

# Effect of the Strengthening Opioid Misuse Prevention (STOP) Act on Opioid Prescription Practices After Ankle Fracture Fixation

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## Abstract

**Background:** In North Carolina, the Strengthen Opioid Misuse Prevention Act of 2017 (STOP Act) went into effect on January 1, 2018, intending to increase oversight over opioid prescriptions. This study compares postoperative narcotic prescription practices following operative fixation of ankle fractures before and after the STOP Act.

**Methods:** This study was a retrospective review of patients 18 years and older who underwent operative fixation of ankle fractures between January 1 and June 30, 2017 (before STOP Act), and between January 1 and June 30, 2018 (after STOP Act). Variables of interest included demographics, amount of opioids prescribed postoperatively, number of prescription refills, and number of pain-related calls or visits to the emergency department (ED) or clinic after surgery. This study assessed 71 patients in the Pre group and 47 patients in the Post group.

**Results:** There was a statistically significant decrease in the average number of postoperative narcotic pills prescribed after the STOP Act (52.7 vs 76.2,  $P < .001$ ). There was also a statistically significant decrease in the average number of prescription refills (0.6 vs 1.0,  $P = .037$ ). There were no significant changes in pain-related clinic calls (35.2% Pre vs 34.0% Post,  $P = .896$ ), pain-related clinic visits ahead of schedule (4.2% Pre vs 6.4% Post,  $P = .681$ ), or pain-related ED visits (2.8% Pre vs 10.6% Post,  $P = .113$ ).

**Conclusion:** In the postoperative period after operative fixation of ankle fractures, the volume of narcotic prescriptions decreased after the new legislation, without an associated strain on medical resources.

**Level of Evidence:** Level III, therapeutic, comparative study.

**Keywords:** opioid prescription, postoperative pain, narcotics, legislation, ankle fracture

## Introduction

Orthopedic surgeons are the third highest prescribers of opioid prescriptions among physicians, accounting for an estimated 7.7% of all opioid prescriptions in the United States.<sup>11</sup> Although many types of orthopedic procedures necessitate opioid prescriptions for pain management, foot and ankle surgeries are especially associated with elevated levels of opioid prescriptions.<sup>10,14</sup>

Increased control of opioid prescription has been attempted on both clinical and regulatory levels. In North Carolina, the Strengthen Opioid Misuse Prevention Act of 2017 (STOP Act) went into effect on January 1, 2018, augmenting the efforts of established federal opioid misuse prevention programs like the Prescription Drug Monitoring

Program. In 2017, the year prior to enactment of this law, there were 1953 reported opioid deaths in North Carolina, of which 659 cases were attributed to prescription opioids (6.5 deaths per 100 000 persons).<sup>2</sup> The STOP Act seeks to tighten supervision over opioid prescriptions primarily by (1) requiring prescribers and pharmacies to review the patient's

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12-month history before issuing an initial prescription for a Schedule II or Schedule III opioid, (2) instituting a 5-day limit on initial prescriptions for acute pain and a 7-day limit on postoperative prescriptions (with exemptions for chronic pain, cancer care, palliative care, hospice care, or medication-assisted treatment for substance use disorders), and (3) increasing access to naloxone for reversal of opioid overdose.<sup>1</sup>

Several studies have examined the efficacy of both clinical and regulatory oversight of opioid prescriptions.<sup>4,7,15-17</sup> In particular, a few studies have examined the effects of specific state legislature, similar to the STOP Act, on opioid prescriptions in states like Rhode Island and New York.<sup>13</sup> To our knowledge, however, no study has analyzed the effects of state legislation on opioid prescription practices following foot and ankle procedures or the strain on medical resources associated with these regulatory changes.

The purposes of this study were to compare postoperative opioid prescription practices following operative fixation of ankle fractures as well as the frequency of patient pain-related phone calls or visits to the orthopedic clinic or emergency department (ED) before and after enactment of the STOP Act. We hypothesized that the STOP Act would decrease the amount of postoperative opioids prescribed but increase the number of perioperative clinic and ED visits.

## Methods

This study was a retrospective review of patients 18 years and older who underwent operative fixation of ankle fractures between January 1 and June 30, 2017 (before the enactment of the STOP Act, Pre group) and from January 1 through June 30, 2018 (after the enactment of the STOP Act, Post group). The operating room schedule at a Level 1 trauma center was used to identify all eligible patients. Exclusion criteria included patients younger than 18 years, polytrauma patients with multiple other injuries, and patients with open fractures or fractures requiring external fixation.

Electronic medical records (Epic, Verona, WI) were reviewed to identify variables of interest, including patient demographics, mechanism of injury, and fracture characteristics. With respect to pain history, patients with documented chronic pain or who were on medications such as methadone for opioid maintenance therapy were stratified to the chronic pain group. Previous opioid use was defined as documented opioid prescription within 1 year prior to foot/ankle surgery. Additional information was obtained from orthopedic and anesthesia procedure notes, as well as subsequent inpatient, outpatient, ED, and telephone encounters. Ultimately, the type of anesthesia, development of complications, frequency and reason for calls to clinic or visits to the ED, type and number of postoperative pain pills prescribed, and the number of prescription refills were all recorded.

A total of 118 patients met inclusion criteria and underwent operative fixation of an ankle fracture during the study period, including 71 in the Pre group and 47 in the Post

**Table 1.** Comparison of Patient Demographics.

	Pre (n = 71)	Post (n = 47)	P Value
Age, y, mean $\pm$ SD	47.5 $\pm$ 17.1	48.3 $\pm$ 16.3	.797
Gender, % male	53.5	44.7	.347
BMI, mean $\pm$ SD	29.7 $\pm$ 8.2	30.0 $\pm$ 7.2	.865
Medical history: PVD, diabetes, peripheral neuropathy, immunosuppression, %	19.7	23.4	.631
Tobacco use, %	38.0	46.8	.343
History of chronic pain, %	14.1	10.6	.582
History of opioid use prior to surgery, %	5.6	8.7	.710

Abbreviations: BMI, body mass index; PVD, peripheral vascular disease.

**Table 2.** Injury Characteristics and Perioperative Comparison.

	Pre (n = 71)	Post (n = 47)	P Value
Laterality of injury, % right	54.9	51.1	.680
Open injury, %	0	2.1	.398
Cause of injury, %			.772
MVC	9.9	12.8	
Pedestrian-struck	1.4	0	
Ground-level fall	67.6	72.3	
Sports	8.5	4.3	
Other	12.7	10.6	
Injury type, %			.196
Bimalleolar-equivalent	21.1	31.9	
Bimalleolar	35.2	40.4	
Trimalleolar	33.8	17.0	
Maisonnette	0	2.1	
Medial malleolar	7.0	8.5	
Fracture-dislocation	0	0	
Posterior malleolar	2.8	0	
Operative approach, %			.541
Lateral	53.5	51.1	
Medial	5.6	10.6	
Lateral + medial	29.6	34.0	
Posterolateral	8.5	2.1	
Posterolateral + medial	2.8	2.1	
Anesthesia type, %			.283
General	46.5	42.6	
Regional	39.4	31.9	
General + regional	14.1	25.5	
Time from injury to surgery, d, mean $\pm$ SD	6.4 $\pm$ 4.7	6.3 $\pm$ 5.5	.925
Time from surgery to discharge, d, mean $\pm$ SD	0.47 $\pm$ 1.4	0.38 $\pm$ 1.2	.739

Abbreviation: MVC, motor vehicle collision.

group. The 2 groups did not significantly differ with respect to age, sex, body mass index, medical comorbidities, tobacco use, or pain history (Table 1). The mechanism of injury, classification of the ankle fractures, operative approach, and type of anesthesia were similar between the groups (Table 2). On average, patients underwent operative fixation 6.4 and 6.3 days after injury in the Pre and Post

groups, respectively ( $P = .925$ ). Ten of the 71 patients in the Pre group had a history of chronic pain, whereas 5 of the 47 patients in the Post group had a history of chronic pain.

Continuous and categorical parameters were analyzed using Student  $t$  test and  $\chi^2$  or Fisher exact test, respectively. All continuous data were reported in means  $\pm$  SDs. Analyses were performed using SPSS 20 software (IBM, Armonk, NY). Statistical significance was set at  $P < .05$ . Post hoc power analysis was performed using the mean and SD of the primary outcome (number of postoperative pain pills prescribed) to calculate the Cohen  $d$  for effect size.

## Results

As expected, there was a statistically significant decrease in the average number of narcotic pain pills prescribed postoperatively after the STOP Act (52.7 vs 76.2,  $P < .001$ ), as well as a statistically significant decrease in the average number of prescription refills after the legislation (0.6 vs 1.0,  $P = .037$ ; Table 3). Post hoc power analysis demonstrated  $\beta=0.99$ . A slightly smaller percentage of patients made pain-related calls to clinic after the STOP Act (35.2% Pre vs 34.0% Post,  $P = .896$ ). After the STOP Act, a greater percentage patients made pain-related ED visits (2.8% Pre vs 10.6% Post,  $P = .113$ ), and a greater percentage required unplanned clinic visits secondary to pain (4.2% Pre vs 6.4% Post,  $P = .681$ ), though neither of these results reached statistical significance. The percentage of patients requesting opioid refills did not differ significantly before and after the STOP Act (16.9% Pre vs 17.0% Post,  $P = .986$ ).

Postoperative complication rates were similar between the 2 groups. One patient in the Pre group (1.4%) was noted to have delayed healing with cellulitis, which resolved with antibiotics. In comparison, wound complications occurred in 2 of the 47 patients in the Post group (4.3%). Two other patients in the Pre group were diagnosed with postoperative deep vein thrombosis. No other operative complications were noted in either group. One patient in the Pre group was referred to a pain specialist 4 months after operative fixation of a trimalleolar fracture.

When reviewing the entire cohort, the type of anesthesia did not significantly affect the proportion of patients who called a clinic with pain-related concerns (37.2% regional vs 32.1% general only,  $P = .858$ ) or who had a pain-related ED visit (4.7% regional vs 5.7% general,  $P = .768$ ). There was also no difference in the average number of prescription refills for patients who received regional anesthesia versus general anesthesia (0.86 vs 1.0,  $P = .279$ ). Patients who sustained ankle fractures as result of motor vehicle accident made significantly more pain-related calls to clinic (mean 1.6) compared to patients who sustained mechanical falls (0.45) or sports injuries (0.25,  $P = .005$ ). Patients with a documented chronic pain history were more likely to require pain-related ED visits (20.0% vs 3.9%,  $P = .043$ ) and ahead of scheduled clinic visits (20.0% vs 2.9%,  $P = .027$ )

**Table 3.** Narcotic Prescription Comparison.

	Pre (n = 71)	Post (n = 47)	P Value
Type of opioid prescribed, %			.328
None	2.8	6.4	
Oxycodone	73.2	72.3	
Percocet	12.7	4.3	
Norco	9.9	14.9	
Oxycontin + percocet	1.4	0	
Hydromorphone	0	2.1	
Concomitant prescription of non-opioid analgesia, %	4.2	11.9	.145
Number of opioid pills prescribed, mean $\pm$ SD	76.2 $\pm$ 27.4	52.7 $\pm$ 22.0	<b>&lt;.001</b>
Number of opioid prescription refills, mean $\pm$ SD	1.0 $\pm$ 1.3	0.6 $\pm$ 0.9	<b>.037</b>
Number of patients who made pain-related calls to clinic, n (%)	25 (35.2%)	16 (34%)	.896
Avg number of pain-related patient calls to clinic, mean $\pm$ SD	0.59 $\pm$ 1.1	0.62 $\pm$ 1.1	.902
Number of patients who made calls to request opioid refills, n (%)	12 (16.9%)	8 (17.0%)	.986
Average number of patient calls to request opioid refills, mean $\pm$ SD	0.32 $\pm$ 0.87	0.30 $\pm$ 0.78	.869
Number of patients who made pain-related ED visits, n (%)	2 (2.8%)	5 (10.6%)	.113
Average number of pain-related visits to ED prior to scheduled postoperative appointment, mean $\pm$ SD	0.04 $\pm$ 0.26	0.13 $\pm$ 0.40	.198
Number of patients requiring ahead of schedule visits related to pain control, n (%)	3 (4.2%)	3 (6.4%)	.681
Number of patients requiring postoperative pain specialist referral, n (%)	2.8	2.1	>.99

Abbreviation: ED, emergency department.

compared with controls. Patients who were on opioid medications before surgery were more likely to request early refills compared to controls (62.5% vs 13.8%,  $P = .004$ ).

## Discussion

This study demonstrated, as expected, that the number of narcotic pills prescribed following operative fixation of ankle fractures decreased after the initiation of the STOP Act. On average, patients were prescribed nearly 80 pills postoperatively before enactment of the STOP Act, which decreased by 23.5 pills after the law went into effect. In addition, the number of narcotic prescription refills decreased by 40% after enactment of the STOP Act. These

findings are supported by the investigation of Reid et al<sup>13</sup> on the effects of a 2017 Rhode Island law that implemented similar mandatory opioid prescription limits. They reported that the Rhode Island legislation reduced both morphine milligram equivalents prescribed and the number of pills prescribed by >55% overall in their institution's orthopedics department.

Despite the decrease in overall narcotic prescription volume found in our study, there was no associated increase in the number of patients making unplanned visits or calls to clinic and the ED due to pain control issues, which refuted our hypothesis. Abousayed et al<sup>3</sup> demonstrated similar results when examining the incidence of urgent care visits after ankle fracture fixation, with 10.5% of patients presenting to an urgent care facility within 30 days of discharge, of which one-fifth of the visits were related to pain control issues.

In theory, the decrease in volume of postoperative narcotic prescriptions after the STOP Act could increase strain on medical resources to address pain-related concerns, leading to substantial cost burdens to the health care system. Even patient phone calls, although often brief and having the potential to increase patient satisfaction and decrease ED visits, can place a substantial burden on clinical staff.<sup>6</sup> The data from our study, however, did not support this idea that decreased narcotic prescriptions increases strain on medical resources.

Holland et al<sup>8</sup> examined the effect of discontinuing routine opioid prescription after cesarian sections. The number of patients receiving opioid medication during the hospitalization decreased from 68% to 45%, with no significant change in pain scores and patient satisfaction with pain control. The number of patients discharged with opioid prescriptions decreased from 91% to 40%. Several other studies suggest that this change in prescribing practice may be effective in orthopedic surgery as well. Merrill et al<sup>10</sup> demonstrated that patients are often overprescribed opioid medications after foot and ankle surgeries, and that on average, patients only used half of the narcotics that they were prescribed. The majority of patients were satisfied with their pain control and were willing to surrender the remaining pills.

In an effort to reduce postoperative pain and narcotic requirements, regional anesthesia is often used as a supplement or replacement to general anesthesia. Kir et al<sup>9</sup> demonstrated in a randomized controlled trial that regional anesthesia in combination with general anesthesia for hallux valgus surgery was associated with decreased visual analog scale (VAS) pain scores and higher American Orthopaedic Foot & Ankle Society (AOFAS) ankle-hindfoot scores at 3, 6, and 12 months postoperatively, when compared to general anesthesia alone. Christensen et al<sup>5</sup> found that after operative fixation of ankle fractures, patients who received only general anesthesia required significantly more narcotic pain medication over the 24-hour perioperative period compared with patients who received a peripheral nerve block, spinal anesthesia, or both. In our study, we did not see a significant

effect of the type of anesthesia on opioid prescription practice or patient response to pain control.

Various studies have examined factors that might influence the amount of narcotic pain medication a patient might require after foot and ankle surgery. Saini et al<sup>14</sup> saw that increasing age was associated with less narcotic use. Mulligan et al<sup>12</sup> showed that a history of chronic pain, mood disorders, tobacco use, and preoperative narcotic use were all associated with increased postoperative narcotic use. In our study, patients who sustained ankle fractures as a result of high-energy trauma were more likely to make pain-related calls to clinic than patients who sustained twisting, falling, or sporting injuries. The chronic pain patients in our study more frequently required early clinic and ED visits related to poor pain control. Furthermore, patients who were already on opioids at the time of surgery were more likely to request refills.

The present study has several limitations inherent to a retrospective review study that relies on accuracy of chart documentation. We elected to include only surgeries performed in the first half of 2017 and 2018 to avoid potential overlap in prescribing practices in anticipation of the law going into effect on January 1, 2018. Patients who visited an ED or another medical provider outside of our medical system would not be captured in our data-reporting, and we did not review the state registry to confirm narcotic prescriptions outside of our medical system, so it is possible that patients may have obtained opioids from other sources. It is also possible, albeit infrequent, that some minor complications or patient phone calls to clinic were not completely documented and therefore under-reported. Lastly, as we did not collect pain scores or patient-reported outcomes, our secondary outcomes of prescription refills, phone calls, and ED visits served as indirect indicators of a patient's pain control and satisfaction with his or her care. Therefore, it is difficult to assess whether the STOP Act and other similar state legislations are leading to undermanagement of postoperative pain.

In conclusion, to our knowledge, this study is the first to look at the effect of legislation on the prescription of narcotic pain medication after foot and ankle procedures specifically. Our study showed that in the postoperative period after operative fixation of ankle fractures, the total volume of narcotic pain prescriptions can be successfully decreased in accordance with legislation, without an associated increase in strain on health care resources such as an increased number of calls or visits to clinic or to the ED related to pain control. Although certain at-risk patients, especially the opioid-tolerant, will still require extra clinical visits or prescription refills, the mandate set forth by this legislation has not thus far resulted in an increase in these resource allocations. The adoption of the STOP Act has demonstrated success in curbing the practice of overprescribing narcotics after surgery without significantly changing the number of postoperative ED visits, calls to clinic regarding pain, or pain-related clinic visits.


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