

A Prospective Randomized Controlled Trial of Methylprednisolone for Postoperative Pain Management of Surgically Treated Distal Radius Fractures

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Purpose Perioperative glucocorticoids have been effectively used as a pain management regimen for reducing pain after hand surgery. We hypothesize that a methylprednisolone taper (MPT) course following surgery will reduce pain and opioid consumption in the early postoperative period.

Methods This study was a randomized controlled trial of patients undergoing surgical fixation for distal radius fracture. Before surgery, patients were randomly assigned to receive preoperative dexamethasone only or preoperative dexamethasone followed by a 6-day oral MPT. Patient pain and opioid consumption data were collected for 7 days after surgery using a patient-reported pain journal.

Results Our study consisted of 56 patients enrolled from November 2018 to March 2020. Twenty-eight patients each were assigned to the control and treatment groups. Demographic characteristics such as age, body mass index, the dominant side affected, smoking status, diabetes status, and current narcotic use were similar between the control and treatment groups. With a noticeable, significant reduction starting on postoperative day 2, patients who received an MPT course consumed substantially less opioids during the first 7 days (7.8 ± 7.2 pills compared with 15.5 ± 11.5 pills, a 50% reduction). These patients also consumed significantly fewer oral morphine equivalents than the control group (81.2 vs 41.2). A significant difference in the pain visual analog scale scores between the 2 groups was noted starting on postoperative day 2, with 48% of the treatment group reporting no pain by postoperative day 6. No adverse events, including infection or complications of wound or bone healing, were seen in either group.

Conclusions There was an early improvement in pain and reduction in early opioid consumption with a 6-day MPT following surgical fixation for distal radius fracture. With no increased risk of adverse events in our sample, MPT may be a safe and effective way to reduce postoperative pain. (*J Hand Surg Am.* 2022;47(9):866–873. Copyright © 2022 by the American Society for Surgery of the Hand. All rights reserved.)

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HAND SURGEONS PRESCRIBE A SUBSTANTIAL quantity of narcotic medication to relieve pain, as evidenced by the current data available describing the US opioid epidemic.^{1–5} Therefore, it is not surprising that orthopedic patients comprise a substantial at-risk population for the addiction and misuse of opioids. There is evidence that perioperative opioid use is directly correlated with clinical outcomes. For instance, in total joint arthroplasty of the hip and knee, prolonged opioid use has been demonstrated to increase the risk of perioperative complications, readmission, increased costs, postoperative narcotic consumption, revision, and dissatisfaction.^{6–15}

Fractures of the distal radius are the most commonly treated upper extremity fractures in the United States, accounting for nearly 20% of the fractures seen in emergency departments.^{16–18} Although most patients who have sustained a distal radius fracture have recovered within 6 months, an estimated 1 of every 6 patients will have prolonged pain, leading to disability and reduced function.^{19–22} Although the mainstay of pain treatment after fracture treatment has historically been opioid medication, these medications have risks. The increased awareness and proven dangers of opioid medications warrant investigation into finding safer modalities to manage postoperative pain and limit prolonged morbidity.^{2–4}

Current efforts to reduce postoperative pain have resulted in the use of multimodal strategies, such as neural blockades, anti-inflammatory drug usage, and the evaluation of other pharmacotherapies. Desai et al²³ evaluated the use of a glucocorticoid taper after surgery in patients with terrible triad injuries of the elbow. Their study found that patients treated with glucocorticoids had reduced pain and increased range of motion compared with those not treated with glucocorticoids.²³ One concern was the risk of perioperative complications associated with glucocorticoid use. Although high-dose glucocorticoids have important side effects, short-term use of low-dose glucocorticoids has demonstrated a relatively safe postoperative profile.^{24–27}

Given the paucity of the current literature on successful multimodal pain protocols, the use of a postoperative course of glucocorticoids as an alternative modality for pain following a distal radius fracture requires further investigation. We hypothesize that administering a 6-day low-dose methylprednisolone course following distal radius fracture fixation will provide improved early pain relief and help reduce total opioid consumption following surgery.

MATERIALS AND METHODS

Design

Before enrollment, the study obtained institutional review board approval and was registered on clinicaltrials.gov (NCT03661645). The study adhered to all Consolidated Standards of Reporting Trials guidelines. The aim of this prospective randomized clinical trial was to evaluate the effect of a 6-day course of oral methylprednisolone on pain and opioid consumption following distal radius fracture fixation.

All patients with a distal radius fracture (including AO/OTA classification 2R2 and 2R3, \pm type A, B, C) who presented to 3 fellowship-trained upper extremity surgeons from December 2018 to March 2020 were screened for inclusion in the study. Patients aged 18–95 years who were not considered a member of a vulnerable population (minors, pregnant women, prisoners, and the cognitively impaired) and who were willing and able to provide informed consent were considered. The exclusion criteria were a concurrent and substantial injury to other bones or organs, a history of alcohol or substance abuse, severe heart disease, renal failure, liver dysfunction, uncontrolled diabetes mellitus, active peptic ulcer disease, and neurological or psychiatric diseases that affect pain perception. Patients with preexisting immune suppression, daily use of, or allergies to, glucocorticoids or opioid pain medication and patients deemed possibly noncompliant by their surgeon and clinical team with the study schedule were also excluded.

Randomization and procedure details

Using an electronic random number generator, an independent member of the study team randomized patients to either the treatment group or the control group. On the day of surgery, a member of the surgeon's team was informed of the patient's group assignment, and appropriate postoperative orders were placed.

The patients assigned to the treatment group received 10 mg of intravenous dexamethasone at the time of surgery followed by a 6-day tapered oral methylprednisolone course (Qualitest Pharmaceuticals). The oral methylprednisolone taper course began on the day of surgery and included 24 mg on day 1, 20 mg on day 2, 16 mg on day 3, 12 mg on day 4, 8 mg on day 5, and 4 mg on day 6. Adherence to this schedule was captured via patient reporting at their initial postoperative visit. The patients assigned to the control group only received 10 mg of intravenous dexamethasone at the time of surgery because this is the current practice at our institution.^{28,29}

Anesthesia and multimodal analgesia

Standard procedures for surgery, anesthesia, and analgesia were followed. A standardized peripheral nerve blockade, consisting of a mixture of 10-mL 1.3% liposomal bupivacaine (Exparel, Pacira Bio-Sciences, Inc) and 10-mL 0.5% bupivacaine was placed for all patients before the surgery. Just before the incision, all patients were given 10-mg dexamethasone intravenously. The patients underwent surgical fixation with a volar locking plate using a standard volar approach and the surgeon's preferred implant. After surgery, the patients were placed in a short arm orthosis and transitioned to a removable volar wrist orthosis at their 2-week postoperative visit. Following outpatient surgery, patients received a prescription for twenty-four 5-mg oxycodone tablets to be taken as necessary, 1 every 6 hours, ondansetron, and acetaminophen (Tylenol). The patients in the treatment group also received a prescription for the methylprednisolone taper course to start on the day of surgery.

Patient variables and outcomes

Patient demographic and comorbidity data were recorded, including age, sex, race, body mass index, surgical side, hand dominance, smoking status, days from injury, and medical history.

Following surgery, patients were followed up in the clinic at standard intervals (2, 6, and 12 weeks and 6 months) for clinical evaluation and to measure functional outcomes. The primary end point was postoperative pain and narcotic consumption for the first 7 days after surgery. The patient was asked to record their visual analog scale (VAS) pain scores, VAS nausea scores, and the number of opioid tablets consumed during the first 7 postoperative days (PODs) in a pain journal. The patients recorded pain and nausea 3 times per day (morning, afternoon, and evening) and the total number of opioid tablets consumed per day. These journals were collected during their 2-week postoperative visit.

The secondary end points included complications (eg, nonunion, malunion, infection, medication side effects) and patient-reported outcomes. Radiographs and clinical evaluation were used to evaluate the possibility of nonunion or malunion. As per our institution's standard, patient-reported outcomes were collected via in-office tablets or automated email surveys. Surveys included the Disabilities of the Arm, Shoulder, and Hand (*QuickDASH*), Patient Rated Wrist Evaluation, and Euro Quality of Life. Survey scores were calculated and recorded at each

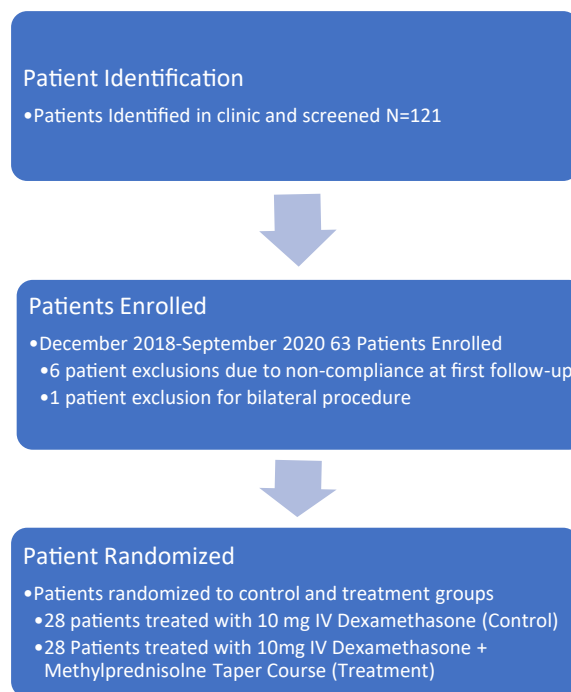


FIGURE 1: Consolidated Standards of Reporting Trials (CONSORT) diagram depicting screening and randomization.

postoperative visit. Cases with missing postoperative patient-reported outcomes, not including opioid consumption or pain, were excluded.

The study was initially powered using the pain VAS. The minimal clinically important difference of 1.2 was used according to prior literature.²³ It was determined that 26 patients were needed in each group for this study.

Statistical analysis was performed to evaluate the differences in reported averages between groups using a repeated-measures analysis of variance model to test the interaction effect and when no interaction effect was found, a simple effect. Pairwise *post hoc* analysis was performed using the Bonferroni correction, a Student *t* test for normally distributed data, and the Mann-Whitney U test. Categorical data, such as diabetic status, were analyzed using a χ^2 test. A *P* value of $<.05$ was considered statistically significant. The Bonferroni correction was incorporated in the *P* values set by the statistical software used, and the *P* value significance remained at $<.05$.

RESULTS

Fifty-six patients with follow-up primary outcome data were included in the analysis of early results. Twenty-eight patients were assigned to receive preoperative dexamethasone alone (control), and 28

TABLE 1. Demographic Characteristics and Comorbidities of Methylprednisolone Taper Use

Cohort Characteristics	Methylprednisolone Taper Use	
	Control	Methylprednisolone Taper Course
Total, n (%) [*]	28 (50)	28 (50)
Average age (SD), y	54.0 (4.25)	55.9 (4.25)
Sex [†]		
Male	3 (10.7) [#]	9 (32.1) [#]
Female	25 (89.3) [#]	19 (67.9) [#]
Complication [‡]		
Nonunion	0	0
Malunion	0	0
Infection	0	0
Wound complication	0	0
Comorbidity [§]		
Smoking	3 (10.7)	1 (3.6)
Body mass index	25.9	25.4
Fracture type		
2R3A	7 (25)	6 (21.4)
2R3B	6 (21.4)	9 (32.1)
2R3C	15 (53.6)	13 (46.5)
Average length of follow-up [¶]	173.4	193.7

^{*}Presented as percentage of total.
[†]Presented as percentage of males/females in each treatment group.
[‡]Presented as percentage of patients with complications in treatment groups.
[§]Presented as percentage of patients with comorbidities.
^{||}Presented as percentage of 2R3A/2R3B/2R3C fracture classifications in each treatment group.
[¶]Presented as days after surgery.
[#]Denotes that there was a predominance of men in the treatment group over the control group.

patients were assigned to receive a 6-day methylprednisolone taper course in addition to preoperative dexamethasone (treatment) (Fig. 1). At the baseline, 12 patients in the control group and 9 patients in the treatment group were prescribed narcotics from the emergency department before enrollment and surgical intervention. Demographic characteristics such as age, body mass index, the dominant side affected, smoking status, fracture type, or diabetes status were similar in both the groups (Table 1). There was a slight predominance of men in the treatment cohort.

There was a significant reduction in the VAS pain score for the treatment group compared with the control group starting as early as on POD2 (Table 2, Fig. 2). This significant reduction continued through

TABLE 2. Comparison of Average VAS Pain Score

POD	Study Group			P Value [*]
	Control	Treatment	Difference	
0	3.85	2.48	1.37	.10
1	6.1	4.48	1.62	.17
2	4.78	2.75	2.03	<.001
3	4.32	2.53	1.79	<.01
4	3.96	1.75	2.21	<.001
5	3.58	1.57	2.01	<.001
6	3.14	1.17	1.97	<.001
7	2.53	1.13	1.4	<.01

^{*}Bonferroni correction incorporated in the P value; threshold is P < .05 for significance.

POD7, with an average reduction of 1.8. The maximum reduction in pain of 2.2 was seen on POD4 (P < .05), and a minimum reduction of 1.4 was seen on POD7 (P < .05). It was also noted that 71.4% of patients in the treatment group reported being pain free by POD6 compared with 50% in the control group.

Accompanying the significant reduction in VAS pain scores between the groups was a significant reduction in opioid consumption (Table 3, Fig. 3). Over the 7-day postoperative period, the patients in the control group took twice the oral morphine equivalents as those treated with the 6-day methylprednisolone taper course (81.2 vs 41.2, respectively). This significant reduction in cumulative opioid consumption began on POD2 and continued through POD7.

The VAS nausea scores and patient-reported outcomes using the QuickDASH, Patient Rated Wrist Evaluation, and Euro Quality of Life were similar between the 2 groups at all postoperative time intervals, except for QuickDASH at the 2-week follow-up (Tables 4–6). The patients in the treatment group demonstrated a difference of 20 points versus the control group for QuickDASH. Neither the control group nor the treatment group demonstrated any adverse events, including infection, wound complications, nonunion, malunion, or blood clots (eg, deep venous thrombosis or pulmonary embolism). The number of prescription refills needed between the groups was similar (Table 7).

DISCUSSION

Preoperative and prolonged postoperative opioid usage has been correlated with increased rates of

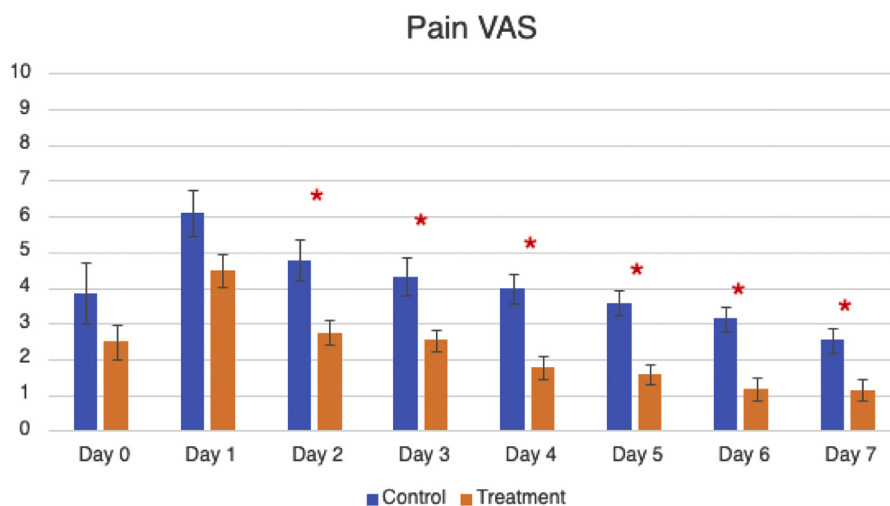


FIGURE 2: Graph demonstrating the average pain score by day. Red asterisk denotes statistical significance between cohorts at the time point.

TABLE 3. Comparison of Cumulative Opioid Consumption*

POD	Study Group		Difference	P Value [†]
	Control	Treatment		
0	9.6	7.1	2.5	.38
1	31.1	21.7	9.4	.14
2	47.32	28.0	19.3	.04
3	59.8	33.5	26.3	.03
4	68.3	36.5	31.8	.02
5	73.8	38.7	35.1	.02
6	77.5	40.4	37.1	.02
7	81.2	41.2	40.0	.02

*Presented as the cumulative oral morphine equivalents.

[†]Bonferroni correction incorporated in the P value; threshold is $P < .05$ for significance.

complications and poor clinical outcomes after lower and upper extremity procedures.^{8,9,12,30–36} This is particularly concerning for procedures involving fractures of the upper extremity, such as distal radius fractures, because these require, in general, a higher amount of postoperative opioids to adequately control pain.^{37–43} Recent efforts have identified effective multimodal pain regimens and institutional opioid prescribing protocols within hand and upper extremity surgery.^{37,39,41,42,44,45} Although studies have found promising results regarding early pain control using preoperative and intraoperative intravenous corticosteroids, there remains a paucity of studies examining these medications after surgery.^{24,25,46–57} In the upper extremity trauma setting, oral corticosteroids have

been demonstrated to be safe when treating terrible triad injuries.²³ Therefore, the purpose of this study was to examine the efficacy and safety associated with oral methylprednisolone tapered 6-day course when treating operative distal radius fractures.

Our study found that after distal radius fracture surgery, short-term oral low-dose corticosteroids were associated with excellent pain relief and reduced total opioid consumption compared with the control group. Within the first postoperative week, patients in the treatment group had reduced pain scores and total oral morphine equivalents than those in the control group. Possibly through modulating the inflammatory cascade, these results appear to indicate that a low-dose corticosteroid taper course is able to reduce early pain levels and resultant opioid usage after operatively treated distal radius fractures.

One of the major concerns for surgeons when considering using postoperative corticosteroids, particularly with hardware in place, involves the risk of postoperative complications. Both low- and high-dose intravenous corticosteroids have been studied extensively in the immediate preoperative and intraoperative setting, without any risk of postoperative complications.^{24–27,46,47,49,55} However, the safety of this regimen could not be studied in our cohorts because of the small sample sizes.

Preoperative and intraoperative intravenous glucocorticoids given in either high or low 1-time doses appear effective at reducing pain for the first 24–48 hours after surgery in many areas of hand surgery.^{25,47,49–52,54,56,57} However, less is known regarding a longer course of oral corticosteroids and their potential effect on postoperative pain. In a

Cumulative Opioid Consumption

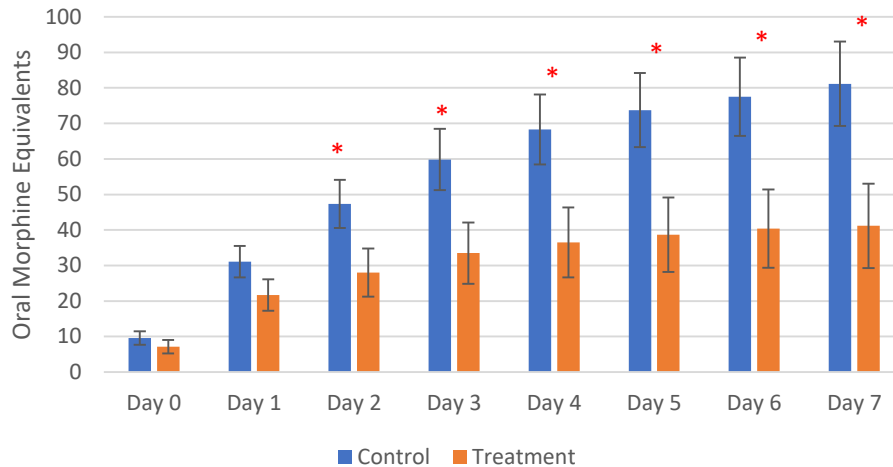


FIGURE 3: Graph demonstrating the cumulative opioid consumption by day. Red asterisk denotes statistical significance between the cohorts at the time point.

TABLE 4. Comparison of Average Nausea Score

POD	Study Group		Difference	P Value*
	Control	Treatment		
0	0.98	0.62	0.36	.50
1	0.83	0.66	0.18	.70
2	0.42	0.25	0.17	.63
3	0.42	0.11	0.31	.21
4	0.26	0.13	0.13	.53
5	0.21	0.04	0.18	.25
6	0.13	0.11	0.02	.87
7	0.12	0	0.12	.27

*Bonferroni correction incorporated in the P value; threshold is $P < .05$ for significance.

TABLE 5. Comparison of Average QuickDASH Score*

Postoperative Week	Group		Difference
	Control	Treatment	
2	72.5	51.8	20.7
4–6	46.4	38.9	7.5
12	26.7	20.3	6.4

*Week 2: control (14/28) treatment (19/28); week 6: control (20/28) treatment (20/28); week 12: control (18/28) treatment (18/28)

TABLE 6. Comparison of Average Euro Quality of Life Score*

Postoperative Week	Group		Difference
	Control	Treatment	
2	0.66	0.75	-0.09
4–6	0.79	0.82	-0.03
12	0.84	0.871	-0.03

*Week 2: control (21/28), treatment (13/28); week 6: control (20/28), treatment (17/28); week 12: control (16/28), treatment (14/28).

TABLE 7. Comparison of Refills

Group	Refills	
	No	Yes
Control	25 (89.3%)	3 (10.7%)
Treatment	26 (92.9%)	2 (7.1%)

postoperative elbow range of motion at 2 and 6 weeks after surgery.²³ Nevertheless, there was no difference in the pain scores at these time points, and there was no analysis of pain or total opioid usage within the first postoperative week. Our study found that, in the early postoperative period, there was a significant improvement in both pain and opioid usage.

There are many limitations to be considered when interpreting the results of this study. The primary limitation is the lack of blinding of subjects and surgeons. There is also a possibility of selection bias because patients who were thought likely to be

prospective study of patients undergoing operative treatment of terrible triad injuries, the groups that received the methylprednisolone taper had improved

noncompliant were not enrolled in the study. This affects the generalizability of the study because these patients pose a risk for poor outcomes in addition to opioid/substance abuse. Patients knew whether they received a tapered course or not and, therefore, could be biased in their reporting of pain outcomes. Additionally, as part of our postoperative multimodal protocol, we prescribed ondansetron to all our patients in both groups, which likely influenced the low rates of narcotics-related side effects. In addition, this small sample was not intended to be able to comment on safety and the benefit on outcomes and is only able to rationalize on postoperative pain control in the early setting of surgically treated distal radius fractures with a volar plate.

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