2021 SAGES ORAL





The NOpioid Project: a prospective observational feasibility study examining the implementation of a non-narcotic post-operative pain control regimen

Joseph DeVitis¹ · Emily Flom² · Tristan Cooper-Roth³ · Alan Davis¹ · Laura Krech¹ · Chelsea Fisk¹ · Steffen Pounders¹ · Douglas Kwazneski¹ · Alistair Chapman¹ · Carrie Valdez⁴

Received: 7 September 2021 / Accepted: 15 February 2022 / Published online: 4 March 2022 © The Author(s), under exclusive licence to Springer Science+Business Media, LLC, part of Springer Nature 2022

Abstract

Background Post-operative prescription of opioids has fueled an increase in opioid-associated morbidity and mortality. Alternative post-operative pain control with non-opioid pharmaceuticals can help counteract this effect. We investigated a non-opioid pain management protocol following emergent laparoscopic appendectomy and laparoscopic cholecystectomy. **Methods** Our tertiary referral center performed a prospective observational feasibility study of patients from October 2019 to 2020 who underwent emergent laparoscopic appendectomies and cholecystectomies. Patients aged 18–65 with no prior history of chronic pain or opioid abuse, no contraindications to taking acetaminophen and ibuprofen, and Glomerular Filtration Rate > 60 ml/min were included. Counseling was provided about non-narcotic pain control. Patients were not prescribed narcotics at discharge and were instead prescribed ibuprofen and acetaminophen. Patients were surveyed at their 2-week post-operative appointment to assess pain control and other patient-reported outcomes, including quality of life (QOL). **Results** Fifty-one patients met the inclusion criteria and completed the postoperative survey. Thirty-two were female (63%), average age 38, and BMI 30.4. 30 (59%) underwent laparoscopic appendectomy for acute non-perforated appendicitis and 21 (41%) underwent laparoscopic cholecystectomy for acute cholecystitis or symptomatic cholelithiasis. 88% of patients

felt satisfied or neutral with their post-operative pain control at discharge. After 2 weeks, 34 patients (66.7%) rated QOL as high, 17 (33.3%) rated QOL as moderate, and none rated QOL as poor. Fascial suture was not associated with poor outcomes. Anxiety, depression, alcohol use, and prior abdominal surgery were not associated with increased need for post-operative narcotics. There were no significant differences between appendectomy and cholecystectomy in satisfaction with pain control or QOL (p > 0.05).

Conclusion Patients undergoing surgery have an increased risk of developing an opioid disorder. The NOpioid Project demonstrated a non-narcotic multimodal pain regimen can be effectively adopted in the post-operative period after an emergent laparoscopic appendectomy or emergent laparoscopic cholecystectomy.

Keywords Non-narcotic pain protocol after surgery \cdot Emergent laparoscopic appendectomy/cholecystectomy \cdot Patient-reported pain scores \cdot Quality of life \cdot Acute care surgery

Carrie Valdez carrievaldezmd@gmail.com

- ¹ Trauma Research Institute, Spectrum Health, Grand Rapids, USA
- ² Department of Surgery, Yale New Haven Hospital, New Haven, USA
- ³ Department of Surgery, Tucson Medical Center, Tucson, USA
- ⁴ Department of Surgery, The Ohio State University, 395
 W. 12th Ave Rm 614A, Columbus, OH 43210, USA

The opioid crisis remains an ongoing issue for the American public [1, 2]. Approximately 1.7 million patients in the United States carry a diagnosis of opioid misuse disorder, while another 93,000 died of an opioid-related overdose in 2020, according to provisional data from the CDC [2, 3]. Patients undergoing surgery have an increased risk of developing an opioid misuse disorder, even following minor surgeries such as laparoscopic appendectomy or laparoscopic cholecystectomy [4, 5]. Some studies report nearly a 15-fold increased risk of opioid misuse in previously opioid-naïve patients following minor surgery [4]. Surgeons can help combat this epidemic by implementing discharge prescribing practices that limit or eliminate narcotics after minor surgeries.

Published prospective studies aimed at reducing narcotic administration have focused on standardized pain protocols, such as small "rescue" opioid prescriptions for breakthrough pain, as well as multimodal analgesic "bundles" promoting co-analgesia and patient education [6–8]. Patient education regarding opioid-sparing regimens has demonstrated adequate pain control along with high patient satisfaction in the post-operative period; one study reported up to 85% with "very good" pain control after intervention [6–8].

While the literature has largely focused on elective operations, one study on acute care laparoscopic cholecystectomies demonstrated opioid overprescribing at discharge to be a common occurrence [9]. However, no study to date has explored the use of non-opioid post-operative pain protocols once patients are discharged after emergent care operations, such as laparoscopic appendectomy and cholecystectomy.

We developed a non-opioid post-operative pain management protocol for emergent laparoscopic appendectomies and laparoscopic cholecystectomies. We hypothesized that implementation of the NOpioid Project, a non-opioid postoperative pain regimen on discharge, would demonstrate satisfactory patient outcomes. The primary outcome was patient pain scores on post-operative day (POD) #1, POD #3 and at the two-week post-operative visit. Secondary outcomes included patient satisfaction with pain management, urgent care visits, narcotic prescriptions, days of non-opioid pain medication use, and days to return to work.

Materials and methods

This prospective observational feasibility study was conducted at a tertiary care center that is part of a fourteenhospital system. The Acute Care Surgery (ACS) service is supported by surgeons who are board certified in general surgery and surgical critical care. Additionally, the ACS service is staffed by an in-house surgeon with an operating room available for emergent operations. This study was approved by our IRB and did not receive any specific grant from funding agencies in the public, commercial, or notfor-profit sectors. Patients who underwent surgery between October 1st, 2019, and October 1st, 2020 were evaluated. The following two populations were included in the NOpioid Project:

- 1. Laparoscopic appendectomy with no evidence of perforation.
- 2. Laparoscopic cholecystectomy with fewer than five consecutive days of symptoms.

Inclusion criteria are displayed in Table 1. Patients were excluded if pregnant, incarcerated, or part of a protected patient population. Pre-existing patient comorbidities, such as alcohol use, anxiety and depression did not exclude patients. Intra-operative bile spillage did not exclude patients. Patients were counseled pre-operatively and at the time of discharge about expectations of post-operative pain and the medications they would be prescribed at the time of discharge. The study goal was to include 50 patients utilizing convenience sampling and to then assess the feasibility results.

To strengthen our protocol, principal investigators approached anesthesia colleagues, post anesthetic care unit (PACU) nursing, and floor nursing units with presentations detailing our protocol. The presentation included the current research related to non-narcotic-based post-operative protocols, our planned protocol at discharge, and reassurance to all groups that no inpatient protocols would be manipulated. Standardized presentations were given at these groups' monthly meetings and handouts of the presentation were provided to those who could not attend.

On discharge, patients received prescriptions for ibuprofen 600 mg and acetaminophen 650 mg to be taken every six hours for three days. This staggered dosing schedule ensured the patient was receiving non-opioid pain medication every three hours while awake. Both medications were used as needed after the first three days. A detailed handout was also provided at discharge, which explained the dosing schedule and communicated instructions to call the office if pain control was inadequate (Fig. 1). Patients were not incentivized or compensated for their participation.

Intra-operative factors were determined by the surgeon, including the use of local anesthetic, the number of laparoscopic ports, and the use of a fascial suture. Transabdominal Plane (TAP) blocks were not used for any patient. Intraoperative and PACU use of narcotics was determined by the anesthesia providers. No changes were made to our in-hospital, post-operative pain medication regimen. The patient

Table 1Patient inclusioncriteria

Patient inclusion criteria		
Age (18–65)	No history of opioid misuse	
Glomerular filtration rate > 60 mL/min/1.73 m^2	No history of chronic pain	
No contraindications to taking both acetaminophen and ibuprofen		



Spectrum Health Laparoscopic Appendectomy and Cholecystectomy Pain Management

What kind of pain will I experience after surgery?

All surgery involves a certain degree of expected soreness. With most procedures, the greatest amount of pain occurs immediately after, and tapers in the following days with minor fluctuations. Your medication regiment will not eliminate your pain, but rather decrease it to an acceptable level so that you may continue your normal daily activities. It is best to continue to walk and move around as able. Some degree of pain will help indicate your healing process and can be controlled with the non-opioid based medications post-operatively.

What medications will provide the best relief for my pain?

The best strategy and standard of care are anti-inflammatory agents Tylenol (acetaminophen) and Motrin (ibuprofen or Advil) with ice packs or heating pads. Alternating these medications every 3 hours will maximize pain control. The daily limit is 4000 mg of Tylenol and 3200 mg of Motrin. While you will receive scripts for both Tylenol and Motrin, these medications are available over the counter and, in some instances, will be less expensive when using generic brands.

Schedule of Pain Medications:

Time	Medication	Dosage
7:00 AM	Motrin	Three 200 mg tabs – 600 mg
10:00 AM	Tylenol	Two 325 mg tabs – 650 mg
1:00 PM	Motrin	Three 200 mg tabs – 600 mg
4:00 PM	Tylenol	Two 325 mg tabs – 650 mg

Here is a sample schedule for administering pain medications:

Continue to alternate every 3 hours for 3 days while awake. After 3 days, you may use either medication as needed for pain control.

What if my pain is not controlled with these medications?

If you still have uncontrolled pain with the provided pain medications, do not hesitate to call our staff using the number provided. We will help make sure you are managing your pain in the best way possible, and if necessary, we can provide a prescription for additional pain medication.

Fig. 1 Patient education handout

received oral or intravenous narcotics as needed while in the hospital. The anesthesiology team, PACU nurses, and general surgical floor nurses were educated on the NOpioid Protocol.

Patients were surveyed (Fig. 2) during their 2-week postoperative follow-up appointment—either in-person or by phone. Patients were asked to confirm whether prescriptions were provided for both acetaminophen and ibuprofen at the time of discharge. Patients were also asked to rate their pain at the time of discharge, POD #3, and at the time of survey on a scale of 1–10, with 10 being the worst pain [10]. Patient satisfaction ratings of pain control, quality of life (QOL) data as "high", "moderate/fair", or "poor", and the number of recovery days required to return to work were collected.



Spectrum Health Laparoscopic Appendectomy and Cholecystectomy Post-Operative Survey

Thank you for participating in this survey. By completing this survey, you agree to having your responses used for research purposes. These responses will help us improve how we care for patients after surgery in the future. The responses you provide will not be entered into your medical record or shared with your insurance company.

- 1. Our records show that you were discharged with a script for both Tylenol and Motrin. Is this correct?
 - O Yes O No, wrong medication
- What is your current pain rating on a scale from 1-10 with 10 being the worst pain of your life?
- 3. On a scale of 1-10, with 1 meaning your pain was completely controlled and 10 meaning pain not controlled at all, how would you rate how your medications controlled your pain after discharge?
- 4. How satisfied or dissatisfied were you with your pain control after discharge?
 - O Very satisfied
 - **O** Somewhat satisfied
 - **O** Neither satisfied nor dissatisfied
 - **O** Somewhat dissatisfied
 - **O** Very dissatisfied
- 5. What is your current quality of life after surgery?
 - O High
 - O Moderate/Fair
 - O Poor
- 6. What was your pain rating on a scale from 1-10 with 1 meaning your pain was completely controlled 10 meaning your pain was not controlled at all after the first three days? _____
- 7. Did you receive any <u>prescription</u> pain medications AFTER leaving the hospital?
 O Yes O No

Fig. 2 Patient post-operative survey page 1

- 8. How easy was it for you to get a <u>refill</u> for these *prescriptions* OR <u>any additional</u> *prescription* pain medications AFTER leaving the hospital?
 - O Very easy
 - O Somewhat easy
 - O Neither easy nor difficult
 - O Somewhat difficult
 - O Very difficult
- Did you call the clinic for a prescription pain medication after leaving the hospital?
 O Yes O No
- 10. Did you go to urgent care or the Emergency Department for a prescription pain medication after leaving the hospital?
 - O Yes O No
- 11. How many days after surgery did you STOP taking your prescription pain medications?
 - O Day of surgery, I did not require any pain medication
 - O Day 1
 - O Day 2
 - O Day 3
 - O Day 4
 - O Day 5
 - O Day 6+

12. How many days after surgery were you able to return back to work? _____

Fig. 2 (continued)

These metrics were based on a 2019 study examining postop opioid-sparing pain control after laparoscopic cholecystectomy and other minor procedures [6]. Our researchers collected data on any attempts the patients made to contact the surgery clinic for pain control issues, visits to the emergency room/urgent care for additional narcotic pain medications, as well as the day patients stopped taking non-opioid pain medications altogether.

Summary statistics were calculated. Quantitative, normally distributed data are expressed as the mean \pm SD, while non-normally distributed quantitative data are expressed as the median (and interquartile ranges of the 25th and 75th percentiles). Nominal data are expressed as a percentage. All statistical summaries were calculated using Stata v.16.1 (StataCorp, College Station, TX).

Results

Between October 1st, 2019, and October 1st, 2020, 51 patients who met inclusion criteria completed the post-operative survey. Patient demographics are listed in Table 2.

63% of patients were female with an average age of approximately 38 years and average BMI of 30.4. 59% of patients underwent laparoscopic appendectomy, and 41% underwent laparoscopic cholecystectomy. In accordance with the inclusion criteria, all appendectomy patients presented with acute non-perforated appendicitis. Of the cholecystectomy patients, 62% presented with acute cholecystitis and 38% had symptomatic cholelithiasis. Two-thirds of all patients were given a fascial suture and 39% of patients had previous abdominal surgery. Further, when examining patient comorbidities through their electronic medical records upon admission, 7 patients (13.7%) had documented anxiety and depression, 4 (7.8%) had depression, 4 (7.8%) had anxiety, and 25 patients (49%) had a history of alcohol use (drinking within the past month.).

We elected to include 51 patients to assess operational and technical feasibility of the NOpioid approach, which included an evaluation of patient surveys and statistical evaluation of outcomes. Initially, surveys were given to all patients two weeks post-operation at their in-person follow-up appointment. Secondary to ongoing high volume of COVID-19 in our community, we adopted a telehealth approach to follow-up care for uncomplicated emergent

Table 2 Demographics

Variable	N=51
Age, y, mean (SD)	37.8+14.3
Female sex	32 (63%)
BMI, kg/m ² , mean (SD)	30.4 + 7.9
Anxiety	11 (22%)
Depression	11 (22%)
Alcohol use	25 (49%)
Previous abdominal surgery	20 (39%)
Current/previous smoking	11 (22%)
Hypertension	10 (20%)
Diabetes	2 (4%)
COPD	0 (0%)
GERD	6 (12%)
Diagnosis	
Acute non-perforated appendicitis	30 (59%)
Symptomatic cholelithiasis	8 (16%)
Acute cholecystitis	13 (25%)
Operation, n (%)	
Laparoscopic appendectomy	30 (59%)
Laparoscopic cholecystectomy	21 (41%)
Fascial suture, n (%)	34 (67%)

BMI body mass index, *COPD* chronic obstructive pulmonary disease, *GERD* gastroesophageal reflux disease

surgeries. While we transitioned to what we thought would be a temporary workflow, there was a pause in survey distribution. As we adapted to this new workflow and telehealth visits became our standard follow-up care, we elected to include patients with both in-person and virtual follow-up. As a result of this transition to a virtual approach, patient surveys were not filled out for four months, and patients during this time were excluded.

An analysis of patient survey responses is displayed in Table 3. The maximum median pain score was 4, which was reported on POD #3. We found a median of seven days to return to work, and 76% of patients were satisfied with their pain control after discharge. QOL two weeks post-discharge was rated "high" in two-thirds of patients; no patients reported "poor" QOL. Less than 10% of patients required a narcotic prescription, and only one patient visited an urgent care or ED for supplementary pain control. There were no significant differences between appendectomy and cholecystectomy in QOL or satisfaction in pain control (p > 0.05).

Discussion

This study demonstrates that a non-narcotic postoperative pain management strategy in patients who present acutely for laparoscopic appendectomy or laparoscopic

Table 3 Patient survey responses

Variable	N=51*
Pain	
Discharge pain	3 (1, 6)
Pain at 3 days	4 (2, 6)
Current pain (post-op 2 weeks)	1 (0, 2)
Return to work, (d)	7 (5.5, 14)
Pain control after discharge	
Very/somewhat satisfied	39 (76%)
Neither satisfied/dissatisfied	6 (12%)
Very/somewhat dissatisfied	6 (12%)
Current quality of life	
High	34 (67%)
Moderate/Fair	17 (33%)
Poor	0 (0%)
Any prescription pain meds after	4 (8%)
Urgent care/ED for pain medication	1 (2%)
When did you stop taking medication? (Acetaminophen and ibuprofen)	
Day of surgery	2 (4%)
Post-operative day 1	4 (8%)
Day 2	8 (16%)
Day 3	9 (18%)
Day 4	8 (16%)
Day 5	9 (18%)
Day 6+	11 (22%)

*Pain scores and return to work are expressed as median (25th percentile, 75th percentile)

cholecystectomy is feasible and provides acceptable pain relief. This is important, as up to 10% of opioid-naive patients can develop long-term opioid dependence after undergoing an operation [11]. To increase patient safety, the CDC recommends prescribing the "lowest effective dosage" when prescribing opioids [12]. Our study suggests that the lowest effective dosage may be no narcotics whatsoever for emergent laparoscopic general surgery procedures.

The results of our study demonstrate that 88% of patients rated their post-operative pain control as "satisfactory" or "neither satisfied nor dissatisfied". The absence or presence of a fascial suture was not associated with unacceptable outcomes. The presence of preexisting anxiety, depression, or alcohol use was not associated with an increased need for post-operative narcotics. Having prior abdominal surgery was also not associated with an increased need for pain medications. Finally, all participants rated their QOL as either "high" or "moderate" two weeks after discharge. We did not include perforated appendicitis or patients with RUQ pain for more than five days as we expected these patients may inherently experience more pain due to more complex disease processes. These patients represent another cohort for future evaluation of a non-narcotic discharge pain regimen.

Previous studies have demonstrated that pain control protocols can be assessed through patient surveys [13]. In addition, patient responses help to adjust and improve protocols and provide validation [13]. A 2020 study found that three institutions successfully implemented opioid prescribing protocols based on post-operative patient surveys [13]. These patient-driven protocols reduced opioid prescribing by up to 63% while maintaining satisfactory pain control and did not increase refill requests [13]. However, these institutions did not study opioid-free pain control; all three prescribed hydrocodone/acetaminophen or oxycodone [13]. Notably, University of Michigan's Opioid Prescribing Recommendations (OPEN) sets pain control guidelines for a variety of elective procedures [14]. For elective laparoscopic cholecystectomy (or appendectomy), zero to ten oxycodone 5 mg tablets are recommended [14]. Despite the current recommendations, our results suggest that these procedures could be managed with a non-narcotic pain control approach. This is further supported by the fact that 45%of patients stopped using non-narcotic pain medications by POD #3, despite being instructed to continue these medications as scheduled for three days.

Despite efforts to reduce narcotic prescriptions, a 2020 study found that surgeons prescribe the highest dosages of opioids to opioid-naive patients [11]. Additionally, surgical patients were most frequently prescribed opioids such as hydrocodone, which is responsible for more overdose deaths than weaker opioids, such as acetaminophen with codeine or tramadol [11]. This has contributed to an increase in opioidassociated morbidity and mortality and carries a significant risk to patients of developing chronic opioid dependence [4, 5, 15, 16]. In 2017, 35% of opioid overdoses were linked to prescribed narcotics [11]. Furthermore, presence of a past opioid prescription is a common risk factor associated with later heroin use [2, 17, 18]. Physicians and hospitals have an opportunity to combat the opioid crisis and limit opioid prescriptions while providing safe and effective strategies for pain management, including a non-narcotic approach as we have proposed.

Over 90% of the patients in our study recovered without opioid prescriptions. While our study approach is novel, a similar study corroborated these findings and reported 52% of elective laparoscopic, endoscopic, and robotic surgical repair patients used no opioids [6]. Another study found 44% of elective laparoscopic hernia repair patients also took no opioids during recovery [7]. In that study, 75% of all prescribed opioids remained unused [7]. Leftover pills represent a key source of opioid misuse. Over 80% of adolescent opioid users, for example, begin by abusing their parents' or guardians' prescriptions [19]. The research team leveraged this existing literature to demonstrate to our clinical teams that a non-narcotic post-operative course was a reasonable approach that was ultimately supported by our findings. Central to advocating for this approach was educating our clinical staff on the potential for negative downstream ramifications even from a small narcotic exposure following uncomplicated laparoscopic surgery. This data and study have resulted in a cultural change around the potential impact of opioid prescriptions from our team.

Our experience demonstrates that setting expectations about pain management with the patient prior to surgery and at the time of discharge likely had a positive influence on patient adherence and satisfaction with pain control. Additionally, educating members of the hospital team-including anesthesia providers, recovery and floor nurses, and residents-provided patients with consistent education. Our discharge instruction sheet presented medication instructions in a clear, accessible manner and offered next steps if the non-narcotic protocol proved inadequate. Providing patients with either a physical or electronic prescription stressed the importance of taking non-narcotic pain medications on a defined schedule rather than instructing patients to obtain these medications OTC and take them on their own terms. This, combined with patient follow-up, also likely influenced the success of this project. Proactive patient counseling has proven successful in other studies as well. For example, a 2021 study found in-hospital opioid counseling increased the disposal rate of unused opioids at 6 weeks post-surgery [20]. This reduces potential opioid misuse as there are fewer unused opioid pills in patients' possession after surgery [20]. A 2020 study reported that the frequency of proper opioid disposal doubled after counseling, and that overall knowledge of opioid risks increased [21]. Both studies highlight patient education methods that may prevent misuse of opioids and some long-term consequences of overprescribing.

Despite efforts to provide patients with sufficient education and set appropriate expectations for post-operative discomfort, not all patients were satisfied with their pain control after surgery. A total of six patients, representing 12% of the study population, fell into the "dissatisfied" category. Three of these patients rated their satisfaction after discharge as "somewhat dissatisfied," however, at their post-operative visit, these patients report their pain was adequately controlled and did not indicate any concerns in the post-operative period on their survey. Three other patients reported feeling "very dissatisfied" with their pain control. Of these, only one patient received a narcotic prescription for breakthrough pain on POD #2. This demonstrates that a non-narcotic approach to post-operative pain control should also include a rescue option for patients.

Our study has several limitations. This was a patientreported outcomes survey study with all expected inherent limitations of recall bias, patient self-selection for followup, and willingness to complete a survey. Patient QOL data were not collected using validated survey questions; patients instead subjectively rated QOL as "high", "moderate/fair", or "poor". Ideally, the QOL data of our patients would be collected before and after surgery, but this was not feasible due to the unexpected nature of acute surgery. Additionally, we did not compare patients who went home with a narcotic prescription versus those who did not. This was a single center study using a convenience sample. Lastly, the results are subjective due to the nature of quantifying pain; this was unavoidable.

Further studies using our NOpioid protocol could expand the inclusion criteria to other diagnoses, such as early perforated appendicitis, umbilical hernia repair, gastric perforations repaired laparoscopically, and laparoscopic adhesiolysis.

Patients undergoing surgery have an increased risk of developing an opioid misuse disorder. The NOpioid Project demonstrated a non-narcotic multimodal pain regimen can be effectively adopted in the post-operative period after an emergent laparoscopic appendectomy or emergent laparoscopic cholecystectomy.

Funding No funding was awarded for this research.

Declarations

Disclosures Drs. Devitis, Flom, Kwazneski, Chapman and Valdez, Cooper-Roth, Davis, Krech, Fisk and Pounders have no conflict of interest or financial ties to disclose.

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