

Mandatory Prescription Limits and Opioid Use After Anterior Cruciate Ligament Reconstruction

Saygin Kamaci,^{*†‡} MD, Erdi Ozdemir,[†] MD, Christopher Utz,[‡] MD, and Angelo Colosimo,[‡] MD
Investigation performed at the University of Cincinnati College of Medicine, Cincinnati, Ohio, USA

Background: Because of the need for perioperative pain management, orthopaedic surgeons play an important role in opioid use.

Purpose/Hypothesis: To evaluate the impact of opioid-limiting legislation on postoperative opioid use and pain-related complications after anterior cruciate ligament reconstruction (ACLR). The hypothesis was that the opioid-limiting legislation would reduce postoperative opioid use after ACLR.

Study Design: Cohort study; level of evidence, 3.

Methods: We retrospectively reviewed patients who underwent ACLR 1 year before and 1 year after Ohio's opioid-limiting legislation, which was passed in August 2017. Clinicians were prohibited from prescribing more than 30 morphine milligram equivalents (MMEs) per day, with a maximum duration of 7 days for adults. The Ohio Automated Rx Reporting System database and patients' medical charts were reviewed for prescriptions of all controlled substances (oral oxycodone, hydrocodone, morphine, codeine, tramadol, and hydromorphone) filled from 30 days before and 90 days after ACLR. The total number of postoperative prescriptions, total MMEs, the number of pills in each patient's prescription, and pain-related complications (emergency department visits, office calls for pain control issues, unplanned readmissions, unplanned surgeries, and provider notes indicating opioid prescription refill demands) were evaluated.

Results: A total of 243 patients (127 prelegislation, 116 postlegislation) were included in the study. There were no significant differences in demographics or preoperative opioid use between the study groups. The number of pills prescribed initially decreased by 34% after legislation (63.5 ± 16.7 [prelegislation] vs 42 ± 15.7 pills [postlegislation]; $P < .001$). Correspondingly, there was a significant decrease in total quantity of initial prescriptions in the postlegislation period (474.6 ± 123.8 vs 310.7 ± 115.3 MMEs; $P < .001$). The number of documented pain medication refill demands and pain-related complications did not increase in the postlegislation period (42 prelegislation vs 43 postlegislation; $P = .514$). Preoperative opioid use was the strongest predictor of opioid-refill demand (odds ratio, 4.19 [95% CI, 1.76-9.99]; $P = .001$).

Conclusion: After the Ohio legislation was passed limiting opioid prescription, there was a significant reduction in opioids provided for patients undergoing ACLR. In spite of this decrease, no rebound increase in refill demands or postoperative pain-related complications were observed.

Keywords: opioid; narcotic; legislation; law; ACL; anterior cruciate ligament; complication

Opioid abuse has become an epidemic in the United States, with more than 11.5 million Americans reported misusing prescription opioids in 2018.²¹ In 2017, the number of opioid overdose deaths increased by 6-fold compared with 1999, and on average, 130 Americans die every day from an opioid overdose.²¹ According to a 2018 article in the *New England Journal of Medicine*, 80% of Americans believe the opioid crisis is a national emergency or a major problem.⁵ Orthopaedic surgeons play an important role in perioperative pain management and thus prescribe 7.7% of all

opioids in the United States, ranking fourth among all specialists in terms of total opioids prescribed.²²

Opioid use after anterior cruciate ligament (ACL) reconstruction (ACLR) has previously been studied.^{3,4,11,14} The ACLR patient population is typically younger and more active, with fewer comorbidities, than patients undergoing surgery for end-stage degenerative conditions. Rao et al¹⁴ identified several risk factors for postoperative prolonged opioid use including race, acute injury, meniscal injury repair, and multiligamentous injury for the early postoperative period, as well as 1 preoperative opioid prescription, female sex, motor vehicle accident as the mechanism of injury, and body mass index greater than 25 for the late recovery period after ACLR.

The Orthopaedic Journal of Sports Medicine, 9(9), 23259671211027546
 DOI: 10.1177/23259671211027546
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In March 2016, Massachusetts became the first US state to pass legislation limiting postoperatively prescribed opioids.⁷ Similarly, the Ohio government implemented new opioid-prescribing rules in August 2017, imposing strict limitations on opioid prescriptions to address the opioid epidemic.²⁰ Prescribers were prohibited from prescribing more than 30 morphine milligram equivalent (MMEs) per day, with a maximum duration of 7 days for adults. This is equal to a maximum of 4 doses of 5 mg oxycodone daily, up to 28 doses. Exceptions can be made for opioids prescribed for cancer, palliative care, end-of-life/hospice care, medication-assisted treatment for addiction, and postoperative care for major orthopaedic surgery if appropriately documented.

The literature supports that opioid-limiting legislation effectively limits the amount of opioids prescribed after orthopaedic surgeries, including ACLR.^{17,19} However, to our knowledge, the possible rebound effect on pain-related complications has not yet been investigated. The purpose of this study was to evaluate the effect of opioid-limiting legislation on postoperative opioid use and pain-related complications after ACLR. We hypothesized that opioid-limiting legislation would reduce postoperative opioid use after ACLR.

METHODS

This study was a retrospective review of patients who underwent ACLR 1 year prior to Ohio's opioid-limiting legislation²⁰ (September 1, 2016, to August 31, 2017) and 1 year after passage of the legislation (September 1, 2017, to August 31, 2018). All adults who underwent ACLR at our institution by 4 fellowship-trained, board-certified sports medicine specialists (C.U., A.C.) were included in the study. Patients with concomitant chondroplasty, partial meniscectomy, and meniscal repair procedures were also included. Patients with combined ligamentous knee injuries (ACL + posterior cruciate ligament, posterolateral corner, medial/lateral collateral ligament injury), who were younger than 16 years, and who required more than 1 primary procedure (such as open reduction and internal fixation or external fixation because of fracture/dislocation) in addition to ACLR were excluded. This study was determined to be exempt from institutional review board approval.

The Ohio Automated Rx Reporting System (OARRS) database as well as patients' medical charts were reviewed for prescriptions of all controlled substances filled from 30 days before to 90 days after the surgical procedure. The OARRS database and medical chart reviews were

performed by the lead author (S.K.), who was not involved in the treatment of the study patients. Opioid prescriptions for oral oxycodone, hydrocodone, morphine, codeine, tramadol, and hydromorphone were recorded. All opioids were converted to MMEs for accurate comparison. Postoperatively, all opioid prescriptions filled within 90 days of the surgical procedure were recorded. Opioid use for more than 30 days was considered prolonged opioid use. This 90-day cutoff value was used to exclude secondary reasons for opioid use.¹⁸ The total number of postoperative prescriptions, total MMEs, and the number of pills in each patient's prescription were examined.

To define the pain-related complications, patient charts were reviewed for any emergency department (ED) visits, office calls for pain-control issues, unplanned readmissions, unplanned surgeries, and provider notes indicating opioid prescription refill demands. To identify potential risk factors for additional opioid demand, data on postoperative complications (during the first 6 weeks), unplanned readmissions, secondary surgeries for any reason, additional surgical procedures, type of ACLR (primary vs revision), ACL graft type (autograft vs all allograft), preoperative femoral nerve block, and postoperative nonsteroidal anti-inflammatory drug (NSAID) prescriptions were collected. Patients who filled an opioid prescription at least 30 days prior to surgery were considered to be opioid-tolerant for the purposes of this study.^{8,17}

Distribution of variables was measured with the Kolmogorov-Smirnov test. The Mann-Whitney *U* test was used to compare continuous variables, and chi-square analysis was used for categorical variables. Multiple logistic regression was performed to determine the risk factors of opioid refill demand after first prescription. An a priori power analysis was performed for the primary outcome (total MME in first 30 days). Using an α value of .05, β of 0.80, and a standardized Cohen *d* value of 0.5, the estimated sample size required at least 64 patients per cohort or 128 total patients to obtain 0.8 actual power. Statistical analysis was performed with SPSS Statistics for Windows Version 23.0 (IBM). The level of significance was set at 0.05.

RESULTS

Patient Population

Of 297 patients in our ACL registry, 18 patients with combined knee ligamentous injury, 12 patients younger than 16 years, 8 patients with more than 1 primary procedure, and 16 patients with inadequate follow-up were excluded. A total of 243 patients fulfilled the inclusion criteria and

*Address correspondence to Saygin Kamaci, MD, Department of Orthopaedics and Traumatology, Hacettepe University School of Medicine, Sıhhiye, 06100 Ankara, Turkey (email: sayginkamaci@gmail.com).

[†]Department of Orthopaedics and Traumatology, Hacettepe University School of Medicine, Ankara, Turkey.

[‡]University of Cincinnati College of Medicine, Cincinnati, Ohio, USA.

Final revision submitted February 18, 2021; accepted March 2, 2021.

One or more of the authors has declared the following potential conflict of interest or source of funding: S.K. has received education payments from Arthrex. AOSSM checks author disclosures against the Open Payments Database (OPD). AOSSM has not conducted an independent investigation on the OPD and disclaims any liability or responsibility relating thereto.

Ethical approval for this study was waived by the University of Cincinnati (No. 2019-0551).

TABLE 1
Patient Demographics^a

	Prelegislation (n = 127)	Postlegislation (n = 116)	Total	P
Age, mean ± SD, y	31.4 ± 10.8	32.0 ± 10.7	31.7 ± 10.7	.592
Male sex	66 (52)	62 (53.4)	128 (52.7)	.817
Opioid-tolerant	13 (10.2)	12 (10.3)	25 (10.2)	.978
Additional procedures to ACLR	85 (66.9)	86 (74.1)	171 (70.4)	.219
Preoperative femoral nerve block	122 (96.1)	113 (97.4)	235 (96.7)	.724
Concomitant NSAID prescription	107 (84.3)	92 (79.3)	199 (82)	.405
Primary ACLR	117 (92.1)	112 (96.6)	229 (94.2)	.229
Graft type				
Hamstring autograft	54 (42.5)	37 (31.9)	91 (37.4)	.146
Bone—patellar tendon—bone autograft	38 (29.9)	51 (44.0)	89 (36.6)	.023
Tendon allograft	35 (27.6)	24 (20.7)	59 (24.3)	.212

^aData are presented as n (%) unless otherwise indicated. Bold P value indicates statistically significant difference between study groups ($P < .05$). ACLR, anterior cruciate ligament reconstruction; NSAID, nonsteroidal anti-inflammatory drug.

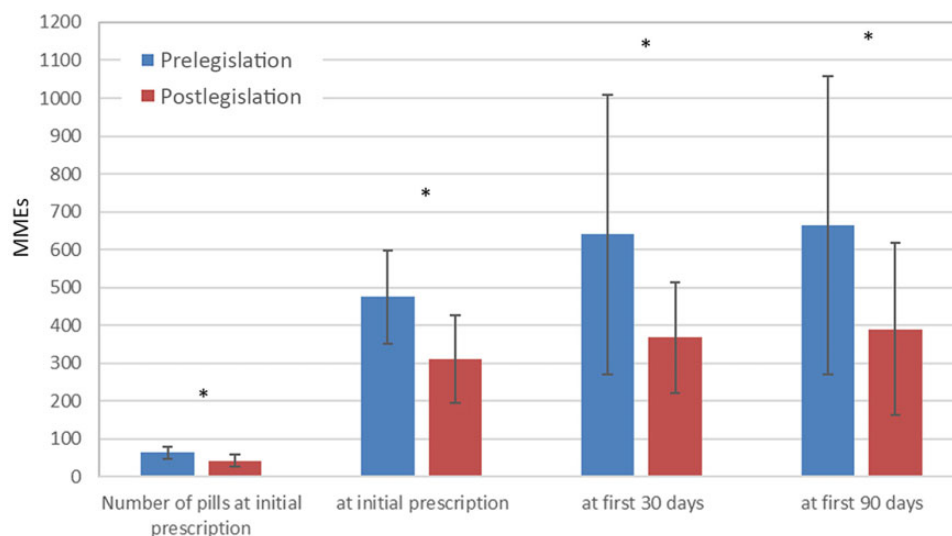


Figure 1. Opioid use before and after legislation, in morphine milligram equivalents (MMEs). Data are presented as means with SDs. * $P < .05$.

were included in the study: 127 patients were from the prelegislation period and 116 patients were from the postlegislation period. The prelegislation and postlegislation groups were similar in terms of demographic characteristics, additional procedures performed (64 meniscal procedures, 21 chondroplasties [prelegislation] vs 68 meniscal procedures, 18 chondroplasties [postlegislation]), preoperative femoral nerve block use, concomitant NSAID prescriptions, and all allograft tendon usage. There were more bone—patellar tendon—bone autografts in the postlegislation group ($P = .023$) (Table 1).

Ten (4%) patients had prolonged opioid use (5.5% prelegislation; 2.5% postlegislation), and approximately 10.2% (10.2% prelegislation; 10.3% postlegislation) were found to be opioid-tolerant. A preoperative femoral nerve block was performed in 96.7% (96.1% prelegislation vs 97.4% postlegislation) of the patients. Primary ACLR was

the main procedure in 94.2% of all patients (92.1% prelegislation; 96.6% postlegislation).

Comparison of Opioid Use

Compared with the prelegislation period, the number of pills prescribed at the initial prescription significantly decreased by 34% in the postlegislation period (63.5 ± 16.7 vs 42 ± 15.7 pills; $P < .001$). Correspondingly, there was a significant decrease in the total quantity of initial prescriptions in the postlegislation period (474.6 ± 123.8 vs 310.7 ± 115.3 MMEs; $P < .001$). The mean quantity prescribed in 30 days decreased from 639.7 ± 368.9 to 367.7 ± 145.9 MMEs in the postlegislation period ($P < .001$). Parallel to that, the mean quantity prescribed in 90 days decreased (664.7 ± 394.6 vs 390.4 ± 227.0 MMEs; $P < .001$). There was no statistically significant difference in the total

TABLE 2
Opioid Prescriptions Filled Based on Preoperative Opioid Use^a

MMEs in First 90 d	Opioid-Tolerant (n = 25)	Opioid-Naive (n = 218)	P
Prelegislation	889.2 ± 852.1	638.4 ± 300.1	.029
Postlegislation	433.1 ± 141.8	385.5 ± 234.8	.494
P	.016	< .001	

^aData are presented as mean ± SD. Bold P values indicate statistically significant difference ($P < .05$). MME, morphine milligram equivalent.

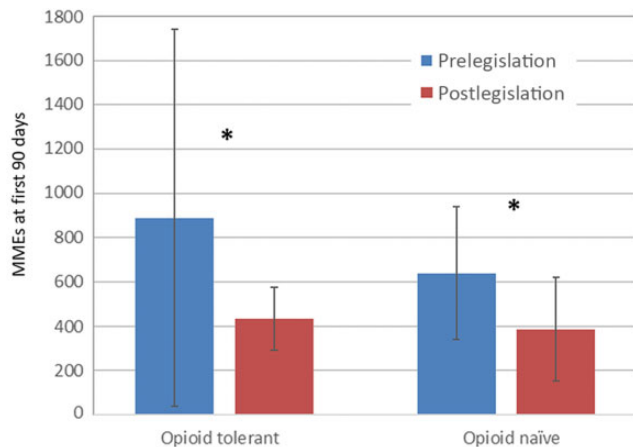


Figure 2. Effect of preoperative opioid tolerance on postoperative opioid requirements. Data presented as means with SDs. * $P < .05$. MME, morphine milligram equivalent.

number of postoperative prescriptions between the prelegislation and postlegislation cohorts (1.46 ± 0.7 vs 1.36 ± 0.6 prescriptions; $P > .05$) (Figure 1).

A decline in the mean MMEs in the first 90 days' prescriptions was observed both in opioid-tolerant (889.2 ± 852.1 vs 433.1 ± 141.8 MMEs; $P = .016$) and opioid-naïve (638.4 ± 300.1 vs 385.5 ± 234.8 MMEs; $P < .001$) patients after legislation (Table 2). However, the opioid-tolerant group demanded more total opioids than the opioid-naïve group during the first 90 days after legislation (433.1 ± 141.8 vs 385.5 ± 234.8 MMEs; $P = .494$) (Figure 2).

Opioid Refill Demand

A multiple regression analysis was performed to control potential confounders including additional procedures (meniscal, cartilage, collateral ligament procedures), concomitant NSAID use, sex, age, previous opioid use, surgical procedure, and ACL graft type. Preoperative opioid use was the strongest predictor of opioid refill demand (odds ratio, 4.19; 95% CI, 1.76-9.99; $P = .001$). An opioid prescription refill was provided for 64% of the opioid-tolerant patients. In contrast, 29.6% of the opioid-naïve patients went on to fill subsequent opioid prescriptions.

TABLE 3
Multiple Logistic Regression Analysis of Independent Risk Factors for Refill Demand^a

	Odds Ratio (95% CI)	P
Additional procedure	1.062 (0.588-1.917)	.841
Concomitant NSAID use	0.959 (0.481-1.914)	.906
Female sex	1.078 (0.630-1.845)	.784
Age	1.000 (0.976-1.025)	.990
Opioid-tolerant	4.194 (1.762-9.986)	.001
Postlegislation cohort	0.839 (0.490-1.438)	.523
Primary ACLR	6.986 (0.897-54.392)	.063
Graft type		
Hamstring autograft	Reference	
Bone—patellar tendon—bone graft	0.984 (0.530-1.828)	.960
Allograft	0.789 (0.387-1.610)	.515
Quadriceps tendon graft	1.903 (0.256-14.170)	.530

^aBold P value indicates statistical significance ($P < .05$). ACLR, anterior cruciate ligament reconstruction; NSAID, nonsteroidal anti-inflammatory drug.

Age ($P = .99$), sex ($P = .784$), having additional procedures (meniscal, cartilage, collateral ligament procedures) ($P = .841$), and all allograft use ($P = .53$) had no significant effect on opioid refill demand. When ACL graft types were compared using the hamstring autograft as a reference, there were no statistically significant differences regarding opioid refill demand among the graft options (Table 3).

Pain-Related Complications

Although total MMEs at the time of initial prescription significantly decreased, the number of documented pain-related complications did not increase in the postlegislation period (42 prelegislation vs 43 postlegislation; $P = .514$). Of 43 postlegislation patients, 38 were prescribed opioids, and 5 of them were managed with nonopioid pain medication. There were no differences between the proportion of prelegislation and postlegislation patients visiting the ED in the first 30 days (4 [3.1%] prelegislation vs 3 [2.5%] postlegislation; $P > .05$) or having unplanned readmission rates (for any reason) in the first 30 days (2 [1.6%] prelegislation vs 2 [1.7%] postlegislation; $P > .05$). There was no increase in unplanned readmissions noted specifically for pain-control issues.

DISCUSSION

The most important finding of this study was that, since the development of Ohio's opioid legislation, the amount of opioids provided by our surgeons decreased after ACLR without pain-related complications. There was an overall reduction of more than 34% in opioid pills provided in the initial postoperative prescription. In addition, the overall cumulative 90-day MMEs decreased by 37% in the postlegislation cohort. Despite the significant reduction in opioids provided, no rebound increase in pain-related complications, including opioid represcription demand, office calls, ED visits, unplanned readmissions, or unplanned

surgeries, was observed. This finding suggests no major detrimental effects of the legislation on postoperative pain control.

Unused opioid pills that are not properly disposed of might increase the risk of opioid diversion for nonmedical use. Ninety percent of heroin abusers reported that their addiction started with prescribed opioids.¹⁰ The present study showed that the legislation safely decreased the total opioid use by 346 MMEs per patient, roughly equal to 34 pills of 5 mg oxycodone.

Although provided opioids decreased significantly in the postlegislation period, opioids still played an important role in postoperative pain control. At least 1 opioid prescription was filled by 99% of patients during the postlegislation period. Among the opioid-tolerant, this was 91.7%. Mandatory prescription limits raised concerns among many surgeons that the limitation would increase the number of ED visits, office calls, unplanned admissions, and refill requests. This did not happen, suggesting that we may have been overprescribing during the prelegislation period. Similar to our findings, recent studies in spine literature showed no increased pain-related complications after legislation.^{16,17}

The rate of opioid demand after ACLR tends to decrease over time.^{3,4,14} Beck et al⁴ reported a decreasing trend in opioid use, with a nadir at 7 days after surgery. Anthony et al³ analyzed opioid demand during a 1-year period after ACLR, showing a significant decrease in opioid consumption in 3 months. Rao et al¹⁴ studied opioid consumption after ACLR and reported that 17.7% of ACLR patients had 2 or more opioid prescriptions filled during the early postoperative period (3 months). In addition, 2.7% of patients were assessed as prolonged opioid users during late recovery. Our findings are consistent with the current literature during the early period. Almost one-third of the postlegislation patients (32.4%) had their opioid prescriptions refilled at least once in the 30-day period. Interestingly, only 2.5% of the patients had an opioid prescription refilled in the 30- to 90-day period. Opioid legislation might be one of the reasons for the decreased opioid prescription refill rate in the early postoperative period.

Multiple studies show that preoperative opioid use is the strongest predictive factor for prolonged opioid use after orthopaedic surgery.^{3,6,11,12,14-16,18} Similarly, we found a 4-fold higher risk for prolonged opioid use in opioid-tolerant patients. Decreasing any preoperative opioid prescriptions might help to reduce postoperative opioid use.

Reid et al¹⁸ analyzed the effect of Rhode Island's opioid legislation on opioid use after orthopaedic surgery. A significant reduction of opioid use was reported in rotator cuff repair, lumbar discectomy, total knee arthroplasty, upper- and lower-extremity trauma surgeries, and ACLR cohorts. In their ACLR subgroup, the mean 30-day opioid consumption decreased from 571 to 292 MMEs, which is consistent with our findings. However, that study did not assess pain-related complications.

The strengths of our study include a large patient sample with detailed surgical, demographic, and pharmacological data from a single center. We were able to observe similar populations before and after the passage of legislation in

the same geographic area. In addition, potential confounders including medical, surgical, and demographic factors were adjusted for by using a multivariate analysis. Furthermore, Ohio's Prescription Drug Monitoring Program database allowed us to track pre- and postoperative opioid prescriptions regardless of prescriber and location filled for accurate evaluation.

The present study has several limitations. Although we were able to monitor all opioid prescriptions, the actual amount consumed was not tracked. Self-reporting of outpatient opioid consumption has been previously studied.^{1,9,13,23} However, this methodology is poorly validated and might be affected by social-desirability bias. Thus, we found that analyzing opioids filled rather than used to be more accurate and without self-reporting bias. Although we were able to track ED visits to our hospital and surrounding health systems in the city (because of shared electronic medical records), we may have missed urgent care visits. However, any opioid prescriptions from those visits should still have been captured by the OARRS system. In addition, the decrease in the initially prescribed opioid volume without increasing the represcription rates and pain control issues in the postlegislation cohort supports the prelegislation overprescription and underconsumption of opioids. Although prelegislation and postlegislation cohorts were similar in terms of variables measured, there may still be unmeasured differences. Importantly, there is increasing pressure by policy makers, health care organizations, patient advocacy groups, and specialty-specific groups for providers to reduce opioid prescribing.² Therefore, the immediate and drastic decrease in opioid prescribing might not be attributed to legislation alone in the setting of national and global changes in practice management. In addition, this study lacks a clinical outcome assessment, and the effect of the legislation on clinical outcomes remains unclear. As a single-center study, the study results could not be generalized.

CONCLUSION

After the passage of legislation limiting opioid prescriptions, there has been a significant reduction in opioids provided by the orthopaedic surgeons in our institution for patients undergoing ACLR. Despite this decrease, no rebound increase in postoperative pain-related complications, represcription rates, office calls, ED visits, or unplanned readmissions has been observed. Although there is certainly a need for future research regarding appropriate prescription amounts for various procedures, this study provides evidence that opioid-limiting legislation may be effective in decreasing opioid use in patients undergoing ACLR. Opioid-prescribing guidelines seem to be essential in reducing postoperative opioid reliance: Therefore, such legislation could be implemented into health care systems where opioid-prescribing rules are not present. Further studies are required to show the effect of opioid-limiting legislation statewide or nationwide.

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