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A Randomized, Prospective, Double-Blind Study to Investigate the Effectiveness of Adding DepoMedrol to a Local Anesthetic Injection in Postmeniscectomy Patients With Osteoarthritis of the Knee

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Background: Patients with osteoarthritis of the knee are at risk for poorer outcomes after arthroscopic meniscectomy. Intra-articular corticosteroid injections have been shown to be efficacious both in patients with osteoarthritis and postarthroscopy patients.

Hypothesis: A postoperative, intra-articular methylprednisolone and lidocaine injection in patients with chondromalacia undergoing meniscectomy will improve patient-rated pain and function compared with control patients.

Study Design: Randomized, controlled trial; Level of evidence, 1.

Methods: A total of 58 patients (59 knees) were randomized in a double-blinded fashion to receive either saline plus lidocaine (saline) or methylprednisolone plus lidocaine (steroid) after arthroscopic meniscectomy in which chondromalacia (modified Outerbridge grade 2 or higher) was confirmed. Preoperatively and at follow-up—6 weeks and 6, 9, and 12 months—patients underwent an examination and completed a subjective functioning survey. Scores were calculated using several validated scoring systems including the Lysholm, International Knee Documentation Committee (IKDC), and Short Form–12 (SF-12).

Results: No statistically significant differences were observed between the saline (n = 30) and steroid (n = 29) groups in their demographics and preoperative scores. At 6 weeks, the steroid group had higher scores than the saline group on multiple scales, including the IKDC. No differences in outcome scores existed at later time points. At 12 months, 86% of the steroid and 69% of the saline group were completely or mostly satisfied with the procedure ($P = .01$). In the saline group, 4 patients required reinjection and 2 underwent joint replacements within 12 months, while the steroid group had 3 reinjections and 2 meniscus transplants.

Conclusion: The addition of a postoperative corticosteroid injection resulted in improved pain and function at an early time point; however, it provided no lasting difference compared with only local anesthetic injection.

Keywords: osteoarthritis; chondromalacia; meniscectomy; corticosteroid; meniscal tear; clinical trial; DepoMedrol; lidocaine

Chondromalacia and meniscal injury are known to be coexisting lesions of the knee. In one study, greater than 75% of patients with osteoarthritis (OA) demonstrated a meniscal tear by magnetic resonance imaging (MRI).[4] It is also known that loss of normal meniscal function confers a substantial risk toward the development and progression of OA.[1,16,23]

Treatment of meniscal injury through arthroscopic partial meniscectomy provides excellent functional outcomes and symptomatic relief.[9] However, the presence of moderate to severe OA at the time of surgery correlates with poor long-term clinical outcomes.[13] Interestingly though, even patients with grade 4 OA experience symptom relief after arthroscopic meniscectomy.[5,19]

Corticosteroids are a mainstay in the treatment of OA and have also been used successfully as an adjunct to operative procedures. Intra-articular corticosteroid

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injections, as part of nonoperative management, may provide functional improvement and symptomatic relief of up to 24 weeks.[2] Administration after diagnostic arthroscopy or meniscectomy is noted to decrease postoperative pain scores, consumption of analgesics, and recovery time.[14,20,21]

The cohort of patients with existing OA undergoing meniscectomy is potentially at higher risk of further joint degeneration and poor symptomatic outcomes, as the relative contribution of OA to the patient's symptoms may exceed that which is due to the meniscal injury. Postoperative corticosteroid injection may alleviate postoperative discomfort and improve the outcomes in this at-risk population. The principal objective of this study was to evaluate the effect of adding methylprednisolone (DepoMedrol, Pfizer Inc, New York, New York) to a postoperative injection of local anesthetic in patients undergoing meniscectomy who have coexisting OA. We hypothesize that the cohort receiving the corticosteroid will have improved symptomatic and functional outcomes.

MATERIALS AND METHODS

Patient Selection

Between December 2004 and January 2007, 58 consecutive patients (59 knees) were indicated for arthroscopic meniscectomy and included in this study. Study protocols and procedures were approved by the Institutional Review Board at this institution. The inclusion criteria were as follows: (1) age between 18 and 85 years at surgery, (2) written informed consent provided, (3) had an arthroscopic meniscectomy with (4) confirmed chondral changes (modified Outerbridge grade ≥2 in the ipsilateral compartment). Exclusion criteria were as follows: (1) presence or suspected allergy to agents used in the study, (2) corticosteroid injection within prior 2 months, and (3) insufficient follow-up data for analysis. A total of 72 patients were initially consented into the study. There were 8 patients completing no follow-up visits and 6 with only 1 follow-up visit, leaving 58 (81%) for analysis and inclusion.

Study Design

Preoperatively, after consent was obtained, the patient was randomly assigned in a 1:1 fashion to either the saline group (1 mL 0.9% normal saline plus 9 mL 1% lidocaine injection) or the steroid group (1 mL [40 mg] DepoMedrol plus 9 mL 1% lidocaine injection). Both the patient and the clinician administering the injection were blinded to the contents. One researcher prepared the injection and delivered the prefilled, numbered syringe to the operating room. The treatment key was unblinded after all data collection was completed.

All operations were performed by a single attending surgeon. A diagnostic arthroscopy was performed via standard inferomedial and inferolateral portals. Location and grade (modified Outerbridge classification) of cartilage defects were noted in the ipsilateral compartment. The torn medial or lateral meniscus was resected to a stable rim using an arthroscopic shaver and biter. The assigned injection was administered into the knee joint after closure of the arthroscopic portals. Postoperatively, patients used crutches for 24 to 48 hours, advancing to full weightbearing as tolerated, and were encouraged to obtain full range of motion as soon as possible. Subjects returned to the clinic for suture removal 10 to 14 days after surgery.

Preoperatively and at follow-up visits (6 weeks and 6, 9, and 12 months), patients completed a standardized survey and knee examination. The subjective questionnaire included the Knee Injury and Osteoarthritis Outcome Score (KOOS), Lysholm, International Knee Documentation Committee (IKDC), Tegner, Noyes, and Short Form–12 (SF-12) scales. The KOOS score is subdivided and scored in 5 categories: Pain, Other Disease-Specific Symptoms, Activities of Daily Living Function (ADL), Sport and Recreation Function, and Knee-Related Quality of Life (QOL). Information on treatment satisfaction and willingness to have the procedure on the contralateral knee was collected at 12 months postoperatively. Duration of pain medication use and back-to-work time were also assessed. Objective measures included active range of motion and quadriceps size (measured 10 cm proximal to the superior pole of the patella). Data inclusion continued until 12 months or until the patient was excluded because of reinjection or reoperation. The decision to reinject was based on clinical symptoms of ongoing inflammation and failure to progress with postoperative rehabilitation.

Statistical Analysis

Statistical analysis was performed using Prism 5.0a (GraphPad Software, San Diego, California) and SPSS v.11.5 (SPSS, Chicago, Illinois). Descriptive statistics included frequencies, means, standard deviations, and ranges where appropriate. Tests used in this analysis include the χ^2, Mann-Whitney, Wilcoxon signed-ranks, and Friedman test for nonparametric repeated measures. Results were considered statistically significant when $P < .05$.

A power analysis was conducted based on the primary outcome measure, the IKDC score. A sample size of 21 per group (42 total) was calculated to provide 80% power to detect a difference between cohorts, if the probability is .75 that an observation in one group is less than an observation in the other group with a .05 significance level (based on a 2-sided Mann-Whitney test). The initial sample size goal was 50 to take into account an expected dropout rate of 16%.

TABLE 1
Demographics of the Study Cohorts

	Saline Group	Steroid Group
Patients, n	30	29
Average age, y	52 ± 9 (range, 34-64)	49 ± 11 (range, 19-68)
Male/female	22/8	19/10
Left/right knee	16/14	15/14
Medial/lateral/both meniscectomy	15/4/11	18/5/6
Chondromalacia: uni/bi/tricompartmental	13/8/9	17/10/2
Mean time to return to work, d	13 ± 19 (range, 1-80)	13 ± 19 (range, 1-84)
Mean duration of pain medication use, d	5 ± 7 (range, 0-28)	4 ± 6 (range, 0-21)
Reinjected, n	4	3
Reoperated, n	2	2

TABLE 2
Subjective Survey Scores After Meniscectomy[a]

	6 Weeks			6 Months		9 Months		12 Months	
Scoring System	Saline	Steroid	*P* Value	Saline	Steroid	Saline	Steroid	Saline	Steroid
KOOS QOL	41 (19)	55 (24)	.035	48 (23)	56 (27)	59 (29)	60 (26)	57 (28)	68 (28)
KOOS Sport	29 (24)	50 (26)	.005	42 (29)	54 (33)	55 (30)	51 (34)	45 (28)	63 (33)
KOOS Pain	65 (16)	74 (16)	.050	67 (19)	71 (22)	73 (21)	75 (22)	70 (23)	79 (22)
KOOS ADL	75 (17)	83 (17)	.056	76 (20)	79 (19)	82 (19)	81 (18)	79 (22)	85 (19)
KOOS Symptoms	67 (17)	73 (18)	NS	72 (17)	72 (17)	76 (17)	73 (22)	73 (21)	75 (22)
Lysholm	62 (20)	69 (23)	NS	65 (19)	65 (23)	68 (21)	66 (22)	67 (24)	68 (24)
IKDC	49 (16)	59 (20)	.010	53 (21)	59 (24)	58 (22)	59 (25)	55 (26)	62 (27)
Tegner activity scale	3.6 (3)	4.8 (3)	.061	5 (3)	5 (3)	5 (3)	5 (3)	4 (3)	5 (4)
Current sports activity scale	40 (26)	55 (29)	.056	54 (29)	58 (29)	56 (33)	58 (32)	48 (34)	54 (38)
SF-12 Physical	37(7)	40 (8)	NS	39 (8)	38 (8)	41 (6)	39 (6)	40 (7)	42 (6)
SF-12 Mental	56(9)	55 (11)	NS	53 (11)	53 (10)	55 (11)	54 (11)	55 (10)	50 (13)

[a]KOOS, Knee Injury and Osteoarthritis Outcome Score; QOL, Quality of Life; ADL, Activities of Daily Living; IKDC, International Knee Documentation Committee; SF-12, Short Form-12; NS, not significant. Data presented as mean (standard deviation). Differences between the saline and steroid groups at 6, 9, and 12 months were not significant. *P* values were calculated using a Mann-Whitney *U* test.

RESULTS

Comparison of Groups

The saline group (saline + lidocaine) consisted of 30 patients (22 male, 8 female) with a mean age of 52 ± 9 years (range, 34-64 years). The steroid group (DepoMedrol + lidocaine) was composed of 29 patients (19 male, 10 female) with an average age of 49 ± 11 years (range, 19-68 years). The demographics of the saline and steroid groups were not significantly different (Table 1). In both groups, 90% of the subjects completed 2 or more of the follow-up visits. Subjects returned to work at a mean of 13 days after meniscectomy regardless of injection. At 6 weeks, 2 people in both groups had not returned to work.

In both groups, isolated medial meniscectomies were the most common procedure, although 37% of the saline and 21% of the steroid group required both medial and lateral meniscectomies. Chondromalacia was unicompartmental in 43% of the saline and 59% of the steroid group, with bicompartmental (27% and 34%, respectively) and tricompartmental (30% and 7%, respectively) changes occurring less frequently (Table 1). There was no statistical difference in the distribution of meniscectomies or chondromalacia.

Patient-Rated Pain and Function Assessment

Preoperatively, the saline and steroid groups were not different in their subjective knee scores ($P > .05$). Scores in the steroid group were significantly higher at 6 weeks for KOOS Sport ($P = .005$), KOOS QOL ($P = .035$), IKDC ($P = .010$), and treatment satisfaction ($P = .010$) (Table 2). The steroid group trended toward statistical significance on several additional scales, including the KOOS Pain ($P = .05$) and KOOS ADL ($P = .056$). At subsequent time points (6, 9, and 12 months), score differences between the steroid and saline groups had disappeared.

Score improvements for both the saline and steroid groups over time (from preoperative to most recent

TABLE 3
Improvement in Subjective Outcomes Over Time[a]

Scoring System	Saline	Steroid
KOOS Quality of Life	<.001	<.001
KOOS Sport	<.01	<.001
KOOS Pain	<.001	<.001
KOOS Activities of Daily Living	<.001	<.001
KOOS Symptoms	<.001	<.001
Lysholm	<.01	<.001
IKDC	<.001	<.001
Tegner activity scale	NS	NS
Noyes sports activity scale	NS	<.05
SF-12 Physical	NS	NS
SF-12 Mental	NS	NS

[a]KOOS, Knee Injury and Osteoarthritis Outcome Score; IKDC, International Knee Documentation Committee; SF-12, Short Form-12; NS, not significant. Individuals with complete data sets (ie, preoperative and 4 follow-up visits) from both the saline (n = 16) and steroid (n = 15) groups were evaluated over time with a Friedman test for nonparametric repeated measures.

follow-up) were significant for all scales except the SF-12 component scores, Tegner activity scale, and Noyes sports activity scale (only saline not significant) (Table 3). At the end of the study (12 months), 86% of patients in the steroid group and 63% of saline subjects reported that they were completely or mostly satisfied with the procedure ($P = .01$). A majority of patients, 86% of the steroid and 81% of the saline group, reported they would have the surgery again.

Physical Examination

Preoperatively, the steroid group had greater range of motion compared with the saline group (117º vs 105º; $P = .031$) (Table 4). At all follow-up time points, no apparent difference in range of motion was observed between the steroid and saline groups. Quadriceps muscle atrophy, namely the difference of the operated and contralateral leg, was not significantly different between the saline and steroid group at any time point.

Additional Treatment

In the saline group, 4 patients required reinjection (4 corticosteroid, 0 viscosupplementation) at an average of 8.0 months (range, 4.6-11.8 months). Three patients in the steroid group received an additional injection (1 corticosteroid, 2 viscosupplementation) at an average of 7.6 months (range, 5.9-10.1 months).

In the saline group, one patient had a total knee arthroplasty before their 6-month follow-up, and another underwent a unicompartmental arthroplasty within 12 months of meniscectomy. In the steroid group, 2 patients underwent subsequent medial meniscus transplantation within 6 months and 12 months of meniscectomy, respectively.

Adverse Events

No adverse events were reported during the study period. There were no superficial or deep infections in either the saline or steroid group after surgery and injection. No patient in the steroid group experienced postinjection steroid flare, arthropathy, synovitis, skin atrophy, or tendon rupture.

DISCUSSION

The goal of this study was to compare the effects of adding methylprednisolone to a postoperative local anesthetic injection in patients with OA of the knee. The question of this study was "Does the corticosteroid improve the functional and symptomatic outcomes of this patient cohort?" The subjective outcomes of patients receiving the steroid were higher at 6 weeks postmeniscectomy than the saline group; however, at longer time points, this difference was no longer apparent.

Meniscal tears are common injuries, with an estimated incidence of 60 to 70 per 100 000 persons. Standard treatment includes partial meniscectomy, which is demonstrated to provide symptomatic relief and functional improvement out to 15 years.[9] Thus, it was not surprising that subjects in the control group, receiving a placebo injection, had an improvement in their subjective scores. Of greater relevance to our study is the outcome of patients with pre-existing chondromalacia at the time of arthroscopic meniscectomy. At 12-year follow-up, Higuchi et al[13] found that patients with defects of modified Outerbridge grades 0 or 1 had significantly better outcome scores than did those with higher grade changes. Over the past 25 years, many other studies have shown that OA patients are at risk for worse outcome after meniscectomy.[3,8,11,17,18]

While functional outcomes in OA patients are not as good as those of patients free of significant chondral changes, symptomatic improvement after meniscectomy has been demonstrated even in patients with advanced OA. Bin et al[5] noted that partial meniscectomy improved symptoms in patients with grade 4 OA. A similar study noted an initial improvement (12 months) of symptoms in 65% of patients with exposed subchondral bone after meniscectomy, with 40% reporting subjective improvement in the longer term.[19] In the short term, Roos et al[22] observed improvement in KOOS scores from the preoperative level at 15 weeks; however, the scores of patients having cartilage and meniscal damage were significantly lower than those with isolated meniscal tears. Both the control and treatment groups of the present study demonstrated significant improvement over time with regard to multiple subjective scales. Interestingly, score increases occurred on knee-specific scales, but not on the global health assessment.

Intra-articular corticosteroid injection is a common treatment modality that improves symptoms in the setting of OA. A meta-analysis by Godwin and Dawes[12] established a significant reduction in pain after 1 week and possibly up to 3 to 4 weeks in OA patients. Arroll and Goodyear-Smith[2] performed a meta-analysis that similarly demonstrated that OA patients experience significant short-term symptom relief (up to 2 weeks), with a longer duration of relief (16-24 weeks) possible when larger doses are administered (ie, 50 mg). Most evidence regarding the

TABLE 4
Objective Assessments[a]

		Saline	Steroid	*P* Value
Quadriceps atrophy, cm	Preoperative	–1 (–11 to 2)	–1 (–10 to 3)	NS
	6 weeks	–1 (–2 to 1)	0 (–2 to 5)	NS
	12 months	0 (–3 to 2)	–1 (–2 to 2)	NS
Range of motion, deg	Preoperative	105 ± 26 (30–137)	117 ± 20 (59–143)	.031
	6 weeks	119 ± 13 (85–142)	126 ± 9 (105–140)	.051
	12 months	124 ± 12 (95–144)	127 ± 12 (95–145)	NS

[a]NS, not significant. Quadriceps atrophy was determined as operated minus contralateral. Range of motion is reported as maximum flexion minus maximum extension.

efficacy of these injections is anecdotal, with limited reports of controlled clinical trials in the literature.

On the other hand, the use of postoperative corticosteroid injections is supported by several randomized clinical trials. Rasmussen et al[20,21] conducted 2 studies assessing the effect of adding glucocorticoid to a standard bupivacaine and morphine injection after diagnostic knee arthroscopy or meniscectomy. Pain during movement, leg muscle force, joint effusion, and duration of sick leave were all significantly improved in the group receiving the steroid injection compared with the control group. In another study, OA patients receiving intra-articular triamcinolone acetonide had lower pain scores (visual analog scale) from 6 to 24 hours after arthroscopic knee surgery and required less rescue analgesia than the control subjects receiving a saline injection.[24] Similarly, Kizilkaya et al[14] noted that patients receiving a sufentanil plus methylprednisolone injection after arthroscopic meniscectomy experienced significantly less pain from 30 minutes to 24 hours postoperatively and consumed fewer analgesics compared to saline- or sufentanil-only injection. These studies confirm the use of intra-articular corticosteroid injection to reduce immediate postoperative pain.

To our knowledge, no study has assessed the longer term consequences of this adjunctive treatment specifically in a population with pre-existing chondromalacia. Based on reports of symptomatic relief in OA patients[2] and short-term postoperative pain relief,[20,21] we hypothesized that a postmeniscectomy injection would accelerate and improve recovery. Interestingly, the present study demonstrated a significant difference in subjective outcome scores at 6 weeks; however, no differences were observed in back-to-work times or analgesic usage. At longer time points, the control and treatment groups had similar subjective scores, suggesting that the control group had "caught up" in terms of improvement. Analysis of score improvement over time was significant in both cohorts except for the SF-12 component or Tegner activity scores. This is not altogether surprising as neither the meniscectomy nor the corticosteroid injection could reverse the existing degenerative joint changes. Previous studies demonstrate lower subjective scores in postmeniscectomy patients having cartilage damage, with grade 3 or 4 changes being predictive of worse postoperative quality of life.[22]

Limitations to this study exist despite its randomized, double-blinded design. Despite surpassing the minimum number necessary to achieve statistical power for comparison in the primary outcome measure (IKDC), the study was underpowered to detect a significant difference in the distribution of chondromalacia and meniscectomies. Treatment randomization occurred preoperatively, which prevented incorporation of chondromalacia severity and meniscectomy performed into the allocation algorithm. The saline group had a higher prevalence of tricompartmental arthritis and bilateral meniscectomies, suggestive of a more advanced disease state, which may contribute to the lower scores observed in these patients. The steroid group had a wider age range, including patients as young as 19 years, compared with a minimum age of 34 years in the saline group. Interestingly, despite this difference, the saline group had "caught up" to the steroid group in all outcome measures by 6 months. Future work should seek to better stratify the cohorts in terms of age, chondromalacia, and meniscal injury or limit inclusion to only ipsilateral chondromalacia and meniscectomy. Additionally, the outcomes scores demonstrated a difference at 6 weeks, which had disappeared at 6 months. Further assessment at 3 months could have narrowed the time frame in which the control group attained the level of the treatment group.

Despite the observed benefits of intra-articular steroid injections, local and systemic side effects do occur. Skin atrophy, tendon rupture, infection, and altered blood glucose levels have been reported in small numbers of patients.[6,7,10,15] The number of patients needed to accurately assess the incidence of these adverse events is large and outside the realm of this study; thus we are unable to draw any definitive conclusion regarding the complications of this treatment. Although none occurred, the question of adverse events could be confounded by the administration of surgical intervention.

In patients with OA of the knee, who are inherently at greater risk for poorer outcomes following meniscectomy, adding an intra-articular corticosteroid injection to postoperative care is safe and effective at decreasing pain and improving function for the first 6 weeks after surgery. Additional high-quality clinical trials are necessary to further characterize the benefits, indications, and durability of intra-articular corticosteroid injections in the setting of OA and in that of postoperative care.

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