($P = 0.004$ and $P = 0.002$, respectively) and at 3 months ($P = 0.003$ and $P = 0.001$, respectively).

Outcome Evaluations

Pain

Table 2 reports all profiles pain measured by VAS at baseline and 1, 3, and 6 months after treatment.

Groups TA1 and TA2 significantly improved in activity pain and pain at night at all time points vs baseline while only Group TA1 significantly improved in rest pain at 1 and 3 months ($P < 0.05$). Groups differed in pain at night score and activity pain at 1 and 3 months only. Activity pain score of Groups TA1 and TA2 was lower than that of the Control Group at 1 month ($P < 0.001$ and $P < 0.001$, respectively) and at 3 months ($P < 0.001$, and $P < 0.001$, respectively), while it did not differ between Groups TA1 and TA2 at same time points ($P = 0.983$ and $P = 0.875$, respectively).

The same pattern was observed for pain at night score of Groups TA1 and TA2: it was lower than that of the Control Group at 1 ($P = 0.010$ and $P = 0.003$, respectively) and at 3 months ($P = 0.036$ and $P = 0.002$, respectively). There was no statistically significant difference in pain at night between groups TA1 and TA2 at 1 ($P = 0.922$) and at 3 months ($P = 0.596$).

Functional Status of the Shoulder

Table 3 reports functional status measured by and Constant–Murley scores at baseline and at 3 and 6 months after treatment.

Groups TA1 and TA2 significantly improved in Total Constant–Murley and Constant–Murley ADLs scores at all time points vs baseline.

There was no statistically significant difference among groups at any time points in Constant–Murley scores.

Discussion

The aim of the current study was to evaluate the effect of intraarticular injections of TA in patients with symptomatic RCT. The results show that patients who received TA injections and rehabilitation had pain relief in comparison with those who underwent rehabilitation only, providing

Table 2 Visual analog scale pain scores

	Group TA1 (n = 20)				Group TA2 (n = 20)				Control Group (n = 20)			
	Baseline	1 Month	3 Months	6 Months	Baseline	1 Month	3 Months	6 Months	Baseline	1 Month	3 Months	6 Months
Rest Pain	1.8 ± 2.1	0.5 ± 1.1*	0.6 ± 1.2*	0.8 ± 1.8	1.9 ± 2.0	1.0 ± 1.4	1.1 ± 1.6	1.5 ± 2.0	0.6 ± 1.2	0.9 ± 1.5	0.6 ± 1.2	0.7 ± 1.4
Activity Pain	7.1 ± 1.8	3.8 ± 1.8***^{C}	3.7 ± 1.8***^{C}	5.4 ± 1.9**	7.3 ± 0.8	3.9 ± 1.7***^{C}	4.0 ± 1.8***^{C}	5.4 ± 2.0***	6.9 ± 1.4	6.7 ± 1.4	6.5 ± 1.7	6.8 ± 1.6
Pain at Night	5.8 ± 2.0	2.1 ± 2.1***^{A}	2.7 ± 1.9***^{A}	3.5 ± 2.2***	5.5 ± 0.1.5	1.8 ± 2.2***^{B}	1.9 ± 2.4***^{B}	2.9 ± 2.8***	4.6 ± 2.7	4.5 ± 2.7	4.6 ± 2.5	4.6 ± 2.7

Within-group comparison was performed by Student's *t*-test: * $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$ vs baseline. Data are shown as mean ± standard deviation.
Comparison among groups was performed by analysis of variance (post hoc analysis with Scheffé correction): ^{A} $P < 0.05$; ^{B} $P < 0.01$; ^{C} $P < 0.001$.
TA1 indicates group of patients who received a single injection of triamcinolone; TA2, group of patients who received two injections of triamcinolone at 21-day intervals.

Table 3 Constant–Murley scale scores

	Group TA1 (n = 20)			Group TA2 (n = 20)			Control Group (n = 20)		
	Baseline	3 Months	6 Months	Baseline	3 Months	6 Months	Baseline	3 Months	6 Months
Total constant score	23.7 ± 11	34.7 ± 14***	28.0 ± 15*	24.8 ± 10	35.6 ± 12***	29.2 ± 11***	30.5 ± 15	30.7 ± 15	29.9 ± 14
Constant ADL	5.2 ± 2.6	7.7 ± 4.1***	6.6 ± 3.9**	5.4 ± 2.4	7.5 ± 2.8**	6.9 ± 3.0**	7.4 ± 5.4	7.4 ± 5.1	7.3 ± 5.2
Constant active ROM	14.0 ± 7.4	17.0 ± 8.8**	14.8 ± 8.6	15.3 ± 6.9	20.1 ± 8.7***	16.7 ± 6.7*	16.6 ± 8.5	17.0 ± 8.6	16.4 ± 8.5

Data are shown as mean ± standard deviation.
Within-group comparison was performed by Wilcoxon test: * $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$.
Comparison among groups was performed by Kruskal–Wallis and Mann–Whitney's *U* tests: not significant. ADL, activities of daily living; ROM, range of motion; TA1, group of patients who received a single injection of triamcinolone; TA2, group of patients who received two injections of triamcinolone at 21-day intervals.

further evidence that patient with RCT may benefit from TA treatment.

Our results are in keeping with those published by Bokor et al. [2], Yamada et al. [5], Koubâa et al. [9], and Shibata et al. [10] but they cannot be strictly compared because designs among studies are different. Bokor et al. [2] and Koubâa et al. [9] used occasional local injections of steroids following an uncontrolled study design. The studies by Yamada et al. [5] and Shibata et al. [10] were controlled but compared sodium hyaluronate vs dexamethasone and conservative treatment vs surgery in massive RCT, respectively.

Our study is randomized and controlled with a control group that did not receive any corticosteroids treatment.

In our study, pain at night and activity pain scores of patients treated with TA at 6 months were lower than those at baseline, and they were significantly lower than those of the Control Group at 1 and 3 months. In addition, NSAIDs request by patients receiving TA was lower than that of the Control Group at 1 and 3 months and did not differ at 6 months. This suggests that a single intraarticular injection of 40 mg of TA may be effective for controlling shoulder pain for 3 months in patients with RCT.

TA is a synthetic corticosteroid, which has a longer duration of action compared with other corticosteroids (methylprednisolone acetate and dexamethasone) [16]. Long duration of action is considered to be due to the slower release of TA, which in turn is related to its lower solubility. This characteristic of the TA may explain its long-lasting activity in RCT [16].

Few studies verified the efficacy duration of corticosteroids in RCT. Yamada et al. [5] and Shibata et al. [10] found improvement in pain and shoulder function 6 months after treatment with intraarticular injections of corticosteroids in RCT. However, it is difficult to interpret these findings as no control group was included in the study.

In the literature, there are several studies published that have verified corticosteroids efficacy in chronic shoulder pain. These studies demonstrate that corticosteroids do not alter the natural progression of subacromial pain, but produce only a symptomatic relief especially in pain [17–19], which may be a result of its anti-inflammatory effect [20]. Corticosteroids can alter the release of noxious chemicals that are triggered by degenerating tendon [21].

In our study, pain-relief in RCT may be due to anti-inflammatory effect of TA. The reasons for pain associated with RCT may include impingement of the tuberosity and humeral head or the cuff stump on the acromion caused by loss of centralization of the humeral head during elevation of the shoulder [22,23] and synovitis caused by impairment of the normal excursion of the humeral head [22]. Corticosteroids are powerful anti-inflammatory drugs and, used locally, may reduce inflammation in patients with tendon disorders [21].

In RCT, they can relieve synovitis pain but not impingement pain. This might explain the improvement in pain relief found in patients of our study without a complete remission of pain itself.

In our study, one group of patients was treated with a single injection of TA (40 mg) and another group with two injections of same drug at a 21-day interval, but both groups of patients presented similar outcome, indicating that adding another TA injection after 21 days does not result in any more subjective benefit than that seen after a single injection. Lack of an additive effect might be due to receptors occupancy by already injected drug [21].

The intraarticular injections were performed with TA alone. However, we did not include concomitant use of steroid drug with the anesthetic which is sometimes added to reduce injection site pain. This would have affected our result as in some studies it has been shown that in RC tendinosis, injections with Steroid/Xylocaine combinations, have in short term, a similar effect to that of Xylocaine alone [24]. There is no explanation to this occurrence and it still remains unknown how corticosteroids and Xylocaine interact in vivo [25].

The approach of the intraarticular injections to the shoulder can be either anterior or posterior. We performed intraarticular injections through a posterior approach.

The posterior approach had a 15–85% accuracy rate [26,27], while the anterior approach had a 26.8–95% accuracy rate [27,28]. The posterior approach has a lower accuracy than that of the anterior approach [29]; however, some studies have suggested that the accuracy is not an important factor in pain relieve and may be irrelevant in treating shoulder pain of multiple origins [30].

In the current study, all the groups presented OA of the gleno-humeral joint, but the OA severity did not differ among groups. This suggests that OA did not influence the response to treatment.

We did not register adverse effects during the study period. Nevertheless, subacromial, and intraarticular injection of corticosteroids is an area of controversy regarding the deleterious effects. Tillander et al. [31] showed focal inflammation, necrosis, and fragmentation of collagen bundles after five corticosteroid injections to the subacromial space of rats, while no pathologic change was observed after three injections.

Several studies have reported that intraarticular injections of steroids have adverse effects not only on the articular cartilagine but also on tendons [31–34].

Osteoarthritic changes and tendon tears are the steroid-related complications more commonly observed [33–35]. However, other studies have reported that no reliable proof exists about deleterious effects of corticosteroids when injected at peritendinous level [21,36], and that

corticosteroid use should not be considered a causative factor of RCT [37].

One reviewer claims that corticosteroids injections into the rotator cuff have not been shown to be deleterious but that it is advisable to limit the number of local corticosteroids injections [38].

A recent review has shown that corticosteroids injections are beneficial in the short term for treatment of tendinopathy [39] and that repeated corticosteroid injections are associated with a poorer long-term effect on reduction in pain when compared with single injections for possible deleterious effects of repeated dosing [39,40].

These observations could explain our findings of diminished rest pain with one and not with multiple doses of TA.

The study has some limitations. First, the sample of patients included preselected patients that do not constitute a representative sample of the entire population of patients with RCT.

Second, the study did not follow a double-blinded design, because the same physician performed both the injections and the assessments.

Finally, we did not use ultrasound guide for the intraarticular injections, which may have resulted in a higher rate of therapeutic success. Nevertheless, the majority of patients in our study had a successful outcome despite the inevitable uncertainty about placement.

Conclusions

In this study, we found that intraarticular injection of TA improves pain relief in RCT for up to 3 months and additional injections after 21 days do not increase TA therapeutic effect.

Therefore, the study shows that in patients with RCT, a therapeutic approach with single instead of double close injections of TA is preferred.

Single TA injections should be used when other conservative treatments fail or when rest or night pain increases, as occurs in acute and inflammatory stages of disease.

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Conflicts of Interest

Authors declare no conflicts of interest.

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