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The Effect of State-Level Prescription Opioid Legislation on Patient Outcomes After Lumbar Tubular Microdecompression

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ABSTRACT

Background: In the United States, a statewide legislation titled the Strengthen Opioid Misuse Prevention (STOP) Act was enacted in 2017 to limit prescription opioid use and reduce dependence. The impact of state legislation curbing opioid prescription on outcomes after spine surgery is unknown.

Study Design: Case series.

Methods: Data from consecutive patients undergoing lumbar tubular microdecompression for symptomatic lumbar spine stenosis from June 2016 to June 2019 were retrospectively analyzed. Cases between June 2016 and December 2017 represent the group before the STOP act (pre-STOP), while cases between January 2018 and June 2019 represent the group after legislation enactment (post-STOP). Preoperative and postoperative patient functional scores including the EuroQol-Five Dimensions Index, Oswestry Disability Index (ODI), and the visual analog scale (VAS) for back and leg pain were compared between both groups. The meaningful clinically important difference (MCID) was calculated for each score and was compared between both groups as well.

Results: A total of 147 patients met inclusion criteria, with 86 in the pre-STOP group and 61 in the post-STOP group. Analysis of postoperative scores demonstrated statistically lower VAS leg pain score averages in the post-STOP group ($P < 0.05$). Higher trends in achieving MCID among the post-STOP group were observed; however, the differences between both groups were not statistically significant ($P > 0.05$ for all). Additionally, there were no statistical differences in rates of unplanned pain-related clinic visits and emergency department (ED) visits, as well as no differences in the number of pain-related calls within 90 days after surgery between both groups.

Conclusion: The enactment of state legislation to curb the prescribing of opioids for postoperative pain did not negatively affect the rate of achieving clinically meaningful outcomes among patients undergoing lumbar tubular microdecompression for spinal stenosis. Additionally, decreasing the amount of opioids prescribed for postoperative pain does not increase the number of unplanned clinic or ED visits due to pain within 90 days after surgery.

Level of Evidence: 4.

Minimally Invasive Surgery

Keywords: opioid crisis, microdiscectomy, MCID, patient-reported outcomes

INTRODUCTION

While opioids are often essential in treating postoperative pain, the recent epidemic has prompted states and institutions to reconsider policies regarding the use of prescription opioid medications for postoperative pain management among the medical community. As the third largest prescribers of opioids, orthopedic surgeons are no exception, prescribing an estimated 7.7% of all opioids in the United States.[1] Spine conditions are highly associated with opioid addiction nationally,[2] highlighting the importance of identifying methods for reducing prescription opioid use for pain management after spine surgery.

In 2017, the state of North Carolina enacted the Strengthen Opioid Misuse Prevention Act (STOP act) to aid physicians in their efforts to curb the opioid pandemic.[3] Regulatory measures like the STOP act function by (1) requiring prescribers and pharmacies to review their patient's 12-month history before prescribing an initial schedule II or III opioid, (2) requiring a 5-day limit on initial prescriptions for acute pain and a 7-day limit on postoperative orders, and (3) improving access to naloxone.[4]

Previous studies have investigated the effects of the various approaches to state regulation of opioid prescribing, concluding that mandatory opioid prescription regulations can bring about a clinically significant decline in opioids dispensed.[5] Additional research has focused on policy changes in orthopedic departments specifically. Aran et al demonstrated a clinically significant decline in opioid prescriptions within their orthopedic department under the STOP Act, while a study led by Hussaini et al concluded that such a reduction can be done without increased strain on health care resources.[6,7] There remains, however, very limited evidence on the effect of prescription opioid control reform on patient functional outcomes and pain after spine surgery. As such, the purpose of this study was to evaluate whether functional scores at 1-year follow-up in patients who underwent lumbar tubular microdecompression (LTMD) differ before and after the state legislation was enacted. We hypothesize that patients undergoing LTMD after the STOP Act was enacted will have lower functional score averages and higher pain scores when compared with patients who had surgery prior to the legislation.

METHODS

After receiving institutional review board approval, data from a prospectively maintained institutional registry of consecutive patients who underwent LTMD by a single orthopedic surgeon between 2016 and 2019 were retrospectively analyzed. Surgeries performed between June 2016 and December 2017 represent the pre-STOP Act group, while surgeries performed between January 2018 and June 2019 represent the post-STOP Act group. Inclusion criteria were patients over 18 years of age with symptomatic foraminal lumbar stenosis who underwent elective LTMD. Patient selection for surgery was based on the preoperative evaluation by the senior author and the persistence of neurologic deficits after at least 90 days of conservative nonoperative treatment (activity modification, nonsteroidal anti-inflammatory drugs, physical therapy, and/or exercises). Exclusion criteria included any patient without record of receiving a prescription for opioid medication after surgery, as well as any patient undergoing revision surgery within the study window period. Electronic medical records were reviewed to collect patient characteristics (age, sex, body mass index [BMI], current tobacco smoker status, etc). Additional data regarding health care burden were obtained by reviewing all patient phone calls, messages, and encounter notes recorded within 90 days of the operation. The North Carolina Controlled Substances Reporting System was queried to assess postoperative opioid prescription filling.[4] This statewide database is organized by the North Carolina Drug Control Unit and falls under management of the Mental Health, Developmental Disabilities, and Substance Use Division of the North Carolina Department of Health and Human Services. The Stop act of 2017 requires statewide providers to report narcotic prescriptions to this central database in order to minimize opioid overprescribing from multiple practitioners. The present academic institution's electronic medical record automatically sends prescription data to this organization. Prescriptions from out of network providers are also visible from this database. As a result, all opioid prescriptions prior to and after operation can be gathered in morphine milliequivalents (MMEs). The MMEs of prescribed opioid medications can be found in appendix I.

Surgical Technique

All LTMD procedures were performed by a single fellowship-trained orthopedic spine surgeon at a high-volume academic hospital using a similar technique that has been well described in the literature.[8–10] LTMD procedures included unilateral hemilaminectomy, unilateral laminotomy with bilateral decompression, and far lateral (transpedicular) decompression of the neuroforamen. All cases utilized the METRx tubular retractor system (Medtronic Sofamor Danek, Memphis, TN).

Postoperative Care

Prior to enactment of the STOP Act, all patients undergoing LTMD were routinely prescribed 60 to 90 hydrocodone-acetaminophen (Norco) tablets 5 to 325 mg, while patients after the act was implemented were routinely prescribed 30 to 60 tablets. In both cases, patients were instructed to take 1 to 2 tablets orally every 6 hours as needed for pain. The postoperative pain management protocol was the same for both opioid-naïve and patients with a history of opioid prescription use. No refills were provided on the initial prescription, and additional opioid prescriptions were made on a case-by-case basis if requested by the patient during postoperative follow-up. Patients are counseled on the risk for opioid dependence by the senior surgeon and/or their physician extenders. Oxycodone is only prescribed in those with hydrocodone allergy. Since there was no established standard of care for providing narcotic prescriptions in LTMD procedures, the protocol utilized by the senior surgeon was based on their clinical experience and was intended to monitor opioid consumption and provide the lowest amount of narcotic needed for analgesic benefit. Every patient in the study was confirmed by electronic medical record review to have been prescribed the routine postoperative opioid medication during the retrospective data analysis.

Functional Outcome Measures

Patient-reported functional measures were collected preoperatively and at 12-month intervals after surgery as standard of care for all patients undergoing tubular microdiscectomy. The questionnaires assigned to evaluate function included the Oswestry Disability Index (ODI),[11] low back pain visual analog scale (VAS), and EuroQol-Five Dimensions Index (EQ-5D).[12] Patient satisfaction, noted as a binomial variable, was also collected at 12-month follow-up. Because ODI is a composite score based on responses to separate questions, the following correction factor was applied in cases in which ≥1 ODI questions were left unanswered:

$$\text{Corrected ODI} = \text{ODI} \times \left(\frac{10}{10-\text{number of missing responses}}\right)$$

No such corrections were applied to the raw score recorded for VAS pain or satisfaction. EQ-5D indices were calculated using a validated valuation model for US patient populations.[13]

To quantify the clinical significance of outcome achievement to ODI and VAS pain, we applied the principles of meaningful clinically important difference (MCID) as defined for functional patient-reported outcome measures (PROMs). Prior work has proposed that MCID be considered a minimum target for outcome improvement, while patient acceptable symptomatic state (PASS) can be considered to represent a satisfactory outcome that is acceptable to the patient.[14,15] MCID can be calculated using an anchor-based or a distribution-based method, each with its own set of limitations. For the current study, ODI and VAS outcome threshold scores for achieving MCID were determined using a distribution-based method by calculating the one-half SD of the change in outcome score average over the 1-year time period, as described in the literature.[15] Patients were considered to have achieved MCID if they achieved this outcome endpoint on any of the administered questionnaires.[15–17]

Statistical Analysis

Prior to analysis, all continuous data were assessed for normal distribution, with any outliers removed from the analysis. All statistical analysis was performed using *R* (R Core Team, Vienna, Austria). A Student *t* test was used for continuous variables, while χ^2 or Fisher's exact test was used for categorical parameters. In order to control for possible confounders, a linear or logistic regression was used to control for any preoperative variable that was statistically different between both groups. All continuous data were reported as mean ± SD, and significance was set at $P < 0.05$. Distribution of the data was evaluated.

RESULTS

Patient Demographics

A total of 147 patients met inclusion criteria with 86 in the pre-STOP Actgroup and 61 in the post-STOP Act group. The cumulative mean age and BMI of the study were 65.3 years and 30.3 kg/m^2, respectively. Comparison of demographics between the 2 groups did not show any statistically significant differences including age, sex, BMI, tobacco use, diabetes, or history of opioid use ($P > 0.05$ for all) (Table 1). Additionally, there was no statistical difference between the number of patients who were not opioid-naïve at baseline, or the average MME average between the pre- and post-STOP groups (70.6 ± 145.1 MME vs 56.8 ± 178.9 MME; $P = 0.309$). All patients were followed up for at least 1 year after surgery. The percentages of each surgical approach did not differ significantly between groups ($P > 0.05$ for all). Intraoperative complications including dural tears, epidural cysts, and length of stay average were compared between both groups. All comparisons were not

Table 1. Comparison of patient demographics.

Demographic	Pre-STOP (*n* = 86)	Post-STOP (*n* = 61)	*P*
Age, y, mean ± SD	63.9 ± 14.8	67.1 ± 12.4	0.078
Sex, male, *n* (%)	43 (50)	29 (47.5)	0.769
Body mass index, mean ± SD	31.0 ± 6.3	29.4 ± 5.3	0.056
Diabetes, *n* (%)	21 (24.4)	16 (26.2)	0.803
Tobacco use, *n* (%)	12 (13.9)	7 (11.5)	0.659
History of preoperative prescription opioid use, *n* (%)	53 (61.6)	28 (45.9)	0.059
Number of unilateral laminectomies for bilateral decompression, *n* (%)	45 (52.3)	33 (54.1)	0.832
Number of far lateral tubular decompressions, *n* (%)	19 (22.1)	12 (19.7)	0.723
Number of unilateral hemilaminectomies, *n* (%)	24 (27.9)	22 (36.1)	0.293

Abbreviation: STOP, Strengthen Opioid Misuse Prevention Act.

Table 2. Assessment of preoperative and postoperative functional outcomes.

Outcome Measure	Pre-STOP	Post-STOP	P
Preoperative			
VAS back pain	6.8 ± 2.9	5.3 ± 2.9	0.001
VAS leg pain	7.6 ± 2.2	7.2 ± 2.8	0.209
EQ-5D	0.29 ± 0.28	0.28 ± 0.27	0.368
ODI	55.6 ± 14.5	59.1 ± 16.3	0.94
Postoperative			
VAS back pain	3.3 ± 3.0	2.6 ± 3.0	0.082
VAS leg pain	2.4 ± 2.9	1.2 ± 2.4	0.003
EQ5-SD	0.71 ± 0.30	0.75 ± 0.31	0.368
ODI	28.4 ± 21.6	21.9 ± 19.7	0.094
Satisfied patients, *n* (%)	66 (77.6)	53 (86.9)	0.156

Abbreviations: ODI, Oswestry Disability Index; STOP, Strengthen Opioid Misuse Prevention Act; VAS, visual analog scale.
Note: Data presented as mean ± SD unless otherwise indicated.

statistically significant ($P > 0.05$). Additionally, there were no postoperative complications in either group.

Functional Outcomes

With respect to preoperative functional scores, VAS back pain was greater in the pregroup (pre 6.8 ± 2.9 vs post 5.3 ± 2.9; $P = 0.001$). All other baseline score averages were similar between the 2 groups. At 1-year follow-up, back pain and leg pain scores were significantly lower (better) in the postgroup ($P < 0.05$) (Table 2). ODI, EQ-5D, and patient satisfaction were similar between the 2 groups.

The VAS back pain, VAS leg pain, EQ-5D, and ODI threshold scores for achieving MCID were 1.8, 1.7, 0.2, and 11.7, respectively. When comparing the rate of achieving MCID between the 2 groups, there were higher trends in rates of reaching the VAS leg pain, EQ-5D, and ODI scores for achieving MCID; however, the differences between the groups were not statistically significant (Table 3). Similar trends were observed when comparing patients who reached at least 1 threshold for achieving MCID ($P > 0.05$).

Comparison of Prolonged Pain Management and Pain-Related Follow-Up

As expected, there was a significant decrease in average narcotic pain pills prescribed after enactment of the STOP Act (442.9 ± 259.7 pre vs 262.4 ± 122.6 post, $P < 0.001$). While there was a trend of more frequent pain-related emergency department (ED) visits in the postgroup (1.2% pre vs 6.6% post), a decrease in unplanned pain-related clinic visits (4.7% pre vs 1.6% post), and a decrease in pain-related calls (37.2% pre vs 36.1% post) within 90 days after surgery, none of these differences were statistically significant ($P > 0.05$ for all) (Table 4).

Table 3. MCID threshold scores and achievement rates.

		Achievement, *n* (%)		
Outcome Measure	Threshold Score	Pre-STOP	Post-STOP	P
VAS back pain	1.8	56 (72.7)	36 (60)	0.116
VAS leg pain	1.7	67 (82.7)	51 (85)	0.717
EuroQol-Five Dimensions Index	0.2	56 (72.7)	44 (77.2)	0.557
Oswestry Disability Index	11.7	63 (77.8)	52 (86.7)	0.178
Achieved ≥1 MCID threshold		81 (95.3)	61(98.4)	0.315

Abbreviations: MCID, meaningful clinically important difference; STOP, Strengthen Opioid Misuse Prevention Act; VAS, visual analog scale.

Regression Analysis

A linear regression was performed using VAS leg pain as the dependent variable and preoperative VAS back pain and the STOP Act binary variable to determine whether preoperative VAS back pain confounded the association observed between postoperative leg pain scores and prescription opioid consumption. The regression analysis indicated that there is a linear association between postoperative VAS pain scores and undergoing surgery after the STOP Act ($P = 0.004$), even after controlling for preoperative VAS back pain (Table 5).

DISCUSSION

The main findings of the study were that patients undergoing LTMD after enactment of a state-level legislation limiting prescription opioid consumption had lower pain score averages at 1-year follow-up when compared with patients who underwent the procedure before the legislation passed. However, there were no statistical differences in functional score averages, rates of achieving clinically meaningful outcomes at 1-year follow-up, or rates of unplanned pain-related clinic visits and pain-related calls.

Previous studies in the orthopedic literature have evaluated the effect of opioids on patient-reported outcomes. Williams et al demonstrated that patients taking opioids prior to arthroscopic rotator cuff repair had greater opioid requirements postoperatively and failed to reach the same level of functionality when compared with patients who had not taken opioids preoperatively. They did, however, find no statistically significant difference in outcomes between groups.[18] Regarding postoperative opioid usage, Beck et al determined patients undergoing hip arthroscopy for femoroacetabular impingement who require 1 or more refills postoperatively were more likely to have lower postoperative functional score averages when compared with those who did not require a refill.[19] Furthermore, while they indicated that patients with prolonged pain management achieved lower rates of the PASS, there were no differences in achieving

Table 4. Postoperative opioid use and pain-related visits.

Outcome Measure	Pre-STOP	Post-STOP	*P*
Postoperative opioids prescribed, MME, mean ± SD	442.9 ± 259.7	262.4 ± 122.6	<0.001
Pain-related calls to clinic, *n* (%)	32 (37.2)	22 (36.1)	0.887
Pain-related emergency department visits, *n* (%)	1 (1.2)	4 (6.6)	0.075
Pain-related outside scheduled postoperative visits, *n* (%)	4 (4.7)	1 (1.6)	0.321
Refills requested, MME, mean ± SD	31.7 ± 24.5	46.4 ± 38.3	0.321

Abbreviations: MME, morphine milligram equivalent; STOP, Strengthen Opioid Misuse Prevention Act.

MCID when compared with their counterparts that did not need additional opioid pain control. Prior literature has indicated that MCID is considered the lowest threshold for outcomes that patients consider clinically meaningful, while PASS is considered a postoperative state that is anchored to patient satisfaction.[17,20] These results are similar to what was observed in the current study. While the current study did not identify the PASS rates of each group, it did indicate a trend in lower pain and higher satisfaction scores among patients who received lower quantities of opioid prescription medication. The trends observed may be due to lower pain thresholds, and therefore less patient satisfaction, when taking higher quantities of opioid medication for postoperative pain control.[21–23] Equally as important, the reduction of prescribing opioid medication did not result in higher postoperative pain and lower satisfaction averages.

Postoperative unplanned clinic visits and pain-related call to providers are a robust representation of the socioeconomic stress placed on health care. Phone calls and patient messages alone can increase the burden on clinical staff significantly.[24] Studies have indicated that decrease in prescribing opioid pain medications after surgery does not increase this burden. Hussaini et al compared outcomes among patients with ankle fractures who underwent treatment before and after the STOP Act enactment and found no significant difference in the percentage of patients who made pain-related phone calls, ED visits, or unplanned clinic visits.[7] Similar findings were observed in the current study, which refutes the notion that increased pain-related concerns could potentially add strain to the health care system. Future studies involving larger cohorts should investigate whether these trends are consistent for enactment of state and institutional policies curbing opioid prescriptions.

Table 5. Linear regression analysis results.

Measure	Coefficient	Standard Error	*P*
Preoperative visual analog scale back pain	0.162	0.079	0.062
Surgery after Strengthen Opioid Misuse Prevention Act	−0.185	0.477	0.033
Intercept	1.435	1.19	0.022

The literature suggests that curtailing opioid prescriptions may improve postoperative patient outcomes. Hills et al found that a shorter duration of postoperative opioids may result in improved patient outcomes and, as expected, faster opioid cessation.[25] Furthermore, they concluded that lower initial postoperative opioid doses were the strongest predictor of eventual opioid cessation. This indicates that reducing initial and total opioid prescriptions can improve cessation rates and patient-reported outcomes simultaneously. Lower opioid doses have also been tied to a reduction in postoperative complications. Using a large national registry, Cozowicz et al[26] evaluated the association between opioid prescription levels and postoperative outcomes after joint replacement and spinal fusions. The authors identified that patients consuming higher doses were more likely to have postoperative complications, including thromboembolic, infectious, and gastrointestinal events; higher hospital cost; and longer length of stay.[26] Previous studies have also demonstrated that patients are often overprescribed opioid medications, and on average, patients only used half of the narcotics that they were prescribed.[27,28] Additionally, the majority of patients in these studies were satisfied with their pain control and were willing to surrender the remaining pills. These findings, as well as those of the current study, suggest that older algorithms used to prescribe opioid medication for postoperative pain were likely overcompensating the amount needed by most patients for analgesic effects. Furthermore, it is possible that the pendulum may be able to swing farther to find a better balance between adequate postoperative pain control and furthering the limited use of opioid medications.

Limitations

This study has limitations. First, although a relatively large group of patients was included in the study, it is possible that some of the analysis, particularly comparison of pain-related ED visits, phone calls, and clinic visits, may have been underpowered. Additionally, patients who made pain-related calls, early clinic visits, or ED visits outside of our system were not captured in the review. Second, it is possible that some variables, including prescription of postoperative opioid medications, were not documented or were documented incompletely or incorrectly, leading to their exclusion from the dataset. Third, quantities of opioid medication before and after the STOP Act were calculated based on records obtained. Data on quantity of medication consumed per prescription filled were not available. Fourth, the senior author did not capture functional outcomes using standardized scoring systems at earlier timepoints prior to 1 year and we were therefore unable to evaluate whether the legislation influenced pain and functional outcomes at earlier timepoints. Last, the senior surgeon had approximately 3 more years of experience between the groups, during which patient selection might have changed or surgical technical skills may have improved.

CONCLUSIONS

The enactment of state legislation to curb the prescribing of opioids for postoperative pain did not negatively affect the rate of achieving clinically meaningful outcomes among patients undergoing LTMD for spinal stenosis. Additionally, decreasing the amount of opioids prescribed for postoperative pain did not increase the number of unplanned clinic or ED visits due to pain within 90 days after surgery.

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