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Original Research

Shared Decision-Making Tool for Opioid Prescribing After Ambulatory Orthopedic Surgery in Veterans: A Randomized Controlled Clinical Trial

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Purpose: We examined whether an educational, shared-decision-making tool designed to empower patients, individualize pain management, and maximize use of nonopioid, over-the-counter analgesics reduces opioid use and waste while maintaining adequate pain relief.
Methods: We developed an educational, shared-decision-making tool regarding postoperative pain medication for outpatient hand surgery. Patients randomized to groups with and without the tool were surveyed for 4 weeks after surgery. Survey variables included Patient-Reported Outcomes Measurement Information System pain intensity and pain interference scores, as well as the number of oxycodone or over-the-counter pills taken. Results were compared using chi-squared, Wilcoxon rank-sum, and Welch's *t* tests.
Results: Fifty-three patients participated: 25 in the shared-tool group and 28 in the no-tool group. The mean age was 60 years, with more women in the no-tool group than the shared-tool group (n =17 versus 11, respectively). The shared-tool group averaged 6.4 prescribed oxycodone pills, versus 10 for the no-tool group ($P < .01$). The median numbers of oxycodone pills taken the first week after surgery were 2 (interquartile range, 6) for the shared-tool group and 3 (interquartile range, 6) for the no-tool group ($P = .97$). Patient-reported outcome measures for pain intensity and pain interference were not significantly different for weeks 1, 3, and 4 after surgery. Pain interference was significantly lower in week 2 in the shared-tool group (difference, −4.4; 95% confidence interval, −8.57 to −0.30; $P = .04$).
Conclusions: The shared-tool group had equivalent or better pain control and were prescribed a lower number of opioid pain pills than the no-tool group. Both groups used nonopioid medications, with no difference in the types of over-the-counter medications used. Shared decision-making strategies could be applied to other outpatient orthopedic surgical settings, and may reduce the amount of opioids prescribed without compromising pain control.
Type of study/level of evidence: Therapeutic II.

Postoperative pain management in the United States has been opioid-centric in recent decades. The increase in prescriptions of postoperative opioids has been accompanied by overprescription: opioids prescribed and filled are often not taken by patients and become available for nonmedical use.[1] Despite advances in the domains of regulation, provider education, and public awareness, opioid prescribing per capita in the United States remains higher than in any other country in the world.[2] Indeed, following surgery, 91% of US patients are prescribed opioids, compared to 5% of non-US patients.[3]

The quest for limiting opioids for pain management has also led to untoward consequences. For example, physicians are often concerned limiting opioids may have a negative impact on their

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online patient satisfaction ratings.[4] In addition, patients with valid reasons for an opioid prescription may be harmed by 1-size-fits-all guidelines.[5] For example, women are more likely to be lifetime opioids users, yet men routinely test positive for methadone more than twice as often as women.[6,7] On top of the well-known gender imbalance among veterans, they are more commonly diagnosed with opioid use disorders compared to nonveterans.[8,9] Hence, the veteran population deserves special consideration, including a patient-tailored approach to postoperative pain management.

Provider-patient shared decision-making enables physicians to respect patient autonomy, ensure beneficence, and avoid harm.[10] Empowering patients by giving them an active role in their care is a critical component of enhanced recovery after surgery pathways in orthopedic surgery.[11] Provider-patient shared decision-making has been used to successfully improve pain management, for example, after cesarean section surgery.[12] Its application to other surgical procedures aligns with the goal of enhancing the patient experience, improving recovery, and reducing unnecessary opioid prescriptions.

Outpatient upper-extremity surgery, in particular, has been associated with a significant amount of prescribed opioids that are not taken after discharge.[13] The objective of this study was to test the effect of a patient-centered, shared decision-making tool on the efficiency and quality of pain management in a sample of US veterans undergoing common hand surgeries. We hypothesized our provider-patient shared decision-making tool would reduce the amount of opioids prescribed and enhance use of nonopioid medications, while not significantly impacting patient-reported pain outcomes.

Materials and Methods

Trial design

With Colorado Multiple Institutional Review Board approval, we screened eligible patients at the Veterans Affairs orthopedic clinic at a single institution in a large, metropolitan area. Patients were individually randomized in a 1:1 ratio to parallel groups. We enrolled a total of 60 patients out of 200 who were screened. We followed Consolidated Standards of Reporting Trials guidelines.

Participants

The inclusion criteria were patients between 18 and 89 years of age who underwent either carpal tunnel release, trigger finger release, or ganglion cyst excision. The exclusion criteria included a history of opioid use disorder, recent surgery within 4 weeks of an indicated upper-extremity procedure, taking opioids prior to surgery, prisoners, pregnant women, allergy to any medication recommended after surgery, and an inability to communicate in English. After informed consent and Health Insurance Portability and Accountability Act authorization, each patient was randomized, using the envelope method, to either use the educational, shared decision-making tool (shared-tool group) or receive the survey only (no-tool group).[14,15] Block randomization and stratification were not used with the envelope method. Patients and the research team were blinded to the group assignment until the envelope was opened. Each envelope contained a group assignment, which was concealed in aluminum foil and placed in a standard envelope. An envelope was drawn from a storage box that had been previously mixed.

Intervention

Patients in the shared-tool group were presented with a short voice-over slide presentation on postoperative pain, opioids, and alternative modalities of treatment (Appendix, available on the *Journal*'s website at www.jhsgo.org). The presentation was given on either a laptop or tablet with sound on, as it was narrated to improve learning. After the presentation, each patient in the shared-tool group was asked how many opioid pills they wanted prescribed to them, up to the standard amount.

Outcomes

The primary endpoint was evaluating equivalency in included Patient-Reported Outcomes Measurement Information System (PROMIS) pain interference and PROMIS pain intensity scores each week. We evaluated the overall weekly change within each group from week 1 to week 4 to identify statistically significant differences. Secondary outcomes included differences in the numbers of opioid pills prescribed at week 0 and consumed each week.

All patients received weekly surveys asking about opioid use, over-the-counter medication use, and opioid storage for 4 weeks after surgery. We used both phone and Internet surveys to include all responders and reduce bias. Pain was measured using Computer Adaptive Test PROMIS pain interference and PROMIS pain intensity scores. We performed a chart review to collect additional covariates, including demographics, mental health history, local anesthesia use, postoperative complications, previous surgeries, and preoperative use of analgesics.

Sample size

We estimated an initial sample size of 30 patients based on a 2-sample t test using a large estimated effect size of 0.8, with the alpha set at 0.05 and the beta set at 0.80, with a 1:1 allocation for approximately 26 patients per group. This should allow us to detect a 5-point difference in PROMIS pain interference scores. We rounded up to 30 to account for losses to follow-up and nonresponders.

Statistical methods

Descriptive statistics were produced for demographics, clinical characteristics, and outcomes data for each group. Categorical data were analyzed with chi-squared or Fisher exact tests, when appropriate. Normality of continuous data was analyzed with histograms and the Shapiro-Wilk test. Normal data were analyzed using Welch's t test, and the Mann-Whitney U test was used for nonnormal data. The PROMIS pain interference and pain intensity data were analyzed using a Welch's t test. Longitudinal data were analyzed using a paired t test. We performed the statistical analysis with Stata software (version 14.2; StataCorp LLC). This trial was registered at clinicaltrials.gov as NCT04625231.

Results

Recruitment

Patients were enrolled from January 2018 to April 2022 (see the participant flow diagram in the Fig). A total of 60 patients were enrolled, with 53 completed surveys leading to 25 patients in the shared-tool group and 28 patients in the no-tool group. The average age was 59.9 years (standard deviation, 13.5 years) with approximately 80% men in each group. Mental health histories were proportionally similar between groups. Our case volume consisted mostly of carpal tunnel release, followed by trigger finger release and ganglion cyst excision. There were no documented postoperative complications, and

CONSORT
TRANSPARENT REPORTING of TRIALS

Patient Flow Diagram

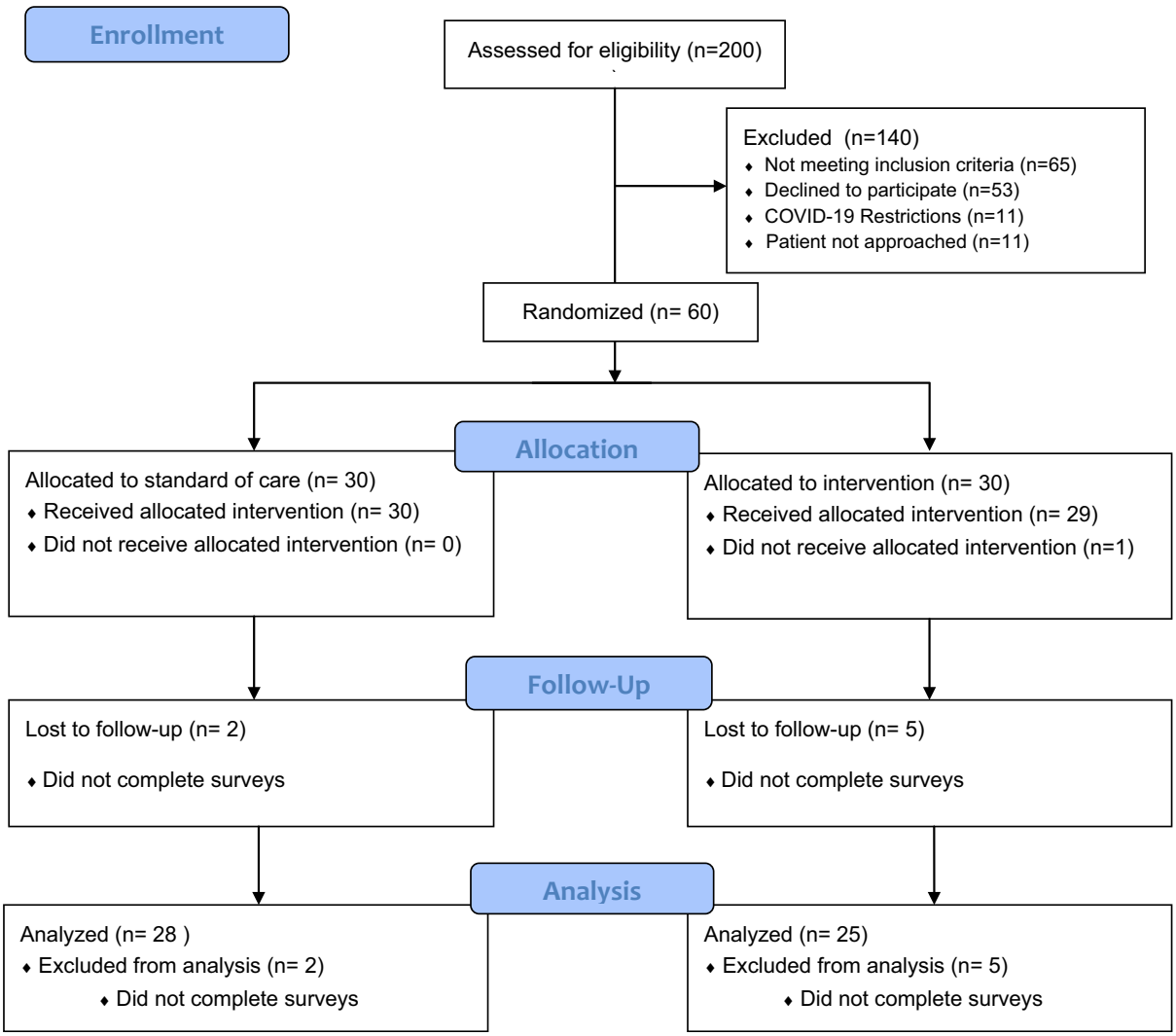

Figure. Patient flow diagram. CONSORT, Consolidated Standards of Reporting Trials; COVID-19, coronavirus disease 2019.

nearly all patients had a previous history of surgery. Preoperative analgesic use was similar between groups. The Table highlights the demographic characteristics of each group, with the lack of significant differences observed suggesting success in randomization. Patients were analyzed based on original group assignment.

Primary outcome

The week 1 PROMIS pain interference scores were 56.1 points in the shared-tool group and 58.3 points in the no-tool group. The difference of 2.1 points between groups was not significantly different (95% confidence interval [CI], −6.50 to 2.19; $P = .33$). For pain intensity, week 1 scores were 47.2 points for the shared-tool group and 48.4 points for the no-tool group. The difference of −1.2 points between groups was not significantly different (95% CI, −4.61 to 2.3; $P = .50$). Week 2 PROMIS pain interference scores were 51.2 for the shared-tool group and 55.6 for the no-tool group (difference, −4.4; 95% CI, −8.57 to −0.30; $P = .04$). Week 2 PROMIS pain intensity scores were 41.2 for the shared-tool group and 43.3 for the no-tool group. The difference of −2.2 points between groups was not significantly different (95% CI, −5.7 to 1.3; $P = .21$). Week 3 PROMIS pain interference scores were 48.2 points in the shared-

Table
Demographics and Clinical Characteristics

Characteristic	Shared Tool, n = 25	No Tool, n = 28	Total, N = 53	*P* Value
Age	61.9 (12.5)	58.2 (14.3)	59.9 (13.5)	.315
Sex, M/F	21/4	17/11	38/15	.060
Race, White/non-White	20/5	23/5	43/10	.842
Mental health history, yes/no	15/10	17/11	32/21	.958
Surgery type				
Carpal tunnel	19	16	35	.723
Trigger finger	6	11	17	
Ganglion cyst	0	1	1	
Local anesthesia, yes/no	24/1	27/1	51/2	.935
Postoperative complications	0	0	0	
Previous surgery, yes/no	24/1	28/0	52/1	.472
Preoperative analgesics, yes/no	10/15	11/17	21/32	.958
Type of analgesics used				
NSAIDs*	5	5		.653
Gabapentin	3	4		
Other	2	2		
Substance use	32.0%	21.4%	26.4%	.384
Opioid pills prescribed	6 (6)	10 (0)	10 (4)	.0001†
Week 1 opioid pills taken‡	2 (5)	3 (5)	3 (5)	.971
Week 2 opioid pills taken‡	0 (0)	0 (0)	0 (0)	.341
Week 3 opioid pills taken‡	0 (0)	0 (0)	0 (0)	.866
Week 4 opioid pills taken‡	0 (0)	0 (0)	0 (0)	.178

* NSAID, nonsteroidal anti-inflammatory drug.
† $P < .05$.
‡ Median (interquartile range), using the Wilcoxon rank-sum test.

tool group and 51.3 points in the no-tool group. The observed difference was −3.16 points lower in the shared-tool group, but was not significantly different (95% CI, −7.6 to 2.7; $P = .34$). Week 3 PROMIS pain intensity scores were 38.9 and 41.3 points for the shared-tool and no-tool groups, respectively. The shared-tool group's pain intensity score was −2.4 points lower but was not statistically significant (95% CI, −6.3 to 1.5; $P = .22$). Week 4 PROMIS pain interference scores were 47.5 and 51.3 points for the shared-tool and no-tool groups, respectively. The −3.8 point difference, while favorable for the shared-tool group, did not reach significance (95% CI, −9.1 to 1.4; $P = .14$). Lastly, PROMIS pain intensity scores were 37.8 points for the shared-tool group and 41.9 for the no-tool group. The observed difference of 4.1 points was not significant (95% CI, −8.6 to 0.41, $P = .07$).

Secondary outcomes

Patients in the shared-tool group chose their own amount of opioid pills, up to the standard amount. The shared-tool group was prescribed an average of 6.4 pills (95% CI, 4.8–7.9), compared to 10 pills in the no-tool group. When examining self-reported pill consumption in week 1, the shared-tool group consumed a median of 2 pills (interquartile range [IQR], 5 pills) and the no-tool group consumed a median of 3 (IQR, 5 pills). In weeks 2, 3, and 4, the median numbers of pills consumed and the IQRs were 0 in both groups, suggesting 75% of patients did not consume opioid pain pills.

We examined the self-reported leftover number of opioid pain pills by group. At week 1, the shared-tool group had a median of 3 leftover pills (IQR, 5 pills) and the no-tool group had a median of 7 (IQR, 5.5 pills), which proved to be statistically significant ($P < .01$). By week 4, the median numbers of leftover pills were 2 (IQR, 4 pills) and 5 (IQR, 10 pills) for the shared-tool group and no-tool groups, respectively.

Ancillary analyses

We conducted an exploratory analysis to compare the mean changes in PROMIS pain interference and pain intensity scores within each group from week 1 to week 4. The shared-tool group saw an 8.6-point (95% CI, 4.6–12.7 points) decrease in PROMIS pain interference scores, whereas the no-tool group saw a 6.7-point (95% CI, 2.8–10.7 points) decrease. The mean difference was 1.9 points between the 2 groups (95% CI, −3.6 to 7.4). The PROMIS pain intensity scores in the shared-tool group had a 9.8-point (95% CI, 6.5–13.2 points) decrease, whereas the no-tool group saw a 6.4-point (95% CI, 3.0–19.8 points) decrease, for a mean difference of 3.4 (95% CI, −1.3 to 8.1).

Participants voluntarily disclosed the storage location of opioid pain pills. The medicine cabinet or other similar storage was reported by 21 patients (38.2%) and the cupboard or wardrobe was used by 8 (14.6%), while the opioid pain pills were disposed of by 8 patients (14.6%). The primary disposal methods reported were: 3 reporting disposal in the sink or toilet, 2 reporting pills were returned to Veterans Affairs, 2 reporting pills were returned to a community take-back program and 1 undisclosed disposal method. Of 34 responders, only 5 (9.4%) reported their storage medication was locked.

Lastly, within the shared-tool group, we examined patient satisfaction with the shared decision-making tool. Overall, 23 (92%) shared-tool participants expressed that they were very satisfied or somewhat satisfied with the shared decision-making tool. Only 2 (8%) expressed that they were somewhat dissatisfied or did not answer.

Discussion

We conducted a randomized controlled trial to determine the impact of a shared decision-making tool on the number of opioid pain pills prescribed and on pain management. We identified no significant differences in pain scores in weeks 1, 3, and 4 between groups, despite fewer opioid pain pills being prescribed in the shared-tool group. Pain interference scores were significantly lower in the shared-tool group for week 2.

There are some limitations with this study. We enrolled patients who underwent a single procedure for 3 different soft-tissue surgeries; thus, there may be some heterogeneity in reported pain scores. The distributions of surgery types are similar between the shared-tool and no-tool groups, with carpal tunnel release comprising 66.0% of all surgeries. Kazmers et al[16] reported 3.4 points as the minimal clinically important difference (MCID) for PROMIS pain interference scores. Later, Bernstein et al[17] used an anchor-based approach to find a clinically relevant 8.9-point difference for those undergoing carpal tunnel release. The largest difference between the shared-tool and no-tool groups was the 4.3 points reported on week 2, with the lower score (less pain) seen in the shared-tool group.

A second limitation is the sample size. We intended to enroll 60 participants, but ended with 53 participants. Some patients were dropped from the analysis due to incomplete surveys or nonresponse (Fig), leading to a small difference in group sizes. We were 1 patient below the threshold of 26 patients per group in the shared-tool group; however, we believe the estimates are still valid, as they are reflective of previously published data and met our a priori power estimate. Block randomization could have potentially solved this issue by creating small blocks of patients throughout the trial, so that every second, fourth, or sixth patient enrolled would ensure 50% of patients received each treatment. Our post hoc power analysis illustrated we achieved approximately 81.3% power to detect a 5-point difference in PROMIS pain interference scores. Our mean difference was 2.1 points (95% CI, −6.50 to 2.19), and our CI excludes anchor-based MCIDs of 8.9–9.7 points.[17] We can conclude that the observed pain score difference is significantly less than a clinically relevant difference, even when evaluating a larger range (CI). Kazmers et al[16] and Bernstein et al[17] reported mean PROMIS pain interference scores of 58.0 and 49.8 after surgery, respectively. One would expect higher scores immediately after surgery, with decreases occurring week to week until a plateau is reached.

Thirdly, the hand surgeon (R.B.) could not be blinded to the study protocol due to their involvement with enrollment and administering the shared decision-making tool. Since we were interested in the interaction between surgeon and patient and there were no other full-time hand surgeons, a lack of blinding seemed appropriate. Fourth, our ancillary analysis of opioid storage and disposal is limited due to the voluntary nature of disclosing the information. Lastly, we used both Internet survey methods and telephone calls to accommodate the older population. Telephone results may be skewed to acquiescence bias, although this may have addressed potential nonresponse and sampling biases.

Overall, patients who were randomized to the shared-tool group experienced similar pain to those in the no-tool group. One interpretation is that patients in the shared-tool group were better able to manage their postoperative pain by using the education provided on over-the-counter medications and nonmedication pain management methods. Both MCID values and statistical testing illustrated equivalence between groups. The MCID value has limitations, as it was solely derived from carpal tunnel release patients and calculated from the within-group change. In addition, MCID research is still new and was based on 1 average MCID change in the postoperative period, which ranges from 5 to 90 days.

We were interested in the number of opioid pain pills prescribed to patients after the shared decision-making tool presentation. Patients asked for 4 fewer pills than the standard amount (10 pills). This is in line with a publication from Stepan et al[18] that used an educational presentation before upper-extremity surgery and found 3 fewer opioid pills were consumed in the education group, along with statistically and clinically equivalent pain scores. Taken in context with equivalent pain scores in both pain interference and pain intensity PROMIS scales, this suggests success in reducing the number of leftover opioid pills, which may mitigate their potential for diversion or misuse.[18] Rodgers et al[13] found that patients who underwent soft-tissue procedures consumed an average of 9 opioid pain pills, with an average of 19 tablets left unused. Later, Alter and Ilyas[19] used formal opioid counseling, and found the counseling group had equivalent pain control as the no-counseling group and consumed 2.8 fewer pills. On average, Chapman et al[20] found the average number of pills consumed after carpal tunnel release was 4.2. Our average opioid consumption falls in line with these estimates, as the average number of pills consumed in the shared-tool group at week 1 was 3.1, versus 3.7 pills in the no-tool group. As noted by previous publications, most pills are consumed by patients during the first week after surgery, and 75% of our study did not consume opioid pain pills patients in weeks 2–4.[13,19]

Lastly, the storage data reported by patients suggest most opioid pain pills are not secured or locked. With common areas such as bathroom medicine cabinets or kitchen cupboards the most frequently reported locations, these pills are at high risk of diversion and abuse.[21] The no-tool group had a median of 5 pills left over, versus 2 pills for the shared-tool group. This difference, when extrapolated to the frequency of carpal tunnel release surgeries, indicates the potential for leftover pills to become problematic at the community level.[22] Of note, it is commendable that approximately 7 (12.7%) patients disposed of their opioids.

The results of this study suggest patients with soft-tissue upper-extremity procedures who used a shared decision-making tool still achieved adequate pain control while receiving fewer prescribed opioids. A shared decision-making process allows the clinician to support patient autonomy in personalized pain management. The benefits of fewer opioids for diversion and abuse outweigh the potential risks of inadequate pain control, as reported by other studies. Use of the shared decision-making tool over different outpatient orthopedic procedures demonstrates its potential for successful application across varied clinical contexts.

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