Standardization of Outpatient Procedure (STOP) Narcotics: A Prospective Non-Inferiority Study to Reduce Opioid Use in Outpatient General Surgical Procedures

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BACKGROUND: There has been a dramatic rise in opioid abuse, and diversion of excess, unused prescriptions is a major contributor. We assess the impact of implementing a new standardized pain care bundle to reduce postoperative opioids in outpatient general surgical procedures.

STUDY DESIGN: This study was designed to demonstrate non-inferiority for the primary end point: patient-reported average pain in the first 7 postoperative days. We prospectively evaluated 224 patients who underwent laparoscopic cholecystectomy or open hernia repair (inguinal, umbilical) pre-intervention to 192 patients post-intervention. We implemented a multimodal intra- and postoperative analgesic bundle, including promoting co-analgesia, opioid-reduced prescriptions, and patient education designed to clarify patient expectations. Patients completed a brief pain inventory at their first postoperative visit. Groups were compared using chi-square test, Mann-Whitney U test, and independent samples *t*-test, where appropriate.

RESULTS: No difference was seen in average postoperative pain scores in the pre- vs post-intervention groups (2.3 vs 2.1 of 10; $p = 0.12$). The reported quality of pain control improved post-intervention (good/very good pain control in 69% vs 85%; $p < 0.001$). The median total morphine equivalents for prescriptions filled in the post-intervention group were significantly less (100; interquartile range 75 to 116 pre-intervention vs 50; interquartile range 50 to 50 post-intervention; $p < 0.001$). Only 78 of 172 (45%) patients filled their opioid prescription in the post-intervention group ($p < 0.001$), with no significant difference in prescription renewals (3.5% pre-intervention vs 2.6% post-intervention; $p = 0.62$).

CONCLUSIONS: For outpatient open hernia repair and cholecystectomy, a standardized pain care bundle decreased opioid prescribing significantly and frequently eliminated opioid use, while adequately treating postoperative pain and improving patient satisfaction. (J Am Coll Surg 2019;228:81−88. © 2018 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

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During the past decade, there has been a dramatic rise in prescription opioid abuse, as well as associated morbidity and mortality in North America.[1,2] Patients who receive opioid prescriptions after operations might be more likely to become chronic opioid users.[3-5] In addition, prescription medication is the most common source of abused opioids, with inappropriate disposal allowing access to individuals for whom the medication was not intended.[6,7] Surgeons have a significant impact in prescribing analgesic medications to patients as part of their postoperative care.[8,9] Although it is essential to ensure adequate pain control, surgeons are overprescribing opioids to general surgery patients, and a substantial number of overdose deaths can be linked to prescriptions written by surgeons.[10-13]

Recent guidelines have advocated for a multimodal approach to reduce opioid use in the treatment of acute pain.[14,15] Physician and patient education, smaller opioid prescriptions, non-opioid analgesic medications and improvement of appropriate opioid disposal have all been proposed recently as strategies to combat the opioid crisis.[14,16-18]

At London Health Sciences Centre, the Division of General Surgery identified opioid prescribing for acute pain as a priority area for improvement based on the 2017 Health Canada-Joint Statement of Action to Address the Opioid Crisis.[19] We designed the Standardization of Outpatient Procedure Narcotics (STOP Narcotics) initiative to standardize pain management approaches, with the objective of reducing excessive postoperative opioid prescriptions, and adequately controlling postoperative pain in outpatient general surgical procedures.

The current study represents a prospective evaluation of the efficacy of the STOP Narcotics initiative with respect to postoperative pain control, patient satisfaction, and compliance. We hypothesized that the introduction of the STOP Narcotics protocol would be associated with equivalent pain control, and reducing narcotic prescriptions among patients undergoing selected outpatient general surgery procedures.

METHODS

Study design and setting

A non-inferiority, prospective pre- and post-intervention study from July 17, 2017 to April 30, 2018 was conducted. The study was conducted at London Health Sciences Centre, a tertiary care academic institution consisting of 2 hospital campuses, and at St Joseph's Hospital, where additional outpatient general surgery procedures are performed in London, Ontario, Canada. The STROBE (Strengthening the Reporting of Observation Studies in Epidemiology) guidelines were followed.[20] Ethics approval was obtained through the Health Sciences Research Ethics Board at Western University (HSREB# 109651).

Intervention

The STOP Narcotics intervention involved the implementation of a 4-pronged strategy: patient education; healthcare provider education (surgeons, anesthetists, residents, and nurses); intraoperative multimodal analgesia and opioid reduction strategies; and postoperative multimodal analgesia and opioid reduction strategies. This intervention was designed with input from multiple stakeholders (surgeons, anaesthetists, and patients) and was instituted across the Division of General Surgery. The Division of General Surgery at London Health Sciences Centre is composed of 20 surgeons who perform the included procedures regularly.

Patient education

Education had 4 areas of focus and was both written and verbal. Education surrounding pain expectations and discomfort after operation was coupled with instructions for optimal use of multimodal analgesic medications. Furthermore, patients were given instructions for appropriate use of a limited supply of narcotics, which were to be used only if deemed required by the patient. They were told not to fill this prescription unless necessary. Finally, patients were educated on appropriate medication disposal. All of this information was reinforced at initial consultation when their operation was booked, on the day of operation by the surgical team, and before leaving hospital with standardized education sheets and verbal reinforcement by nursing staff.

Provider education

Providers including surgeons, anesthetists, residents, and nurses were educated in large group formats (divisional rounds, nursing meetings) through email and individually. Education focused on understanding the need for opioid reduction when appropriate, understanding the recommended multimodal analgesic strategies and supporting patient/caregiver expectations.

Intraoperative pain management strategy

As part of the surgical safety checklist before induction of anesthesia, the surgical team reinforced the use of ketorolac (15 to 30 mg IV), ondansetron (4 to 8 mg IV), and dexamethasone (4 to 8 mg IV), to be given by the anesthesiologist.

Postoperative pain management strategy

A prescription for a non-steroidal anti-inflammatory drug (meloxicam 7.5 mg or naproxen 400 mg) was given with instructions to take it regularly for 72 hours. Patients also received instructions for regular use of acetaminophen 500 mg tablets for the first 72 hours. After 72 hours, patients were instructed to take ibuprofen 400 mg and acetaminophen 500 mg as needed. A separate prescription for 10 tablets of tramadol 50 mg or codeine 30 mg (1 tablet po q6h as needed) with an expiry date of 7 days after operation was provided, with instructions to fill this prescription only if adequate pain control was not otherwise achieved (eDocument 1).

Other postoperative instructions, such as activity, wound care, and return to work, were provided at the discretion of the surgeon.

Pre- and post-intervention groups

To evaluate the efficacy of the STOP Narcotics initiative, we included individuals aged 18 to 75 years undergoing elective, outpatient laparoscopic cholecystectomy or open hernia (inguinal or ventral [umbilical and epigastric]) repair. Bilateral inguinal hernia repairs were also included. Patients were excluded if they were regular opioid medication users preoperatively, or had coexisting chronic pain conditions (not including osteoarthritis or back pain), known chronic kidney disease or nephropathy, or active peptic ulcer disease.

A control group (pre-intervention) from July 17, 2017 to October 18, 2017 was compared with an experimental group (post-intervention) from October 23, 2017 to April 30, 2018, who only differed by exposure to the STOP Narcotics intervention protocol.

Outcomes

The primary end point was patient-reported average pain level in the first 7 postoperative days on a numerical rating scale (0 to 10), captured using a modified Brief Pain Inventory survey at their first postoperative appointment (typically 4 weeks postoperatively at our institution).[21,22] Secondary outcomes included the overall quality of pain management after operation, and patient function in the first postoperative week. The survey also captured the following: patient reported anti-inflammatory and acetaminophen use; filling of narcotic prescription (yes/no); percentage of narcotic medication used; number of narcotic prescription refills; and medication disposal. Medication disposal was considered appropriate if the patient returned the medication to the pharmacy or the outpatient clinic. In addition to self-reported outcomes, all charts were reviewed to identify prescriptions given (all prescriptions are processed and tracked though the electronic medical record) and postoperative complications. Oral morphine equivalents (OMEs) were calculated to standardize the quantity of opioids taken (Table 1).

Statistical analysis

The sample size was calculated based on a meaningful clinical difference of 2 points on the numerical pain rating scale.[23,24] Using an α of 0.025, power of 90%, and a non-inferiority limit of 2 meaningful clinical difference of the numeric rating scale, we required 44 patients per operation type in each of the pre- and post-intervention groups. We hypothesized that our intervention would be non-inferior to our usual care group (pre-intervention).

All statistical analyses were performed using SPSS, version 24 (IBM Corp). Continuous variables were expressed as medians with interquartile ranges (IQR) for non-normally distributed variables, and as means and SDs for normally distributed variables. Mann-Whitney U tests and independent samples *t*-tests were used to assess for a difference between groups for medians and means, respectively. Chi-square tests were performed for categorical data. Non-inferiority was tested using the 2-sample, equal variance, *t*-test for mean difference. Only our primary end point was tested for non-inferiority with a 1-sided test. Two-sided tests were used for secondary variables. A p value of <0.025 for the primary end point was considered statistically significant.

RESULTS

Study population

The study population consisted of 536 patients. After exclusion, there were 224 patients in the pre-intervention group and 192 patients in the post-intervention groups. In addition to the specified exclusion criteria, 69 additional patients in the pre- and post-intervention group were excluded, due to incomplete modified brief pain inventory surveys, duplicates, simultaneous procedures, inpatient procedures, or incorrectly documented procedures. Hernias were sub-grouped into ventral and inguinal hernias (Fig. 1). Pre- and post-intervention groups were similar in age and sex (Table 2).

Table 1. Oral Morphine Equivalents for 10 Tablets of Common Surgical Prescriptions

10 tablets	Oral morphine equivalent
Morphine 5 mg	50
Oxycodone 5 mg	75
Codeine 30 mg	45
Tramadol 50 mg	50
Hydromorphone 2 mg	80

Agency Medical Directors' Group, available at: http://www.agencymeddirectors.wa.gov/calculator/dosecalculator.htm.

Patient-reported quality outcomes

The primary end point of average postoperative pain score in the first 7 postoperative days was non-inferior in the post-intervention compared with pre-intervention groups (2.3 vs 2.1 of 10; $p = 0.12$). The reported quality of pain control improved post-intervention for the cohort as a whole (good/very good pain control 69% vs 85%; $p < 0.001$). This was driven by an increase in reported quality of pain control in the inguinal hernia and ventral hernia groups ($p = 0.001$ and $p < 0.001$), as self-reported pain control did not significantly change in laparoscopic cholecystectomy patients ($p = 0.76$). Other self-reported functional outcomes did not significantly change, with the exception of improvement in walking ability in the post-intervention group (4.0 vs 3.3; $p = 0.01$) (Table 3)

Medication-related outcomes

The median total morphine equivalents for prescriptions filled in the post-intervention group were significantly less (100; interquartile range 75 to 116 pre-intervention vs 50; interquartile range 50 to 50 post-intervention; $p < 0.001$) (Fig. 2). Only 78 of 172 (45%) of post-intervention patients filled their opioid prescription, with no significant difference in prescription renewals (3.5% pre-intervention vs 2.6% post-intervention). Of these 78 patients, 26 (33%) reported they did not use any of these opioid pills. In addition, the median amount of opioids taken in this post-intervention sub-group of 78 patients was reported at 25 OMEs (5 pills). Appropriate excess medication disposal increased from 13 of 173 (8%) to 18 of 78 (23%) ($p < 0.001$) after the intervention was initiated (Table 4).

Anti-inflammatory use increased from 43% of patients to 70% ($p < 0.001$) in the post-intervention group, and acetaminophen use increased from 51% to 79% ($p < 0.001$) (Table 4).

Surgeon and patient adherence

The number of surgeons prescribing greater than a median of 50 OMEs was significantly reduced from 100% pre-intervention to 31% post-intervention ($p < 0.001$). The patients operated on by surgeons prescribing more than 50 OMEs accounted for only 20% of the entire study population. The most common patient-reported reasons for filling the opioid prescription were the following: the patient filled it just in case they needed it (34 of 78 [44%]); the patient was told to fill the prescription (30 of 78 [39%]); and the patient needed it for additional pain control (17 of 78 [21.8%]). This suggests that only 17 of 192 (9%) patients in the post-intervention group reported that they needed the opioid prescription for additional pain control. There were 3 patients who listed more than one of these reasons (Tables 4 and 5).

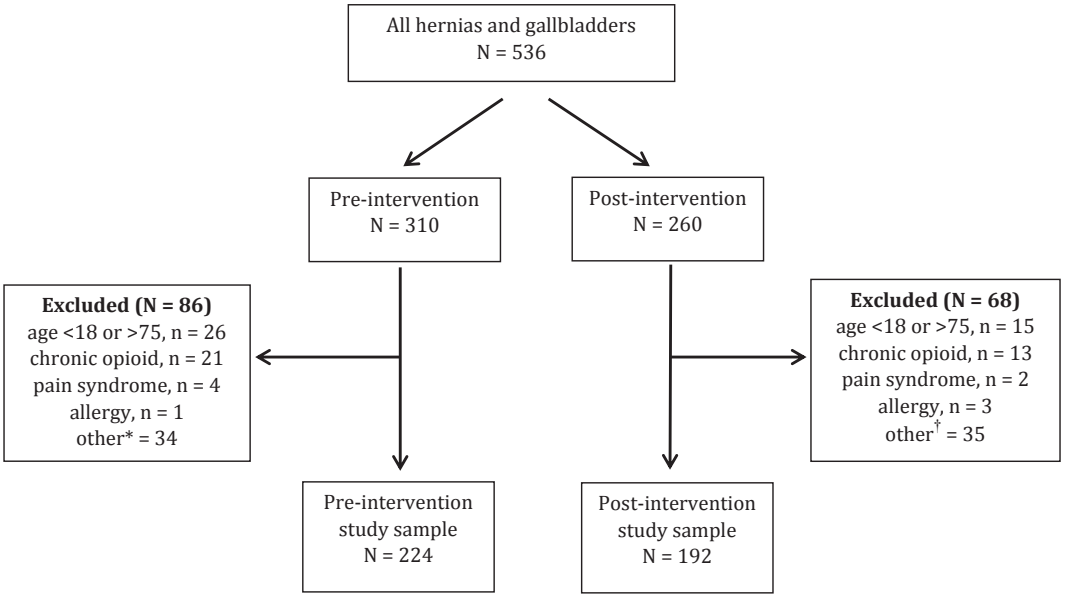

Figure 1. Flow chart of included patients. *n = 29 (did not complete the brief pain inventory; n = 5 (duplicates). †n = 31 (did not complete the brief pain inventory); n = 1 (duplicate); n = 2 (laparoscopic surgery); n = 1 (simultaneous procedure); and n = 1 (inpatient procedure).

Table 2. Patient Demographic Characteristics

Characteristic	Pre-intervention	Post-intervention	p Value
Study population after exclusion, n	224	192	—
Inguinal hernia, n (%)	67 (30)	59 (31)	
Ventral hernia (umbilical/epigastric), n (%)	53 (24)	44 (23)	—
Laparoscopic cholecystectomy, n (%)	104 (46)	89 (46)	—
Age, y, mean (SD)	50 (14)	51 (14)	0.51
Male sex, n (%)	118 (53)	107 (56)	0.57

Complications

There were no documented incidents of upper gastrointestinal bleeding or renal failure in either the pre-intervention or post-intervention cohorts.

DISCUSSION

Patient-reported average pain in the first week after operation was non-inferior after implementing the STOP Narcotics initiative in patients undergoing laparoscopic cholecystectomy and open ventral or inguinal hernia repair. Our intervention provides adequate analgesia for outpatient postoperative pain and at the same time reduces the amount of opioids used, reducing opioid prescriptions filled and increasing proper medication disposal. Patient-rated quality of pain control improved post-intervention for patients who underwent hernia repair but not laparoscopic cholecystectomy, possibly due to the low baseline experienced pain in both the pre- and post-intervention groups after cholecystectomy.

In accordance with previous literature, opioid reduction was achieved through provider education, opioid-reduced prescriptions and multimodal non-opioid analgesia strategies.[14,16,17] Although these opioid-reduction strategies are not new, STOP Narcotics is one of the first programs published that highlighted the integration of these multiple approaches into a standardized pain care bundle, effectively introduced at a division level.

An optional limited supply (10 tabs) of an opioid prescription to be filled only if required, and an expiry date of 7 days, is a novel component of this initiative that has not been studied in the literature and was successful in our study. Although only 45% of patients filled their opioid prescription, the patients who required their opioid prescription for additional pain control was 9% of the post-intervention group. This is less than the percentage of patients using opioids, as reported by other instituions.[10,11] Meta-analyses by the Cochrane Database of Systematic Reviews have indicated that ibuprofen and acetaminophen can be more

Table 3. Pre-Intervention and Post-Intervention Group Comparison

Primary and secondary outcomes	Pre-intervention (n = 224)	Post-intervention (n = 192)	p Value
Pain in first 7 postoperative days, mean (SD)			
All groups	2.3 (1.9)	2.1 (1.7)	0.12
Laparoscopic cholecystectomy (0 to 10)	1.9 (1.7)	1.9 (1.7)	0.39
Inguinal hernia (0 to 10)	2.8 (2.0)	2.4 (1.7)	0.13
Ventral hernia (0 to 10)	2.5 (2.2)	1.8 (1.8)	0.08
Quality of pain control* (good/very good)			
All groups	148 (69)	160 (85)	<0.001
Laparoscopic cholecystectomy, n (%)	72 (73)	65 (75)	0.76
Inguinal hernia, n (%)	41 (64)	53 (90)	0.001
Ventral hernia, n (%)	35 (70)	42 (98)	<0.001
Patient function interference (all groups), mean (SD)			
General activity (0 to 10)	5.2 (2.9)	4.9 (2.9)	0.24
Walking ability (0 to 10)	4.0 (3.1)	3.3 (2.8)	0.01
Work (0 to 10)	5.2 (3.4)	4.7 (3.3)	0.18
Sleep (0 to 10)	4.1 (3.2)	3.8 (3.1)	0.29
Enjoyment (0 to 10)	4.0 (3.2)	3.4 (3.0)	0.06

All outcomes are in means. Eleven-point (0 to 10) numeric rating scale from modified brief pain inventory: 0 = no pain, 10 = worst pain; 0 = no interference with function, 10 = complete interference with function.
*Rated from very poor to very good (5-point scale).

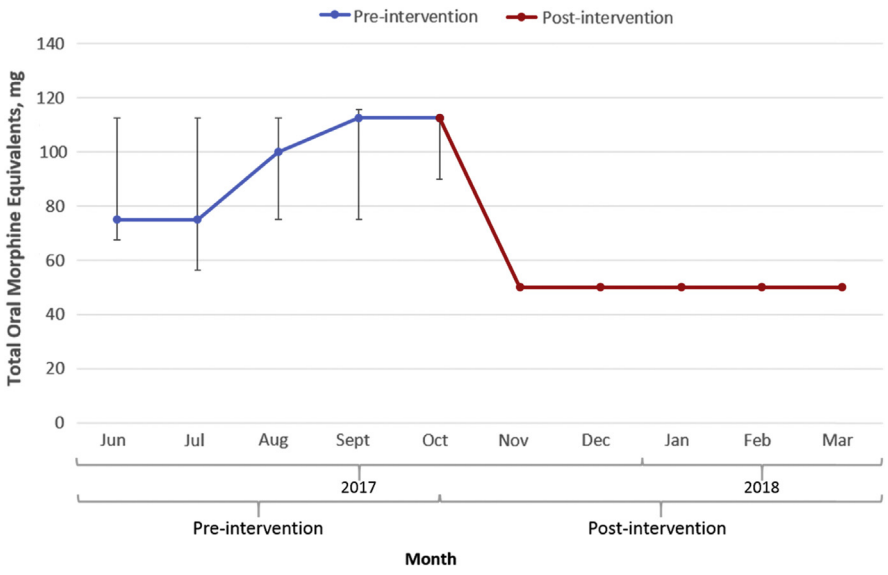

Figure 2. Median oral morphine equivalents prescribed in the pre- and post-intervention groups. Interquartile range demonstrated by bars. If there are no bars, interquartile range = median.

effective pain relievers than opioids for acute post-surgical pain, with ibuprofen 400 mg and acetaminophen 1,000 mg relieving pain in 73% of patients, and oxycodone 5 mg alone relieved pain in only 23% of patients.[25,26] In addition, we believe the prescription for a non-steroidal anti-inflammatory drug, as well as clear medication use instructions and patient education increased patient compliance for use of non-opioid analgesic medication. This also provided the patient with a tangible prescription option for pain control without filling the separate opioid prescription. Although only 9% of patients reported filling their opioid prescription for additional pain control, this is a significant portion of individuals, and we are still providing patients with an optional opioid-reduced prescription, as this is currently the best system in place to ensure adequate timely analgesia.

A multi-pronged patient education protocol to reduce opioid use was introduced in this study. Our results were consistent with previous literature, which suggests that verbal and written perioperative education, including clarifying patient expectations and providing non-opioid use instructions, increases patient satisfaction and reduces opioid use.[27,28] This is consistent with our findings, as

Table 4. Pre-Intervention and Post-Intervention Medication Comparison

Medication comparison	Pre-intervention (n = 224)	Post-intervention (n = 192)	p Value
Narcotic prescription given			
OMEs, median (25^{th}, 75^{th})	100 (75-116)	50 (50-50)	<0.001*
No. of pills, median (25^{th}, 75^{th})	20 (15-30)	10 (10-10)	<0.001*
Narcotic prescription used			
OMEs, median (25^{th}, 75^{th})	36 (19-56)	25 (0-50)	<0.001*
No. of pills, median (25^{th}, 75^{th})	7.5 (5-15)	5.0 (0-10)	<0.001*
Surgeons prescribing more than median 50 OMEs, n/N (%)	20/20 (100)	5/16 (31.3)	<0.001*
Narcotic prescription filled, n/N (%)	173/182 (95)	78/172 (45)	<0.001*
NSAID use, n (%)	96 (43)	134 (70)	<0.001*
Acetaminophen use, n (%)	114 (51)	151 (79)	<0.001*
Simultaneous NSAID + acetaminophen use, n (%)	58 (26)	88 (46)	<0.001*
Prescription renewal, n/N (%)	6/173 (3.5)	2/78 (2.6)	0.62
Appropriate medication disposal, n/N (%)	13/173 (7.5)	18/78 (23)	<0.001*

NSAID, non-steroidal anti-inflammatory drug; OME, oral morphine equivalent.
*Significant.

Table 5. Post-Intervention Patient Adherence

Patient adherence	Post-intervention (n = 192)
Patients received instruction sheet, n (%)	185 (97)
Patients found the instruction sheet helpful, n (%)	174 (94)
Reason for filling prescription, n	78
Patient was told to fill it, n (%)	30 (38.5)
Just in case the patient needed it, n (%)	34 (43.6)
For additional pain control, n (%)	17 (21.8)

94% of our post-intervention group rated these instruction sheets as helpful.

One of the main concerns of surgeons when initiating our study was a potential increase in office calls for prescription refills. Indeed requests for renewals was <8.7% reported by Sekhri and colleagues,[29] which is likely attributable to our strict inclusion criteria of elective common outpatient surgical procedures. Our results support other literature, which suggest that the probability of refill requests is not associated with prescription strength, and that actual opioids taken represents a small proportion of total opioid prescribed.[10,11,29,30] Surgeons need to acknowledge that prescribing a large number of opioid pills "just in case" or to "avoid that phone call" is no longer acceptable, especially in the current crisis of opioid abuse.[9]

Our study has several strengths: it was a standardized, division-wide initiative with significant nurse, anesthesia, and surgeon buy-in. Since study completion, compliance has not appeared to wane, and we have witnessed spill over to the vast majority of outpatient procedures, with additional extension to acute and elective general surgery. However, it is not without limitations. First, our study design is a prospective cohort study and therefore has inherent bias with the observational design, as well as limits in external validity related to our exclusion criteria. There was a firm belief in the division of general surgery that excess opioid prescribing was a priority needing to be addressed, therefore, this was not designed as a randomized controlled trial. An evidence-based intervention was designed by the Departments of Anesthesia and General Surgery and implemented on a certain date, but there might have been small changes in prescription habits being made by some surgeons during the period leading up to the start date of the intervention. Finally, our study does not demonstrate perfect compliance by patients, nurses, or surgeons. Some perioperative nurses were still instructing patients to fill their prescriptions early in the intervention period out of habit, which was contrary to the education given. Although the number of surgeons prescribing more than a median of 50 OMEs was significantly reduced, at least one surgeon also did not change his/her practice. The number of OMEs for this surgeon actually increased in the post-intervention period, and 2 others decreased the median OMEs prescribed, but not to the recommended level.

"Standardized patient care bundles" or "care pathways" are increasingly used to institute multiple evidence-based interventions in quality improvement initiatives. Although every patient requires an individualized approach, our study has shown the value of a standardized bundle, to guide surgeons in ensuring adequate postoperative pain control, and reducing opioids in the outpatient laparoscopic cholecystectomy and open ventral and inguinal hernia repair.

CONCLUSIONS

For outpatient open inguinal or ventral hernia repair and laparoscopic cholecystectomy, a standardized pain care bundle (STOP Narcotics) significantly decreased opioid prescribing, often eliminating opioid use all together, and adequately treating postoperative pain. This decreases the opioid exposure risk in the patient, and potentially prevents diversion of excess medication for abuse. We have demonstrated that this change can be achieved through patient education, multimodal non-opioid analgesic techniques, and dedicated system change by nurses, anesthetists, and surgeons. Considering the number of elective outpatient procedures performed each year, the opportunity to spread this standardized intervention targeting a reduction in opioid prescribing could realistically impact the opioid epidemic in a truly meaningful way. We are currently in the process of implementing the intervention bundle in other outpatient general surgical procedures in our center. Similar standardized interventions can be implemented in other institutions, and expanded to other more complex procedures and surgical disciplines.

Author Contributions

Study conception and design: Hartford, Van Koughnett, Murphy, Hilsden, Clarke, Parry, DK Gray, Leslie

Acquisition of data: Hartford, Hilsden, Allen, SD Gray

Analysis and interpretation of data: Hartford, Van Koughnett, Murphy, Hilsden, Clarke, Parry, DK Gray, Leslie, Allen, Vogt, SD Gray

Drafting of manuscript: Hartford, Van Koughnett, Murphy, Vogt, Leslie, SD Gray

Critical revision: Hartford, Van Koughnett, Murphy, Vogt, Hilsden, Clarke, Allen, Parry, DK Gray, Leslie

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POSTOPERATIVE PAIN MANAGEMENT STRATEGY

Patients were asked to notify their surgeon if they had a history of stomach ulcers, liver disease, kidney disease, or allergies to any of these medications.

First 3 days (72 hours) after operation:

1. meloxicam 7.5 mg: 1 tablet po, q12h, for 3 days (prescription).
2. acetaminophen 500 mg; 1 to 2 tablets po q6h, for 3 days.

If the patient does not have coverage for meloxicam, you may prescribe the following: naproxen 200 mg (Aleve; Bayer): Take 2 tablets orally, every 12 hours, for 3 days. To maximize pain relief, it was strongly recommended to take both of these medications.

After 3 days (72 hours) after operation:

1. continue acetaminophen 500 mg: 1 to 2 tablets po q6h as needed.
2. ibuprofen 400 mg; 1 tablet po q6h, as needed.

Patients are given a prescription with the following instructions:

Tramadol 50 mg: 1 tab po q6h as needed (10 tabs) (expiry date 7 days)

If the patient does not have coverage for tramadol, you may prescribe the following:

Codeine 30 mg: 1 tab po q6h as needed (10 tabs) (expiry date 7 days)

Patients were given instructions to only fill this prescription if the above measures do not adequately control their pain.