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Efficacy of a single, image-guided corticosteroid injection for glenohumeral arthritis

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Background: Limited data are available on the efficacy of cortisone injections for glenohumeral osteoarthritis (GHOA). The amount and longevity of pain relief provided by a single cortisone injection are unclear. Additionally, it remains uncertain how the severity of radiographic GHOA and patient-reported function and pain levels impact the efficacy of an injection. Therefore, we sought to describe the relief provided by a single, image-guided glenohumeral injection in patients with GHOA. We hypothesized that patients with more severe radiographic GHOA and poorer baseline shoulder function would require earlier secondary intervention.

Methods: Patients with symptomatic GHOA who elected to receive a corticosteroid injection for pain relief were prospectively enrolled. A phone interview was conducted to record the baseline Oxford Shoulder Score (OSS) and visual analog scale (VAS) score prior to the injection, as well as the OSS and VAS score at months 1, 2, 3, 4, 6, 9, and 12 after the injection. The endpoint of the study occurred when patients required a second injection, progressed to surgery, or reached month 12. Patients were grouped by their respective baseline OSS (mild vs. moderate or severe) and Samilson-Prieto radiographic classification (mild, moderate, or severe) for analysis.

Results: We analyzed 30 shoulders (29 patients). Of the patients, 52% were men. The average age was 66.1 years. No significant difference in overall survival (defined as no additional intervention) was seen between groups based on either the OSS or Samilson-Prieto grade. Additionally, the OSS and VAS score at each follow-up were compared with baseline values. For the entire cohort, a clinically significant difference was seen between baseline and months 1-4 for the OSS and between baseline and months 1-4, 6, 9, and 12 for the VAS score.

Discussion: This study aimed to determine the efficacy of corticosteroid injections for GHOA. There were no differences in the need for secondary intervention in this population based on the severity of either the OSS or the Samilson-Prieto radiographic classification. However, patients with more severe shoulder dysfunction based on the OSS did experience statistically significantly greater symptomatic relief than patients with milder dysfunction. Additionally, following a single injection, patients in this cohort experienced statistically and clinically relevant improvements in shoulder function and pain up to 4 months after injection.

Level of evidence: Level IV; Case Series; Treatment Study

Keywords: Corticosteroid injections; image guided; glenohumeral osteoarthritis; Samilson-Prieto classification; Oxford Shoulder Score; visual analog scale

The St. Vincent Institutional Review Board approved this study (ID R20170138).

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Level I and II studies on the use of corticosteroid injections in the nonoperative management of glenohumeral osteoarthritis (GHOA) are lacking.[9] Because of this, the American Academy of Orthopaedic Surgeons has been unable to make recommendations for or against the use of corticosteroid injections for GHOA in its published clinical practice guidelines.[19] Previous studies have shown intra-articular injections to be safe for the treatment of osteoarthritis in other large joints.[13] However, these studies have not been performed exclusively on the shoulder, nor have they given us data on the success of corticosteroid injections in delaying the need for secondary intervention, either repeated corticosteroid injections or total shoulder arthroplasty (TSA).[12] Additionally, it is unknown whether the severity of radiographic GHOA or the patient's subjective shoulder pain and function, as documented by visual analog scale (VAS) pain scores and patient-reported outcomes (PROs), affect the efficacy and longevity of a glenohumeral corticosteroid injection for arthritis. These gaps in our understanding limit our ability to provide adequate counseling to patients regarding the usefulness of corticosteroid injections as a nonoperative treatment for GHOA.

Previous studies have attempted to evaluate the benefit of corticosteroid injections in treating shoulder pain.[4,6,10] However, the usefulness of these studies is limited by their heterogeneity, including varying sources of shoulder pain (acromioclavicular joint arthritis vs. adhesive capsulitis) and differing methods of corticosteroid injections; their retrospective nature; and their small sample sizes. The lack of image-guided injections in many of these studies is of particular concern, as previous studies have concluded that image-guided corticosteroid injections are more accurate than blind injections, and they may provide longer symptomatic relief in patients with shoulder pathology.[1,14] Moreover, the available data do little to help us predict which patients will have limited, short-lived improvement in their symptoms and which, if any, will enjoy a robust, long-lasting response.

We hoped to bridge some of the gaps in our knowledge surrounding conservative management of GHOA with corticosteroid injections by establishing a protocol that allows for accurate, image-guided glenohumeral corticosteroid injections and monthly patient follow-up using validated questionnaires for pain and shoulder function. We believe that our study will provide data on the amount and duration of pain relief to be expected from a single corticosteroid injection for GHOA. A second aim of this study is to evaluate the reliability of radiographic GHOA severity and validated shoulder function questionnaires in predicting the amount and duration of pain relief patients may expect from a single injection. We hypothesized that patients with (1) more severe radiographic osteoarthritis based on the Samilson-Prieto classification and (2) a poor baseline Oxford Shoulder Score (OSS) would require earlier secondary intervention with either repeated injections or surgical intervention.

Materials and methods

We prospectively enrolled 29 patients (30 shoulders) in an observational study after obtaining patients' informed consent. Shoulders that met the following inclusion criteria were included: adults (aged $\geq$ 18 years) with radiographically documented, symptomatic GHOA who were indicated for a corticosteroid injection as initial treatment of GHOA. Additionally, only patients who could cognitively consent to participate in the study and continue monthly communication through phone interviews were included. We excluded patients aged $<$ 18 years; those with inflammatory arthritis, rotator cuff tear arthropathy, or significant cervical spine abnormalities; and those with shoulder pain but without GHOA.

Patients were classified using 2 methods: the OSS questionnaire to classify subjective shoulder function and the Samilson-Prieto classification system to classify the radiographic severity of osteoarthritis. The Samilson-Prieto classification system grades arthritis as follows: grade 0, normal; grade I, mild (humeral neck osteophytes $<$ 3 mm); grade II, moderate (osteophytes of 3-7 mm), and grade III, severe (osteophytes $>$ 7 mm). The radiographs of each shoulder were independently graded by a board-certified orthopedic surgeon subspecializing in surgery of the upper extremity and an orthopedic surgery resident. When there was disagreement between independent observers, we used the grade given by the attending surgeon.

The OSS questionnaire consists of a series of 12 questions. A score of 0-4 is given for each patient response, and a cumulative score between 0-48 is calculated; the higher the score, the better the shoulder function. Mild, moderate, and severe shoulder dysfunction was determined by initial OSS values of 30-48, 20-29, and 0-19, respectively.[7,8] Patients with moderate and severe shoulder dysfunction were combined in the study to improve the sample size for comparison.

We identified patients in the clinic by obtaining standard shoulder radiographs. Those who agreed to participate in the study were scheduled for image-guided glenohumeral corticosteroid injections. Prior to the injection, patients were contacted over the phone to obtain the baseline OSS (0-48) and baseline Likert (VAS) pain score (0-10). The anticipated injection date for each patient was then recorded. Subsequent phone interviews were conducted in a similar manner, and the OSS and VAS score were recorded at the following intervals: month 1 (within 2 weeks of the image-guided injection) and months 2, 3, 4, 6, 9, and 12. The endpoint of the study occurred when patients required subsequent intervention with another corticosteroid injection, when patients underwent shoulder arthroplasty, or after 12 months from the initial injection. For patients who underwent a second intervention (cortisone injection or shoulder arthroplasty), we used the last recorded VAS score and OSS prior to the intervention for the remainder of the time points. This methodology was chosen to avoid artificially improving or worsening the PROs by the results of the second intervention.

Statistical analysis

The collected data were imported into SYSTAT (version 13; Systat Software, Chicago, IL, USA) and SPSS (IBM, Armonk, NY, USA) statistical analysis software, and Kaplan-Meier survival plots were created. On the basis of the OSS, we compared the percentage of patients with mild shoulder dysfunction vs. the percentage with moderate or severe dysfunction who did not

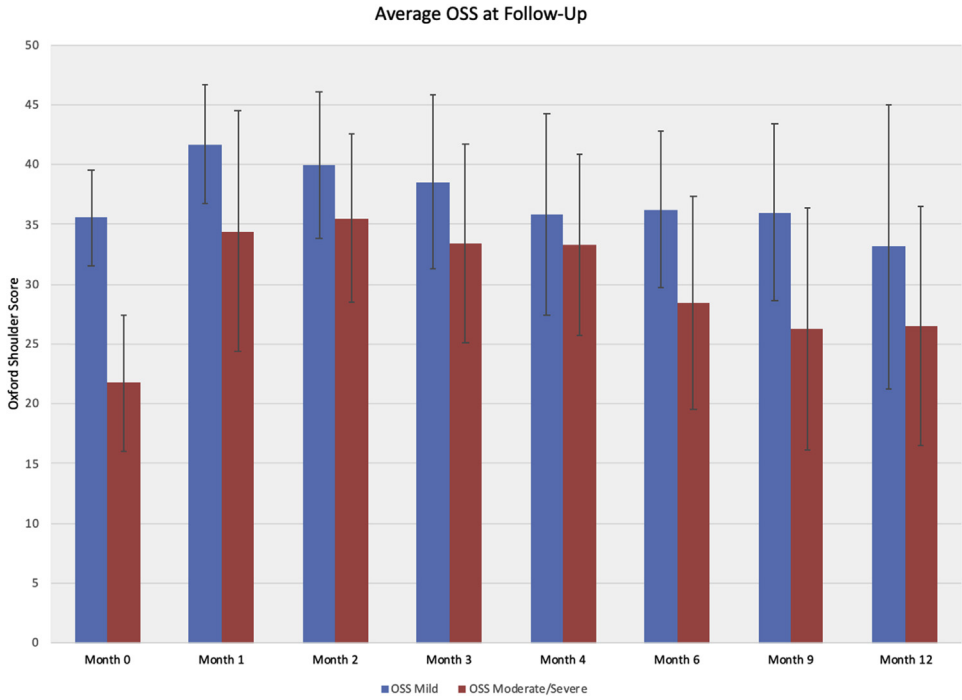

Figure 1 Average Oxford Shoulder Score *(OSS)* in patients with mild vs. moderate or severe shoulder dysfunction.

require secondary intervention at 12 months after injection. This was repeated, comparing patients with mild, moderate, and severe osteoarthritis based on the Samilson-Prieto classification system. Additionally, Mann-Whitney *U* tests were performed to compare VAS scores between patients with mild shoulder dysfunction and those with moderate or severe shoulder dysfunction based on the OSS at various time points, including at baseline and at months 1, 2, 3, 4, 6, 9, and 12 after the injection. The Mann-Whitney *U* test was repeated to determine whether the VAS scores varied significantly at all time points based on the Samilson-Prieto classification. The Student *t* test was performed to compare the change in OSS values from baseline to month 1 between patients with mild shoulder dysfunction and those with moderate or severe shoulder dysfunction. The *t* test was repeated to compare the change in VAS scores from baseline to month 1 between the 2 groups. Finally, the Student *t* test was performed to compare the change in OSS values and VAS scores from baseline at each time point in the study for the entire cohort.

Results

A total of 29 shoulders were available for analysis, with 1 shoulder being lost to follow-up at month 12. Of the patients, 52% were men. The average age of our cohort was 66.1 years (range, 43-86 years). Of the 29 shoulders, 8 were classified as having mild osteoarthritis based on the Samilson-Prieto classification; 13, moderate osteoarthritis; and 8, severe osteoarthritis. The interobserver agreement for the Samilson-Prieto grades between the 2 observers was 93.3%. On the basis of the OSS, 17 patients had mild shoulder dysfunction (average score, 35.5) whereas 12 had either moderate or severe dysfunction (average score, 21.8) (Fig. 1). Additional demographic data are summarized in Table I.

The average baseline VAS score for the entire cohort was 5.8. The average VAS scores for patients with mild, moderate, and severe radiographic osteoarthritis based on the Samilson-Prieto classification were 4.9, 6.5, and 5.7, respectively. The average baseline VAS scores based on our OSS subgrouping for mild shoulder dysfunction and moderate or severe shoulder dysfunction were 5.12 and 7, respectively (Fig. 2). The Mann-Whitney *U* test was

Table I Patient demographic characteristics, including age, sex, laterality, Samilson-Prieto classification, and OSS group (mild vs. moderate or severe)

	Data
Shoulders/patients, n	29/28
Mean age (range), yr	66.1 (43-86)
Male sex, %	52
Laterality: right sided, %	59
Samilson-Prieto classification, n (%)	
Class I	8 of 29 (27.5)
Class II	13 of 29 (45.0)
Class III	8 of 29 (27.5)
OSS classification, n (%)	
Mild	17 of 29 (58.6)
Moderate or severe	12 of 29 (41.4)

OSS, Oxford Shoulder Score.

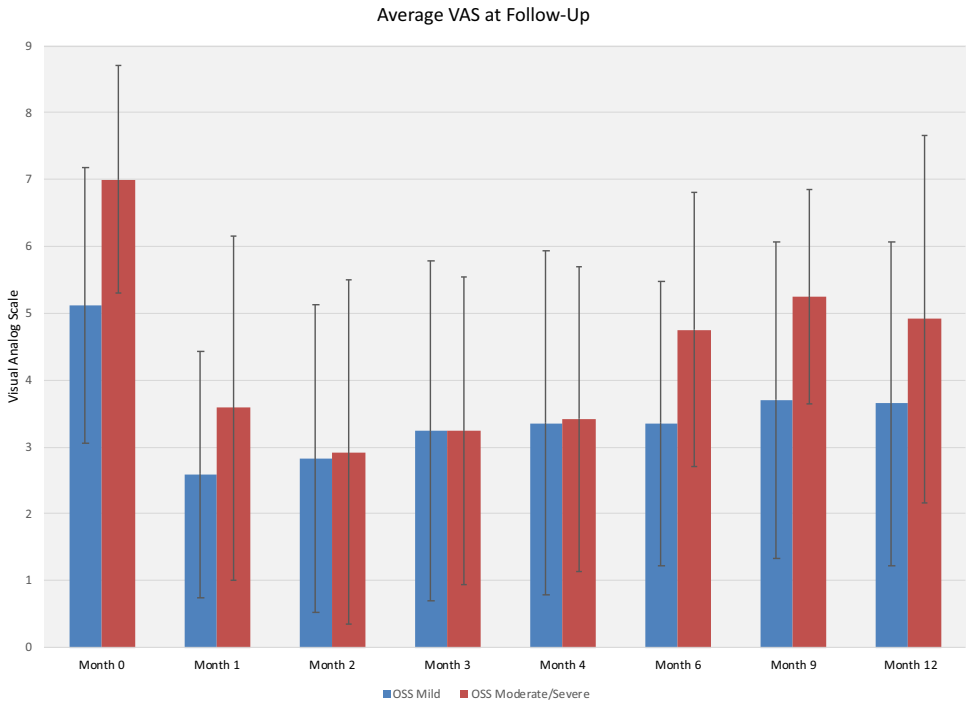

Figure 2 Average visual analog scale *(VAS)* score in patients with mild vs. moderate or severe shoulder dysfunction. *OSS*, Oxford Shoulder Score.

performed to compare VAS scores between the 2 groups. The VAS scores were not significantly different between the groups at any time point.

Twelve patients in the study required secondary intervention with either arthroplasty or a repeated injection prior to the end of the 12-month study period. According to the Kaplan-Meier survival analysis, 58.6% of patients in the entire cohort made it to 12 months without requiring secondary intervention overall. When we analyzed our subgroups based on the OSS, 64.7% of patients in the mild group (standard error [SE], 11.6%; 95% confidence interval [CI], 0.38-0.82) and 50% of those in the moderate-severe group (SE, 14.4%; 95% CI, 0.21-0.74) made it to 12 months without requiring secondary intervention. At 6 months after injection, 82.4% of patients with mild shoulder dysfunction did not require secondary intervention (SE, 9.2%; 95% CI, 0.55-0.94) and 83.3% of patients in the moderate-severe group did not require secondary intervention (SE, 10.8%; 95% CI, 0.48-0.96). To further compare the survival distributions, we performed a log-rank analysis (a nonparametric hypothesis test to compare the survival distributions of 2 samples) and failed to show a difference in overall survival curves between the 2 groups ($P = .446$).

A Kaplan-Meier survival analysis was also performed for patients with mild, moderate, and severe osteoarthritis based on the Samilson-Prieto classification. Patients with mild radiographic osteoarthritis had an 87.5% chance of not requiring a secondary intervention at 12 months (SE, 11.7%; 95% CI, 0.39-0.98). Patients with moderate radiographic osteoarthritis had a 46.2% chance of not requiring a secondary intervention at 12 months (SE, 13.8%; 95% CI, 0.19-0.70). Patients with severe radiographic osteoarthritis had a 62.5% chance of not requiring a secondary intervention at 12 months (SE, 17.1%; 95% CI, 0.23-0.86). The log-rank analysis failed to show a difference in the survival curves between groups ($P = .08$).

The Student *t* test was performed to compare the change in OSS values from baseline to month 1 after the injection. The mean increase in the OSS after the injection in the mild group was 6.2. The mean increase in the OSS after the injection in the moderate-severe group was 12.8. The increase from baseline to month 1 was significantly higher in the moderate-severe group compared with the mild group ($P = .03$; 95% CI, 1.37-11.9). The *t* test was repeated, comparing the change in VAS scores from baseline to month 1 after the injection. The average improvement in the VAS score in the moderate-severe group was 3.4, whereas the average improvement in the VAS score in the mild group was 2.4. This comparison was not statistically significant ($P = .32$; 95% CI, –1.21 to 2.99).

The change in OSS values from baseline was calculated for the entire cohort at each time point. The Student *t* test was then used to compare the change in OSS values from baseline, which did show significant differences in the mean values at months 1, 2, 3, and 4. The difference was not significant at months 6, 9, and 12. This finding was compared against the minimal clinically important difference (MCID) of 3.3 for the OSS, as defined by Xu et al.[18] These data showed an improvement in the OSS above the

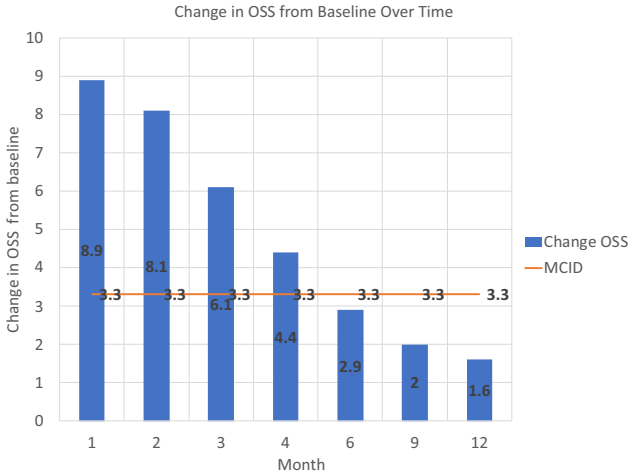

Figure 3 Monthly change in Oxford Shoulder Score *(OSS)* from baseline vs. minimal clinically important difference *(MCID)*.

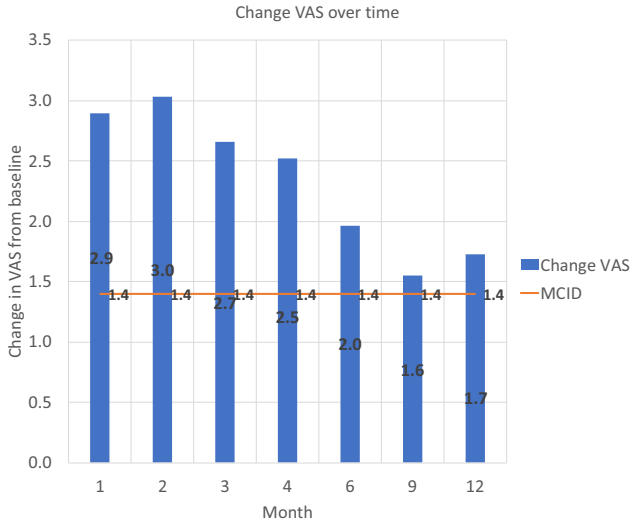

Figure 4 Monthly change in visual analog scale *(VAS)* score from baseline vs. minimal clinically important difference *(MCID)*.

MCID during months 1-4, with the change in the OSS falling below the MCID during months 6, 9, and 12 (Fig. 3).

The change in VAS scores from baseline was calculated at each time point. The Student *t* test was used to compare the change in VAS scores with baseline. This showed a statistically significant change in the mean at months 1, 2, 3, 4, 6, 9, and 12. The change in VAS scores was compared against the MCID of 1.4 for the VAS score, which has been defined in previous studies.[15,16] This comparison demonstrated improvements in VAS scores above the MCID for the entirety of the study (Fig. 4).

Discussion

The goal of this study was to determine the efficacy of a single, image-guided corticosteroid injection in the conservative management of GHOA and determine the magnitude of symptom relief, as well as longevity. We also wanted to determine whether subjective shoulder dysfunction and/or the radiographic severity of GHOA impacted the amount and duration of symptom relief.

To accomplish the aforementioned goals, we developed a protocol to provide standardized, image-guided glenohumeral injections. We believed this was important for several reasons. Soh et al[14] found that patients who underwent image-guided injections had statistically significant improvements in their shoulder pain at 6 weeks compared with patients who received blind injections. Additionally, image-guided glenohumeral injections have been found to be better at achieving intra-articular needle placement. Aly et al[1] performed a systematic review that compared the accuracy of image-guided vs. blind injections surrounding the shoulder girdle. They found that image-guided injections in the glenohumeral joint were 92.5% accurate, whereas blind injections were only 72.5% accurate.

In this study, there was no significant difference in the number of patients who underwent secondary intervention with a steroid injection vs. TSA in the mild group or moderate-severe group based on the OSS. Additionally, the radiographic severity of GHOA based on the Samilson-Prieto classification did not impact the duration of pain relief to be expected from a single injection. However, the value of "survival" to evaluate the efficacy of an injection may be limited owing to the multiple factors involved when indicating a patient for TSA, including both patient and surgeon factors. Of note, no formal guidelines were provided to participating surgeons regarding the timing of TSA following injection. There is some concern that cortisone injections increase the risk of infection after TSA. It is our general practice to avoid TSA within 3 months of an injection; this also has impacts on the usefulness of evaluating survival.[17]

The OSS is a validated questionnaire that gives shoulder surgeons an indication of how patients are doing functionally.[7] Additionally, the VAS score is a validated score that has been used to monitor changes in pain in patients with rotator cuff disease, as well as patients following shoulder arthroplasty.[15,16] We used both the OSS and VAS score in this study to obtain an overall appreciation of how patients were doing both functionally and symptomatically following the injection. Recently, Xu et al[18] sought to determine the MCID for the OSS. In their article, they published the results of >300 patients after arthroscopic rotator cuff repair and followed them up for 24 months postoperatively. They were able to determine that the MCID for the OSS was 3.3 (95% CI, 2.1-4.6) at 12 months postoperatively. Given these results, we were able to extrapolate the MCID to be 3.3 for our study cohort.

It is important to note that we were able to illustrate that a single, image-guided corticosteroid injection can improve the average OSS from baseline to above the MCID for 4 months (Fig. 3). This finding suggests that the image-guided corticosteroid injection did provide clinically significant improvements in shoulder function up to 4 months after injection. Additionally, we were able to show that patients with worse baseline OSS values may expect more functional improvements from a single corticosteroid injection than patients with milder disease. However, some of these data could be a result of the ceiling effect of the OSS questionnaire.[2] Regardless, these findings can prove useful when counseling patients on what to expect from a single injection and help manage patient expectations.

Prior studies by Tashjian et al[15,16] determined the MCID for the VAS score for patients with rotator cuff disease and for patients who underwent shoulder arthroplasty to be 1.4. We extrapolated this MCID to our cohort. On the basis of our results, the average VAS score did remain below baseline for the entirety of the study and, somewhat surprisingly, that improvement was greater than the MCID throughout 12 months, suggesting that this difference was clinically significant (Fig. 4).

One interesting finding was that patients with severe radiographic GHOA, on average, had lower baseline VAS scores and showed a trend toward higher survival based on our Kaplan-Meier survival analysis when compared with patients with moderate radiographic GHOA. This finding could be coincidental given the relatively small sample size, or it could represent lower functionality, older age, or more comorbidities in this population; this again points to the limitations of using survival while evaluating the results of a cortisone injection. Nevertheless, the radiographic severity of disease did not predict the duration of pain relief to be expected from an image-guided corticosteroid injection in this study. There may be some concern that patients presenting with severe GHOA and glenoid bone loss will sustain progression of bone loss during nonoperative management. No specific guidance was provided to study surgeons regarding this; rather, each surgeon could use her or his own judgment when counseling patients regarding injections.

One of the strengths of this study is its prospective, cohort design, which can provide strong evidence in the absence of a randomized controlled trial.[3] Additionally, follow-up in this cohort was excellent. We were able to maintain contact with 28 of 29 patients (29 shoulders) for 12 months following the injection. Another strength is the standardization of our injection protocol. By only using image-guided injections and limiting our study to only patients with GHOA, potentially confounding factors were eliminated. Finally, our study includes not only radiographic measures but also PROs of function and pain.

There were several limitations to this study. First, our sample size is small. Increasing the sample size may have improved the chance of finding a statistically significant difference in survival curves between the study groups and decreased the chance of a possible type II error. Additionally, there was no evaluation of other modalities patients were concurrently using to treat their arthritis, such as physical therapy or nonsteroidal anti-inflammatory drugs. Moreover, we did not examine possible confounders, most notably the presence of a concomitant rotator cuff tear. However, it has been suggested that the likelihood of a rotator cuff tear in the setting of primary GHOA is low.[5,11] No patients had rotator cuff arthropathy. Additional comorbidities such as diabetes, hypothyroidism, and fibromyalgia could have a potential impact on subjective pain and function.

Conclusion

This study sought to prospectively determine the efficacy of a single, image-guided corticosteroid injection. To accomplish this, we used a validated shoulder survey and VAS scores obtained prospectively at routine intervals after injection in patients with radiographically confirmed GHOA. Patients in this cohort experienced statistically and clinically significant improvements in their shoulder function (OSS) for 4 months after injection, with dwindling effects thereafter. Additionally, these patients reported statistically and clinically significant improvements in their pain (VAS score) for up to 1 year, most pronounced over the first 4 months. However, neither baseline OSS severity nor the radiographic severity of GHOA predicted the amount of pain relief patients can expect from a single, image-guided glenohumeral injection. These results may help shoulder surgeons counsel their patients on the duration and amount of pain relief to expect from a single, image-guided steroid injection. Additional larger prospective studies, potentially performed in a randomized fashion with a control group, will be helpful to draw more definitive conclusions on the efficacy of cortisone for GHOA.

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Disclaimer

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