Wide Variation and Excessive Dosage of Opioid Prescriptions for Common General Surgical Procedures

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Objective: To examine opioid prescribing patterns after general surgery procedures and to estimate an ideal number of pills to prescribe.

Background: Diversion of prescription opioids is a major contributor to the rising mortality from opioid overdoses. Data to inform surgeons on the optimal dose of opioids to prescribe after common general surgical procedures is lacking.

Methods: We evaluated 642 patients undergoing 5 outpatient procedures: partial mastectomy (PM), partial mastectomy with sentinel lymph node biopsy (PM SLNB), laparoscopic cholecystectomy (LC), laparoscopic inguinal hernia repair (LIH), and open inguinal hernia repair (IH). Postoperative opioid prescriptions and refill data were tabulated. A phone survey was conducted to determine the number of opioid pills taken.

Results: There was a wide variation in the number of opioid pills prescribed to patients undergoing the same operation. The median number (and range) prescribed were: PM 20 (0-50), PM SLNB 20 (0-60), LC 30 (0-100), LIH $30\,(15-70),$ and IH $30\,(15-120).$ Only 28% of the prescribed pills were taken. This percentage varied by operation: PM 15%, PM SLNB 25%, LC 33%, LIH 15%, and IH 31%. Less than 2% of patients obtained refills.

We identified the number of pills that would fully supply the opioid needs of 80% of patients undergoing each operation: PM 5, PM SLNB 10, LC 15, LIH 15, and IH 15. If this number were prescribed, the number of opioid initially prescribed would be 43% of the actual number prescribed.

Conclusions: There is wide variability in opioid prescriptions for common general surgery procedures. In many cases excess pills are prescribed. Using our ideal number, surgeons can adequately treat postoperative pain and markedly decrease the number of opioids prescribed.

Keywords: dosage, general surgery, opioids, overdose, pills, postoperative pain control, prescription, narcotics

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pioid overdose is now the leading cause of injury related death in the United States, having surpassed motor vehicle accidents for the first time. 1 It is estimated that deaths secondary to prescription opioid overdose have quadrupled in the past 15 years, and now reach almost 19,000 per year.^{1,2}

One potential driver of this mortality is that there has been a dramatic rise in the rate of opioid prescribing in the United States over the past decade. In 2012, 82.5 opioid prescriptions were written per 100 persons; which has quadrupled since 1999. 3-7 This amount is estimated to supply every adult American with 5 mg of hydrocodone every 6 hours for 45 days. 4 Some suggest that the increase in opioid

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prescribing practice is due in part to the identification of pain as a "fifth vital sign" following the institution of rigorous pain assessment standards by the Joint Commission on Accreditation of Healthcare Organizations in 2001 and the curtailing of restrictions that previously limited opioid prescriptions to treat cancer related pain only.4,8,9

The availability of prescription opioids has resulted in their widespread abuse. Over 5 million Americans report that they currently (within 30 days) abuse prescription opioids and 10.3 million have abused them at some point in their lifetime.^{2,4} It has been noted that although most of these pills originated from a licensed prescriber, only 20% of users were the legitimate recipient of the initial prescription, with 71% of users having received the drug through methods of diversion. ^{4,10} In addition, it is reported that 55% of these people received pills for free from a family member or friends who had excess pills.^{4,10} Parallel to the rise in prescription opioid use, the rate of heroin use has been rising.^{7,11,12} This is of concern because 50% to 85% of heroin users began by abusing prescription opioids first. 11,13

In recognition of this deadly problem, both state and federal legislation has been introduced to attempt to control access to prescription opioids and to increase funding for prevention of abuse. 14 In 2014, the Federal Drug Enforcement Agency (DEA) rescheduled hydrocodone combination products from schedule III to schedule II controlled substances, effectively eliminating the ability to authorize refills or to call or fax in prescriptions to pharmacies. 15 This change requires patients to return to clinic to receive additional opioids. As of March 2016, there are now over 375 proposals in state legislatures that aim to regulate several aspects of prescribing practices for opioid analgesics in attempts to decrease excess pills. A bill in Massachusetts passed in March that restricts prescription opioids to a 7-day supply for acute pain. 16 In addition, the Center for Disease Control (CDC) recently issued guidelines for primary care physicians treating chronic pain with opioids; however, these guidelines provided little information on recommendations for acute pain. 17 The guideline states that because chronic pain treatment begins with acute pain treatment, physicians should limit initial opioid prescriptions by prescribing "no greater quantity than needed."17 The FDA has stated that "until clinicians stop prescribing opioids far in excess of clinical need, this crisis will continue unabated."18

The task of decreasing excess opioid prescriptions has been left in the hand of the provider. Providers both have the societal imperative to avoid overprescribing and the obligation to ensure their patients postoperative pain is addressed. Although broad guidelines for treating postoperative pain have been formulated, there are no clear operation-specific guidelines for opioid prescriptions for general surgical procedures. 19 A few studies exist that address optimal postoperative opioid prescriptions in urologic, oral, hand, and outpatient upper extremity surgery. $^{20-23}$ Given the lack of information on ideal prescribing practices for general surgery cases, we evaluated the variation in current opioid prescribing practices and sought to

	Partial Mastectomy	Partial Mastectomy With Sentinel Lymph Node Biopsy	Laparoscopic Cholecystectomy	Laparoscopic Inguinal Hernia Repair	Open Inguinal Hernia Repair	Total
Cases performed	183	112	240	80	85	700
Number patients excluded	8	8	32	4	6	56 (8.0%)
Opioid use/abuse	2	5	24	3	4	38 (5.4%)
Complications	6	3	6	1	2	18 (2.6%)
Patients analyzed	175	104	208	76	79	642
Patients receiving opioid prescription	129 (73.7%)	92 (88.5%)	205 (98.6%)	76 (100%)	79 (100%)	581 (90.5%)
Opioid pills prescribed						
Mean (±SD)	19.8 (10.2)	23.7 (11.3)	35.2 (16.9)	33.8 (9)	33.2 (15.7)	
Median	20	20	30	30	30	
Range	0-50	0-60	0-100	15-70	15-120	
Patients received refills	1 (0.6%)	0	9 (4.3%)	1 (1.3%)	1 (1.3%)	12 (1.9%)

TABLE 1. General Surgery Cases Performed and Opioids Prescribed

estimate a reasonable number of pills to prescribe for common outpatient general surgery procedures.

METHODS

We evaluated the 5 most common outpatient general surgery procedures performed at our academic medical center in 2015. These were partial mastectomy, partial mastectomy with sentinel lymph node biopsy, laparoscopic cholecystectomy, laparoscopic inguinal hernia repair, and open inguinal hernia repair. Postoperative opioid prescriptions entered into the electronic medical record (EMR), refill data, and patient outcomes were tabulated. Only opioid naïve patients, defined as having no history of opioid use within the 30 days prior to their procedure, were included in this analysis. Patients with a history of opioid abuse and those with postoperative complications (which might be painful and require additional opioids) were also excluded.

As patients were prescribed a variety of different opioid formulations, we converted the number of pills prescribed to an equianlagesic equivalent.²⁴ One pill was considered to be the analgesic equivalent of 5 mg of oxycodone.

A phone survey was then attempted on all patients who were operated on from June through December 2015 and also received an opioid prescription (n=330). One hundred forty seven patients were contacted. Patients were queried on how much of their prescribed opioid was taken and whether they required a refill. Twenty patients were not able to recall the amount of opioid they took. Patients who did recall their usage were assigned "% taken" estimations. Those who reported no opioid use were assigned "0% pills taken," those who reported 1% to 49% used were assigned "25% taken," those reporting 50% to 99% used were assigned "75% taken," and those who reported all pills used were assigned "100% taken."

The Dartmouth Committee for the Protection of Human Subjects approved this project and determined that individual patient consent was not required.

RESULTS

In 2015, 183 partial mastectomies, 112 partial mastectomies with sentinel node biopsy, 240 laparoscopic cholecystectomies, 80 laparoscopic inguinal hernia repairs, and 85 open inguinal hernia repairs were performed (Table 1). Thirty eight (5.4%) patients were excluded for recent opioid use or abuse and 18 (2.6%) for postoperative complications (9 hematomas requiring evacuation, 2 wound dehiscence, 2 retained gallstones, 1 bile leak, 1 seroma requiring drainage, 2 urinary retention, and 1 diarrhea requiring admission). Six hundred forty two cases underwent further analysis.

Five hundred eighty one (90.5%) patients were prescribed an opioid (Table 1). This ranged from 73.7% of partial mastectomy patients to 100% of laparoscopic inguinal hernia and open inguinal hernia patients. Of the patients who received opioids, 80.1% received oxycodone 5 mg, 9.5% received hydrocodone 5 mg/acetaminophen 325 mg, 7.4% received hydromorphone 2 mg, 1.7% received tramadol 50 mg, 0.9% received oxycodone 5 mg/acetaminophen 325 mg, and 0.3% received acetaminophen 300/codeine 30 mg.

There was a wide variation in the number of opioid pills prescribed for each operation (Table 1 and Figs. 1A, 1C, 2A, 3A, and 3C). The median number prescribed for partial mastectomy and partial mastectomy with sentinel node biopsy was 20 pills. The median number prescribed for laparoscopic cholecystectomy, laparoscopic inguinal hernia repair, and open inguinal hernia repair was 30. As shown in Figure 1A, patients undergoing partial mastectomy were prescribed a range of 0 to 50 pills. For the partial mastectomy with sentinel node biopsy patients, the range was 0 to 60 (Fig. 1C), whereas laparoscopic cholecystectomy patients were prescribed 0 to 100 pills (Fig. 2A). Open inguinal hernia patients received the largest range of pills, 15 to 120 (Fig. 3C).

When we evaluated the prescribing patterns of individual providers, we observed that there was a wide range in the median number of pills prescribed by different providers, and that individual providers prescribed a wide range of pills to patients undergoing the same surgery. For example, of the 32 providers that prescribed opioids for patients undergoing laparoscopic cholecystectomy, 7 providers prescribed opioids for at least 10 patients. One of these providers prescribed the same number of pills (35) to all their patients. The other 6 providers prescribed a range of pills to their patients. The median number of pills prescribed by these providers and the range were as follows: 20 (15-50), 30 (15-30), 30 (10-50), 37 (10-80), 60 (40-100), and 65 (60-80).

There was no significant relationship between patient age and the number of opioids prescribed.

We obtained phone survey data on prescription opioid pills actually taken for 127 patients (20 partial mastectomies, 21 partial mastectomies with sentinel node biopsy, 48 laparoscopic cholecystectomies, 20 laparoscopic inguinal hernias, and 18 open inguinal hernias). As shown in Table 2, 28.7% of the pills that were prescribed were taken; this ranged from 14.7% in the partial mastectomy and laparoscopic inguinal hernia patients to 32.7% in the laparoscopic cholecystectomy patients. Partial mastectomy with sentinel node and open inguinal hernia repair patients reported taking 25.7% and 31.1% of the prescribed pills, respectively. A total of 3545 pills were prescribed to these 127 patients, therefore 2527 (71.3%) excess pills were prescribed.

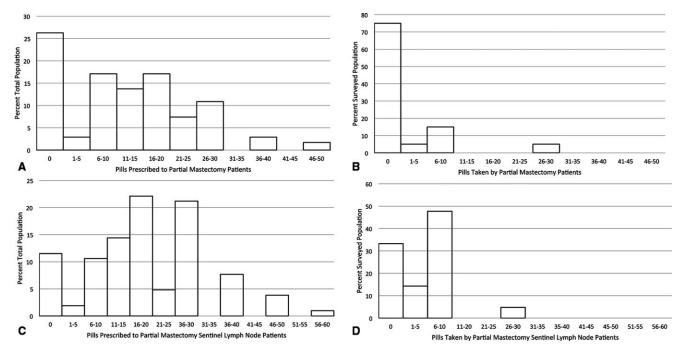


FIGURE 1. Frequency of opioid pills prescribed (A, C) and taken (B, D) after partial mastectomy and partial mastectomy with sentinel lymph node biopsy.

The number of pills taken by individual patients is compared with the number prescribed for individual patients in Figures 1-3. As shown in Figure 1B, 75% of partial mastectomy patients who were prescribed an opioid did not take any. A substantial number of patients in each operative category who were prescribed opioids did not take any: partial mastectomy with sentinel node biopsy: 33% (Fig. 1D); laparoscopic cholecystectomy 34% (Fig. 2B); laparoscopic inguinal hernia repair 45% (Fig. 3B) and open inguinal hernia repair 22% (Fig. 3D). When the proportion of patients who were not prescribed any opioids were combined with the proportion who were prescribed an opioid and did not take any, the following proportion of patients did not require any opioids after their surgeries: partial mastectomy 82%, partial mastectomy with sentinel node biopsy 41%, laparoscopic cholecystectomy 35%, laparoscopic inguinal hernia repair 45%, and open inguinal hernia repair 22%.

We calculated an "ideal" number of pills to prescribe for each operation by determining the number of pills that would satisfy approximately 80% of patients' postoperative opioid use. The ideal number for partial mastectomy was calculated to be 5 pills: 80% of partial mastectomy patients contacted in the phone survey took 5 pills or less (Fig. 1B). The ideal number for partial mastectomy with sentinel node biopsy was 10: 95.2% of partial mastectomy with sentinel node biopsy patients took 10 pills or less (Fig. 1D). The ideal number for laparoscopic cholecystectomy was 15: 85.4% of laparoscopic cholecystectomy patients took 15 pills or less (Fig. 2B). The ideal number for laparoscopic inguinal hernia repair was calculated to be 15: 75% of patients took 15 pills or less (Fig. 3B). The ideal number for open inguinal hernia repair was calculated to be 15: 83.3% of patients took 15 pills or less (Fig. 3D).

A total of 17,167 pills were prescribed for the 642 patients we analyzed. If these patients were prescribed the "ideal" number of pills for each operation, 7360 pills, (42.9% of the actual number prescribed) would have been prescribed. This would lead to a savings of 9787 (57.1%) pills.

Twelve patients (1.9%) were documented in our EMR as having obtained an additional opioid prescription post-operatively.

None of the patients contacted through our phone surveys indicated they obtained a refill from a provider outside of our EMR system. Nine of these 12 patients underwent laparoscopic cholecystectomy. One patient who did not receive an opioid prescription initially required one.

Of the 127 patients with completed phone survey data, 117 had excess pills. Nine percent of these patients disposed of their excess opioids in an FDA approved fashion²⁵: 5% returned them to a DEA approved collection site, 4% flushed them down the toilet. Three percent mixed their pills with coffee grounds or kitty litter and disposed of them in the trash; 14% reported disposing them directly in the trash. The rest of the patients didn't recall a disposal method or still had them in their possession.

DISCUSSION

We found that providers at our institution prescribe a wide range of opioid pills to treat acute pain after common general surgical procedures. Reports of patients undergoing oral, hand, upper extremity, and urologic surgery have also identified wide variations in the number of opioid pills prescribed. 20-23 Variation in the number of pills prescribed can be because of providers' perception that some patients are going to need more opioids than others (patient-centered variation) or it can be because of differences in the "standard" number of pills prescribed for a particular operation by a provider. Our data indicates that both of these mechanisms contribute to variation: the median number of pills prescribed by individual providers for a particular operation varied by a factor of 3 and most individual providers prescribed a wide range of pills for patients undergoing the same operation.

We also found that opioid pills are greatly over-prescribed for the treatment of acute postoperative pain in general surgery patients: over 70% of the prescribed pills were never taken. Similar results were found by Rodgers et al²⁰; 67% of the pills prescribed patients undergoing upper extremity surgery were never taken. Why do providers overprescribe? One reason may be a lack of knowledge

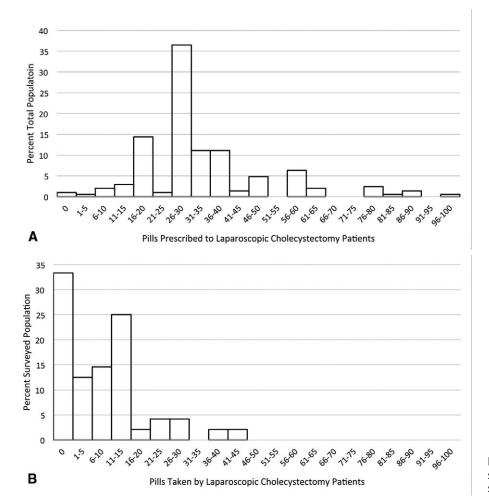


FIGURE 2. Frequency of opioid pills prescribed (A) and taken (B) after laparoscopic cholecystectomy.

of how many pills most patients actually take to relieve postoperative pain. Providers also want to make sure that the pain patients experience from surgery is minimized, so they prescribe enough to satisfy the patient who requires the most opioids. Furthermore, it is likely that an additional driver of overprescription is the desire to avoid the inconvenience (both to the patient and the provider) of a return trip to the clinic to obtain a prescription refill. This is a substantial burden in rural communities such as ours, where patients may live a long distance from the site where their surgery was performed. It is likely that these forces were driving opioid prescriptions at our center, as less than 2% of our patients obtained opioid prescription refills.

Overprescribing opioids would be acceptable if the cost of opioid prescriptions to individual patients and the cost to society were negligible. However, the current epidemic of deaths from opioid overdose, largely fueled by diversion of prescription opioids, makes it clear that the cost to society is not negligible, and must be considered when prescribing opioids for individual patients. In an attempt to balance this societal mandate and the need to satisfy the analgesic needs and minimize the inconvenience of returning for refills for most patients, we felt that satisfying 80% of patients' opioid requirements with the initial prescription was reasonable. Using this as a best practice guideline, we have shown that we can decrease the number of opioid pills initially prescribed for common general surgical operations to 43% of the number actually prescribed.

We are currently evaluating the use of our ideal opioid prescription numbers as part of a best practice guideline in a prospective clinical trial. By setting patient expectations preoperatively regarding the number of opioid pills that will be needed and by routinely incorporating the use of nonopioid analgesics such as ibuprofen and acetaminophen in the treatment of acute postoperative pain (and using other evidence based techniques recommended by the American Pain Society¹⁹), we hypothesize that much fewer than 20% of patients will request opioid refills.

We have also demonstrated that patients undergoing partial mastectomy require very little, if any, opioid for postoperative pain. Twenty seven per cent of partial mastectomy patients did not receive an opioid prescription postoperatively and only 1 of these patients required a prescription after her surgery. Eighty two percent of our partial mastectomy patients did not require any postoperative opioids.

Even if the number of opioids prescribed in the future more closely matches the number taken by the intended user, there will be some opioid pills left over. Proper disposal will decrease the number of these pills available for diversion. The FDA recommends disposing of unused opioids at a DEA approved collection site (eg, in a lock-box at a local police department) or flushing them down the toilet.²⁵ Another recommended safe method of disposal is to place opioid tablets into a sealable plastic bag, add a small amount of water to dissolve them, add dirt, kitty litter or coffee grounds to the mix,

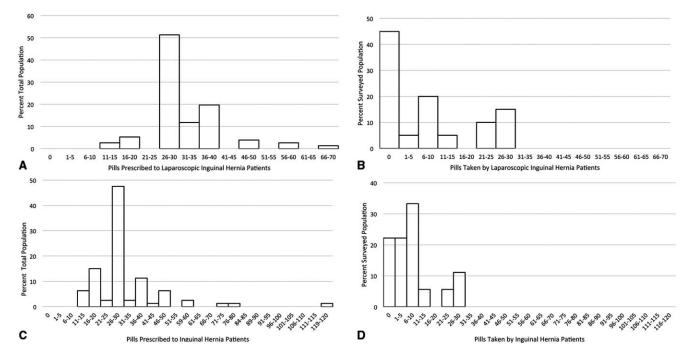


FIGURE 3. Frequency of opioid pills prescribed (A, C) and taken (B, D) after laparoscopic inquinal hernia repair and open inquinal hernia repair.

TABLE 2. Opioid Pills Taken										
Operation	Partial Mastectomy	Partial Mastectomy With Sentinel Node Biopsy	Laparoscopic Cholecystectomy	Laparoscopic Inguinal Hernia Repair	Open Inguinal Hernia Repair	All Cases				
Surveys completed	20	21	48	20						
Pills prescribed	415	490	1450	650	540	3545				
Pills taken	61 (14.7%)	126 (25.7%)	474 (32.7%)	189 (14.7%)	168 (31.1%)	1018 (28.7%)				
Pills remaining	354 (85.3%)	364 (74.3%)	976 (67.3%)	461 (85.3%)	372 (69.9%)	2527 (71.3%)				

seal the bag, and dispose with household trash. 26 We found that very few patients (9%) disposed of their medications according to FDA recommendations and few patients were aware what appropriate disposal methods were. Bates et al²³ also reported that that only 1% of their patients returned excess pills to a sanctioned facility, indicating this is a general problem. There seems to be a need for patient educational efforts, initiatives to make proper disposal more convenient, and strategies to target specific patient populations who might be more likely to engage in diversion.

A limitation of our study was that opioid use information was collected retrospectively using phone surveys of patients who might have had surgery up to 6 months ago. We consider this data to be estimations of the number of opioid pills used; trials that prospectively collect this information will likely generate more precise estimates of opioid use. In addition, opioid refill data was only collected from patients who had documented refills in our EMR and those who were contacted through phone surveys. Although it is possible that there were patients who obtained refills through other means that were not captured in our data collection, discussion with patients who were contacted through our phone surveys would indicate that this number is low.

We found that there is wide variation in opioid prescriptions at our institution for common general surgery cases. We found that patients actually take much fewer opioids than they are prescribed, and have established an "ideal" number to prescribe which is substantially lower than what is currently prescribed. By incorporating these findings into practice it will be possible to both adequately treat patients' postoperative pain and decrease the amount of unused opioid pills available for misuse, abuse, or diversion.

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