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Short-term Low-dose Oral Corticosteroid Therapy of Impingement Syndrome of the Shoulder: A Comparison of the Clinical Outcomes to Intra-articular Corticosteroid Injection

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Background: To assess the clinical outcomes of short-term oral corticosteroid therapy for impingement syndrome of the shoulder and determine whether it can be substituted as an alternative to the intra-articular injection.
Methods: The clinical outcomes of the 173 patients, the oral steroid group (n=88) and the injection group (n=85), were measured at 3 weeks, 2, 4, and 6 months postoperatively. The clinical outcomes were assessed by measuring the the University of California at Los Angeles (UCLA) score, visual analog scale (VAS) and range of motion (ROM) at every follow-up. Any complications and recurrence rate were noted. A relationship between the treatment outcomes and factors such as demographic factors, clinical symptoms and radiographic findings were determined.
Results: No difference was observed in VAS and UCLA scores between the two groups, but forward flexion and internal rotation of ROM were significantly improved in the injection group at the 2nd and 4th postoperative month ($p < 0.05$). At 6th postoperative month, recurrence rate of symptoms was 26% in the oral steroid group and 22% in the injection group. No major adverse effects were observed. When the clinical outcomes of the oral steroid group were compared to either demographic, clinical symptoms, or radiographic findings, UCLA score was found to be significantly low ($p < 0.05$) in patients with joint stiffness and UCLA score, whereas VAS score was significantly improved in patients with night pain ($p < 0.05$).
Conclusions: Short-term low-dose oral corticosteroid therapy of impingement syndrome showed comparable clinical outcomes to intra-articular injection without any remarkable adverse effects. Low-dose oral steroids can be regarded as a partial alternative to intra-articular injection for the initial therapy of impingement syndrome of the shoulder.
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Key Words: Shoulder; Impingement syndrome; Intra-articular steroid injection; Oral corticosteroid

Introduction

Impingement syndrome of the shoulder was first differentiated as a separate clinical condition in 1972 by Neer. Within 30 years, it has become the most commonly diagnosed type of impingement syndrome of shoulder. The criteria for diagnosis and treatment methods of impingement syndrome have been debated for many years, but the general consensus is to conservatively manage at an early stage. Irrespective of the pathology, the success rate of conservative treatment was shown to be around 70%.[1-3] Conservative treatment comprise of stabilizing the shoulder and controlling shoulder pain, in parallel with rehabilitation courses. Exploiting the window for rehabilitation is critical at the early stage of treatment in order to decrease clinical symptoms such as shoulder pain.[4-7] Various ways to control pain include physiotherapy, use of nonsteroidal anti-inflammatory

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drugs (NSAIDs), and intra-articular injections, but of these the anti-inflammatory methods of the latter two are usually used. NSAIDs are generally used, and an exemplary benefit is pain relief even at a low blood concentration. However, limitations of NSAIDs are that its anti-inflammatory effects exerts only at steady state plasma concentration, which is achieved in about 1−2 weeks. This means the time taken to control the clinical symptoms would take at least 4 weeks, thus requiring a relatively long duration of drug administration.[8] This long-term use often leads to gastrointestinal side-effects, adrenal insufficiency, and other drug-related complications[9] that make the rate of patient compliance low.

Intra-articular injection is the most common method of administration and despite advantages such as fast resolving of pain and improved range of motion (ROM), as with other drug therapy, it does not resolve the diseases completely.[10] Other limitations include, the need for technical specialty, steroid flares after injection, and fatal complications such as infections.[11-13] The authors propose oral corticosteroids as an alternative for its speed and strength of effect and its bioability as a non-invasive oral administration.[14] Not only are these benefits make oral corticosteroids a promising alternative, it requires no technical specialty for administration nor is it associated with complications. Thus, to test the applicability of oral corticosteroids in addressing the initial inflammatory response of impingement syndrome, the clinical stability and outcomes, potential problems and limitations, and factors influencing treatment were assessed.

Use of oral corticosteroids as medication is widespread, especially for musculoskeletal disorders such as rheumatoid arthritis. Although a few reports have described the efficacy of oral corticosteroid therapy on adhesive capsulitis,[15-18] so far there is none reporting the efficacy of oral corticosteroids on impingement syndrome. In comparison, systemic exposure of steroids can be expected to modulate various immunological and inflammatory responses, and improve shoulder pain. Thus, we investigated the efficacy of short-term oral corticosteroids, as an intermediate of NSAIDs and intra-articular injections, on impingement syndrome.

Methods

Between June 2010 and December 2011, of the 1,227 patients who were suspected of impingement syndrome, 244 patients who had contracted the condition within 9 months, showed a one-sided symptomatic shoulder, and had a trivial medical history were included in the study. The mean age of patients was 56.4 years (range, 39−73 years), and ratio of sex was 95 males to 149 females.

The diagnosis of impingement syndrome was made when the patient complained of shoulder pain during motion or resting and when there was a clear positive result for Neer sign, Hawkins-Kennedy impingement sign, and painful arc sign by a single orthopedic surgeon.[19] Several exclusion criteria were placed in our study to exclude the possibility of misdiagnosis of an impingement syndrome in the case where additional tests were required to differentiate an impingement syndrome. Patients with stiffness were included; however, patients with when less than 90° forward flexion, or even with more than 90° forward flexion but with tethering at end of motion at passive movement were excluded from the study to rule out patients with adhesive capsulitis corresponding to Neviaser stage 2 and 3.[20] Patients shown to have calcific deposits, degenerative arthritis, or humeral head spurs through plain radiography of the anteroposterior and axillary views at internal and external rotations of the shoulders were excluded as well. Further, ultrasound imaging was taken on all patients by one expert and patients shown to have anatomical lesions such as full-thickness rotator cuff tears, partial rotator cuff tears according to the Ellman's classification,[21] biceps lesion or dislocation were excluded. Although diabetic patients were included in the study, those diagnosed with a diabetic foot, diabetic retinopathy, diabetic kidney disease, or those with uncontrolled glycemic levels were excluded. Lastly, those who were already on steroids, or had tuberculosis or acute/chronic infectious diseases were excluded after questioning.

ROM included the forward flexion, external rotation at 90° abduction, external rotation at neutral position, using a protractor, with the patient at supine position. The internal rotation was noted at the highest vertebra, and these values were fitted into the Mallon system[22] to give a total shoulder internal rotation. Neutral position was set to 0°, umbilicus to 20°, anterior superior iliac spine to 30°, buttocks to 45°, sacrum to 80°, L5 to 85°, and for all values above 2° was added for every vertebra. All patients were questioned and physical tests were performed, the scores of which were standardized using the University of California at Los Angeles (UCLA) shoulder rating scale. To analyze complications, the weight of each patient was taken during their visit the outpatient department. The patients were questioned on their level of pain, function, and satisfaction, whereas physical tests for active forward flexion and strength of forward flexion were performed. These results were standardized into the UCLA score. The visual analogue scale (VAS) was used to assess subjectively the patient's current level of pain in comparison to the worst pain experienced by the patient. The current study randomly divided the patients into either the oral steroid group (n = 125/75 females, 50 males) and the injection group (n = 119/74 females, 45 males) using coin flipping. The oral steroid group included 18 diabetic patients, whereas the injection group included 16. The oral steroid group was prescribed 2 mg of Triamcinolone twice a day to take 30 minutes after breakfast and dinner for 3 weeks, and a reduced volume thereafter of 1 mg Triamcinolone for a further week. The injection group was injected once with

40 mg/ml of Triamcinolone dissolved in 10 ml of saline solution through the posterior portal under the ultrasound guide.[23] From 3 weeks of the start of medication, both groups were administered with NSAID (Meloxicam 7.5 mg twice daily) for 8 weeks. Simultaneous to the start of the oral therapy or the injection therapy, a proton pump inhibitor (Omeprazole 10 mg) was administered for around 3 months until the end of the duration of NSAID administration. Concomitant to the initiation of drug therapy, stretching and shrugging exercises of the shoulder were begun using a door pulley, and from the 8th week, a Thera-band was also used for the rotator cuff strengthening exercise. All patients were instructed to exercise both sides of the shoulder equally 2−3 times a day for a total of 40−60 minutes.

The 173 patients with a high compliance and were able to participate in a 6 month follow-up study were divided into either the oral steroid group (n = 88) or the intra-articular injection group (n = 85). The changes in UCLA score, VAS score, ROM was assessed at 3 week, 2, 4, and 6 month follow-up. Any drug side-effects[24] were noted and recurrence rate were analyzed.

To measure weight gain as one side-effect of the drug, we measured the weight of the patients pre-therapy and throughout the 4 week therapy. A weight gain of more than 1 kg was considered significant and other short-term complications of steroid medication such as gastrointestinal dysfunction (upper abdominal discomfort or pain), infection (fever or chilling), skin problems such as acne, muscle soreness, increase in intraocular pressure (ophthalmalgia or impaired visual acuity) were also investigating by questioning the patient. To discriminate potential adrenal insufficiency, experience of symptoms such as headache, dizziness, nausea vomiting, or sweating was noted. In case of diabetic patients, any loss of glycemic control or hyperglycemia was noted down, and also maximal glucose level was noted.

Other clinical variables analyzed were whether abrupt cessation of oral steroids led to worsening of pain in the oral steroid group, or whether worsening of pain was felt between 3−5 days after the injection was performed in the injection group. The condition was considered to have recurred if the final VAS score was the same or only one stage higher than the initial VAS score, or if the final UCLA score was below or within 20 points higher of the initial UCLA score. The recurrence rate of the patients who were nonresponsive to treatment or had failed remission of symptoms was also determined.

To determine factors associated with the clinical outcomes of oral steroid group were separated demographically. The oral steroid group was divided into sex considering that activity and muscle strength of shoulder would differ between the sexes and this may have an influence on the therapy outcome. As well as sex, since level of activity and disease pathology may differ between age, the oral steroid group was also divided into either below age 40 or above age 40. We made an assumption that the extent of clearance of inflammation and changes will depend on the duration of contraction of the syndrome. Arbitrarily, we set the time of contraction as either more than 6 months prior to or within 6 months of commencement of therapy. To take into consideration the possible effect of joint stiffness on the biomechanics of the joint, the patients were also divided into either stiff or not stiff group by defining a stiff joint as forward flexion of less than 120° or if any one of 3 ROM of rotation was less than half of the contralateral side. Further, to assess the influence of the severity of infection on the outcome of therapy, patients were divided into whether they had night pain that disrupted sleep cycle or not. To assess the effect of drug treatment on mechanical impingement, plain radiographs was taken and examined. Using the radiographic data, the patients were divided into those with a normal acromion and those with either an acromion that was deviated from its normal contour or subacromial congruity that was disrupted by a spur. An association of various demographic, clinical, factors of these two groups with the improvements in the UCLA score (final UCLA − initial UCLA) and VAS score (initial VAS − final VAS) were compared.

Data entry and analysis were done using IBM SPSS Statistics software ver. 20.0 (IBM CO., Armonk, NY, USA) and p value < 0.05 was considered significant.

Results

We found that in general VAS scores was lower in the injection group (n = 85) than the oral steroid group (n = 88) and injection group (n = 85) in the 3 week, 2, 4, 6 month follow (Fig. 1). Although the difference between the groups was statistically insignificant, we found in both groups a greater than 50% decrease in pain at 6 month final follow-up. The changes in UCLA score were statistically insignificant between the two groups over the entire follow-up (Fig. 2). A statistically significant difference in terms of the ROM between the two groups was seen initially.

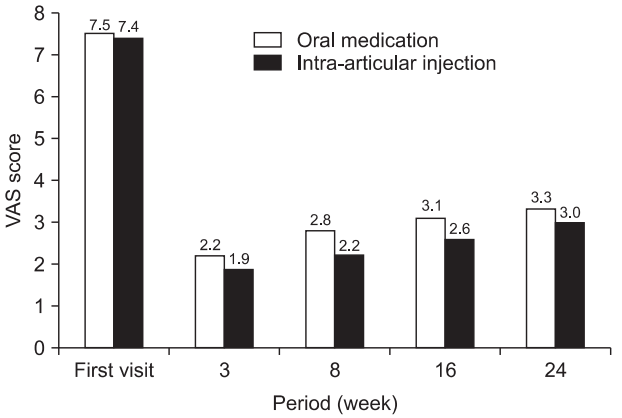

Fig. 1. This graph shows the average change of visual analogue scale (VAS) score between oral medication group and intra-articular injection group. No statistically significant difference was seen.

The forward flexion (*t*-test, $p = 0.007$) and the internal rotation (*t*-test, $p = 0.4$) at 2 month follow-up were better in patients of the injection group (n = 25) with joint stiffness than the oral steroids group (n = 28) with joint stiffness, and this statistically significant was still seen at 4 month follow-up for forward flexion (*t*-test, $p = 0.02$) and internal rotation (*t*-test, $p = 0.02$); however, it was no longer seen at the final follow-up (Fig. 3).

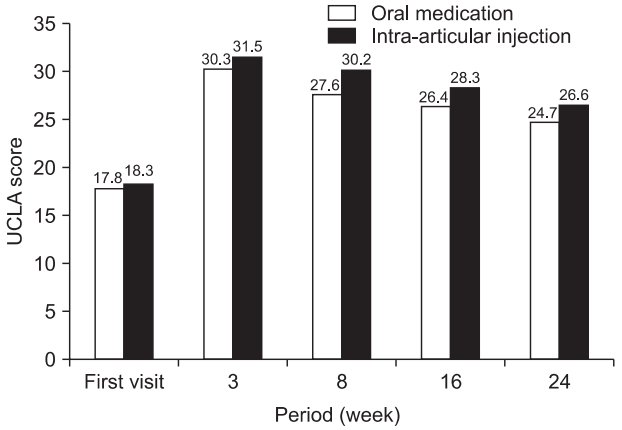

Fig. 2. This graph shows the average change of University of California at Los Angeles (UCLA) score between oral medication group and intra-articular injection group. No statistically significant difference was seen.

We assessed side-effects of drugs and postoperative complications between the two groups. In the oral steroids groups, we found an average weight gain of 2.3 kg/8 weeks in 5 patients, upper abdominal discomfort and pain in 11, loss of glucose control in 4 of the 18 diabetic patients 18, hot flushing in 1, enhanced appetite in 4. But none of these patients had side-effects or complications severe enough to stop the drug administration altogether. In the injection group, we found an average weight gain of 1.4 kg/8 weeks in 3 patients, upper abdominal discomfort in 2, steroid flare after injection in 9, enhanced appetite in 2, and hyperglycemia in 5 of the 16 diabetic patients. In neither of the two patient groups, none were seen to have complication such as focalized or systemic infections or drug withdrawal symptoms such as adrenal insufficiency.

The total recurrences and non-compliant patients were 26% in the oral steroids group (23/88) and 22% in the injection group

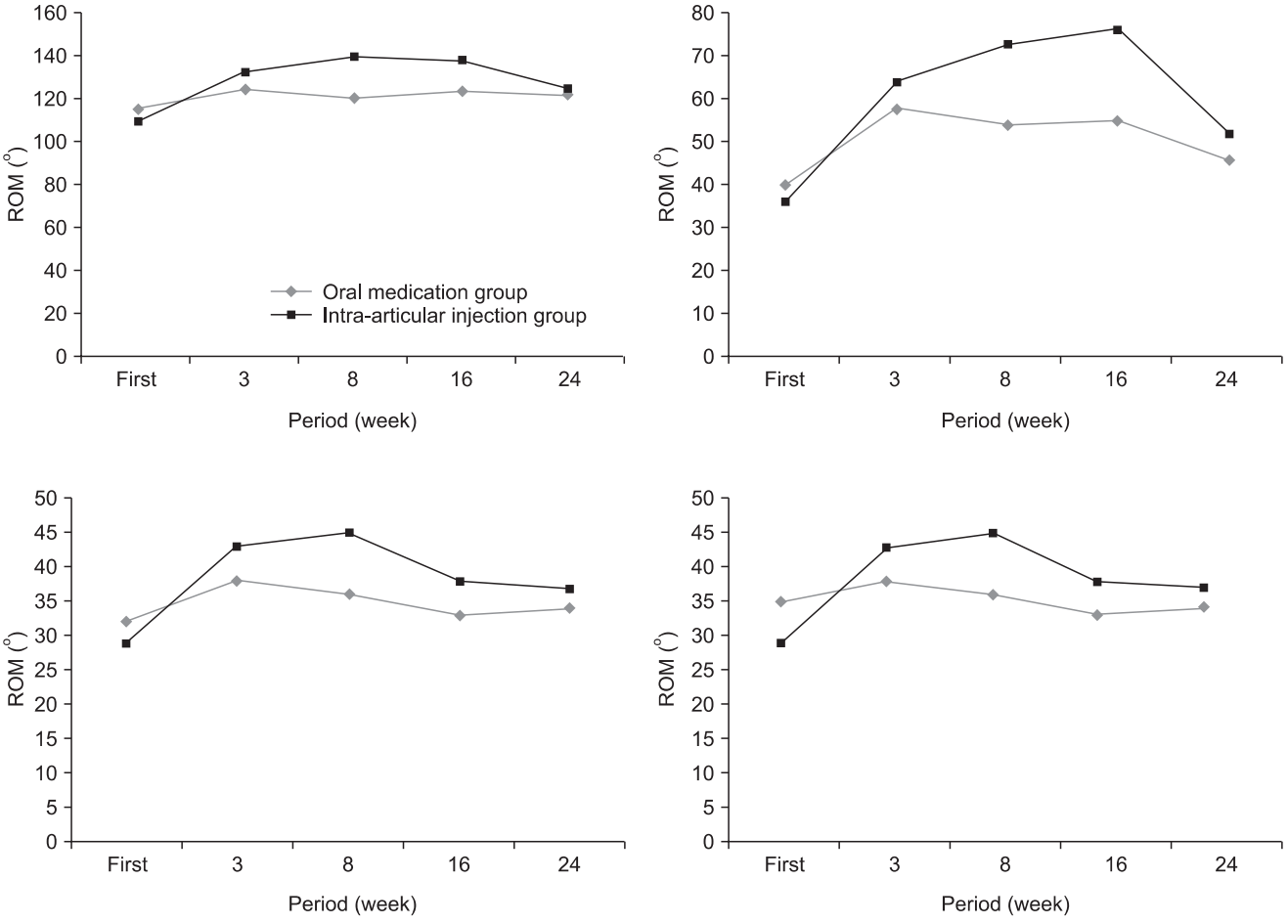

Fig. 3. This graph shows progress of range of motion (ROM) in stiff patients. Forward flexion (A) and internal rotation (B) of ROM are significantly improved more in the injection group. (C) External rotation at side. (D) External rotation at 90° abduction.

(19/85) at the final follow-up.

Patients in the oral steroid group (n = 88) were subdivided within various demographic, clinical, and radiographic categories that were thought possible to influence the treatment outcome of the oral therapy. We determined whether each factor were associated with changes in UCLA score (final UCLA−initial UCLA), improvement in VAS (initial VAS−final VAS) at the final follow up.

In terms of demographic factors, sex did not influence the improvement in the UCLA and VAS scores when these scores were compared between men (n = 37) and women (n = 51) in the oral steroids group. Likewise, age (below or over 40) did not influence the clinical outcomes.

To determine whether the clinical outcomes are associated with certain clinical symptoms, we compared patients with or without the following clinical symptoms; period of disease contraction, joint stiffness, and night pain, to changes in clinical outcomes; VAS and UCLA scores. We found that whether or not the period of disease contraction was longer than 6 months (n = 30) or less (n = 58), no statistically significant difference in VAS and UCLA scores were seen. However, a significantly enhanced UCLA score (*t*-test, $p < 0.05$) was seen in patients with joint stiffness (n = 28) than those without (n = 60). Whereas a significantly enhanced UCLA and VAS scores (*t*-test, $p < 0.05$) were seen in patients with night pain (n = 32) than those without (n = 56) at the 24th week follow-up (Table 1).

Lastly, to determine whether the clinical outcomes are associated with certain radiographic findings, we compared two sets of patients either those with or without the following two radiographic findings; Soucil sign at the acromion and the subacromial spurs, to changes in clinical outcomes; VAS and UCLA scores. We found that whether or not the radiographic marks were present, it did not make a difference on the VAS and UCLA scores between the two groups of patients.

Table 1. Factors Affecting Improvements in the VAS/UCLA Scores

		VAS improvement	UCLA score improvement
Gender	Male (n = 37)	4.0	7.5
	Female (n = 51)	4.4	6.7
	t-test	$p = 0.09$	$p = 0.12$
Age (yr)	Under 40 (n = 29)	3.8	7.1
	Over 40 (n = 59)	4.4	7.0
	t-test	$p = 0.10$	$p = 0.09$
Duration	Less than 6 mo (n = 30)	4.9	8.3
	6 Mo or longer (n = 58)	3.9	6.4
	t-test	$p = 0.14$	$p = 0.9$
Stiffness	Stiff (n = 28)	3.5	8.8
	Not stiff (n = 60)	4.6	6.2
	t-test	$p = 0.08$	$p = 0.009$*
Night pain	Painful (n = 32)	4.8	8.0
	Not painful (56)	3.9	6.5
	t-test	$p = 0.03$*	$p = 0.03$*
Subacromial spur	With spur (n = 24)	4.3	5.7
	Without spur (n = 64)	4.2	7.5
	t-test	$p = 0.11$	$p = 0.15$

VAS: visual analogue scale, UCLA: University of California at Los Angeles.
*Significant values by *t*-test.

Discussion

The conservative treatment of impingement syndrome through drug and injection-based therapies is essential to resolve pain and restore ROM that aids the rehabilitation of the rotator cuff and shoulder muscles, and thus complete remission of the disease. Currently, NSAIDs and intra-articular steroid injections are commonly used as therapy options of impingement syndrome.

NSAIDs are often prescribed for various conditions of musculoskeletal pain and inflammatory conditions such as osteoarthritis, Rheumatoid arthritis, gout, and ankylosing spondylitis. The use of selective COX-2 inhibitors to prevent side-effects after long-term use of NSAIDs have been used, but still complications such as gastrointestinal side effects, cardiovascular abnormalities, adrenal insufficiency, drug-drug interactions are associated with the use of NSAIDs.[8,9]

The analgesic effects of NSAIDs are proportional to its plasma level, thus using high concentration of a drug with a short half-life is most effective to achieve long-lasting effects. However, only low doses can be tolerated due to the drug-related side effects. Another limitation is that the anti-inflammatory effects of NSAIDs are seen when maximal steady state plasma concentration is achieved, the time taken to reach the steady state is about five times the half life of a drug. Thus, antagonists such as COX-2 that has a long half-life would require at least 2 weeks and twice-a-day dosing of the drug and a further 4 weeks before the anti-inflammatory effects are seen.[8]

Subacromial or the intra-articular steroid injection is the widely used early treatment methods for impingement syndrome. Despite recent efforts to improve accuracy of drug targeting by ultrasound guided methods, still limitations to these methods exist. It's a technically demanding and invasive procedure that may elicit infections, vagal response, anaphylaxis, steroid flare, and in rare cases, necrotizing fascilitis or septic arthritis.[25] Further, repeated injections over a long time may cause injury of the articular cartilage and rotator cuffs, which may decrease the likelihood of a successful repair. Thus, in most cases it is recommended that injections are limited to less than 3 times a year.[26]

NSAIDs and intra-articular steroid injection are widely used for impingement syndrome and other acute and chronic musculoskeletal diseases, but although the former is a safe option its potency is weak, whereas the latter has an extremely potent effect but its associated side-effects limit its use.

For decades, the treatment of frozen shouder have used high dose of oral steroids. We investigated short-term low-dose oral steroids as a possible therapy for impingement syndrome for two major reasons. First, its anti-inflammatory effects are greater than NSAIDs and it does not require the technical expertise of administration and also eliminates the related risks of the invasive procedures. We compared the clinical outcomes of oral steroids and intra-articular injections, and further determined possible factors that influence the clinical outcomes in oral steroid use, and thereby assess what possible indicators there are for oral steroids. Historically, potency comparable to the potency of prednisolone 5−10 mg/day is considered as a low-dose and the authors considered duration of 4 weeks as short-term. In this study, we administered triamcinolone 4 mg/day to patients, which has the same potency as prednisolone, for 4 weeks.

Irrespective of the route of administration, the major concerns of exogenous steroids are Cushing syndrome or drug side-effects such as hypothalamic-pituitary-adrenal (HPA) axis inhibition. The likelihood of such complication surfacing increases when exogenous steroids are taken for more than 6−12 months, and in general, the incidence of complications is proportional to the average drug volume and duration. In a large-scale study where corticosteroids to a potency equaling the potency of mean 16 ± 14 mg/day of prednisolone was given for over 60 days, the most common side-effect associated with drug administration was weight-gain (70%), which was followed by bruising and thinning of the skin, and insommia. The most fatal side-effects were cataracts (15%) and bone fractures (12%).[13] Low-dose steroid use of over 2 years was associated with mean 4−8% increase in weight-gain, and use of over 90 days showed a statistically significant association with weight-gain.[27] Although these side-effects should not be dismissed even when small doses of steroids are administered, many side-effects seen from high-dose therapies have been unnecessarily connected to low-dose therapy despite a very small likelihood of manifesting.[27] Including the weight loss period, during the period of 4 weeks of drug administration, the authors found trivial weight-gain and gastrointestinal dysfunction in a small portion of patients. No other complications were noted.

The benefits of short-term low-dose oral steroids were lower than the benefits of the intra-articular injections. The mean extent of pain-relief was shown to be lower through the period of the treatment, and especially, if drug dose was lowered or ceased, the tendency for the pain to resurface was greater in the oral steroid group. Further, improvement in ROM was lower for the oral steroid group than the injection group. Although all mean clinical results were slightly lower than the injection group, it did not influence the patients' ability to follow the rehabilitation program and also there were no statistically significant differences between the two groups across the whole study.

Factors associated with more improvement in the clinical outcome within the oral steroid group was seen in the patients with night pain and joint stiffness. However, rather than to say these factors are indicators for oral steroid medication per say, these findings probably result from an emphasized improvement in patients with these factors who were more symptomatic and had a capacity to improve from inflammatory state and stiffness.

In this study, we found that there were no statistically significant differences in the clinical outcomes we assessed between the oral corticosteroid therapy and intra-articular steroid injection. Although, we found that all mean clinical outcomes were higher in the injection group than the oral steroid group across the whole follow-up, we believe that the oral steroid therapy can partially substitute the injection method to treat the early phase of impingement syndrome without mechanical injury of the rotator cuff, which is not associated with other underlying conditions.

Our study determined the efficacy of short-term low-dose oral corticosteroids in therapy of impingement syndrome, and assessed for associated complications. We compared the clinical outcomes to those of NSAIDs and injection therapies to see whether oral steroids can be substituted as a replacement. However, a limitation to our study is that the changes in clinical factors relating to the HPA axis such as plasma cortisol level, electrolyte level, glycemic levels were not looked into. Another limitation is that volume and dose-response relationships of oral steroids were not analyzed. Thus, further studies are required to address these issues.

Conclusion

Using short-term oral corticosteroids as an anti-inflammatory treatment for impingement syndrome of the shoulder show clinical outcomes comparable to those of intra-articular injection, especially in terms of pain control. Oral corticosteroids don't have remarkable complications or side effects. Although the beneficial effects are less obvious in patients with combined joint stiffness, all in all short term oral corticosteroids can be considered as a partial alternative of intra-articular injections for impingement syndrome in which inflammatory pain is the main clinical symptom.

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