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Opioid Prescription and Use After Laparoscopic Cholecystectomy

Valynn Christina Haslam

A thesis submitted to the faculty of
Brigham Young University
in partial fulfillment of the requirements for the degree of
Master of Science

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ABSTRACT

Opioid Prescription and Use After Laparoscopic Cholecystectomy

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Background: Opioid abuse has become a serious public health issue. While adequate pain management is an ethical responsibility for health care providers, responsible stewardship of controlled substances is of equal concern. Opioids are often prescribed for treatment of acute pain post-operatively. The purpose of this study is to examine opioid prescription practices and use of opioids after laparoscopic cholecystectomy.

Methods: A convenience sample of 42 patients scheduled for laparoscopic cholecystectomy were enrolled in the study. Using a descriptive study design, patients were interviewed by phone 6-10 days post-operatively using a scripted questionnaire. The average number of excess prescribed opioid medication pills, patient perception of prescribed quantity, duration of opioid use, and average pain score with and without activity on the date of contact was determined. Participants were also asked about any instruction received regarding proper medication disposal.

Results: A final sample of 34 patients met inclusion criteria and completed the phone questionnaire. Average number of excess pills ranged from 0-42 (M:14; SD 11.7). Nearly half of patients (47%) perceived the prescribed quantity as 'too many', 41% indicated the prescription quantity was 'just right' but many had left-over pills, and 11.8% believed the prescribed quantity to be 'too few'. The average number of days of opioid use following surgery was 4.2 days with 71% of patients using opioids for five or fewer days. The average pain score at the time of the interview was 2.0 without activity, and 4.1 with activity. Almost all (88%) patients did not recall any instruction or knowledge of appropriate medication disposal. A few participants volunteered plans to dispose of unused medications by various means, while others indicated they planned to keep excess pills.

Conclusion: Pain management experts advise using around-the-clock regimens of over-the-counter analgesics (i.e. acetaminophen or non-steroidal anti-inflammatory medication (NSAID)) and using opioids sparingly as an adjunct therapy following uncomplicated laparoscopic cholecystectomy. The data in this study indicated currently prescribed opioid quantities after laparoscopic cholecystectomy are more than adequate and could be decreased without affecting adequate pain management. In addition, the data show a large majority of patients are not provided with personalized instruction on proper medication disposal procedures.

Keywords: laparoscopic cholecystectomy, opioid, medication disposal, prescription, education

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Opioid Prescription and Use After Laparoscopic Cholecystectomy

Pain is the brain's interpretation of actual or perceived injury. Pain resolves as injury heals or the stimuli is removed (National Pharmaceutical Council, 2001). In 1968, Nurse Margo McCaffery coined the phrase, "Pain is whatever the experiencing person says it is, existing whenever he says it does" (McCaffery & Pasero, 1999, p. 17). Throughout the 1990s, McCaffery's definition of pain resulted in a transformation of beliefs and attitudes surrounding pain management that swept across the United States (U.S). Position statements from quality improvement agencies and other organizations demanded health care professionals be more aggressive in treating pain and relieving suffering. In 1998, the Veteran's Health Administration (VHA) implemented a process where pain was assessed as the '5th vital sign,' as recommended by the American Pain Society, and severity was scored on a 0-10 scale (U.S. Department of Veterans Affairs, 2000). By 2001, The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (2001) mandated certain pain assessment and management standards as part of accreditation requirements. Simultaneously, physicians in training were taught to prescribe opioids "without enough training or support to do so safely" (Murthy, 2016, p. 1). As a result, and in an attempt to control pain, prescriptions for opioid medications increased dramatically from 1991 to 2013. The sharp increase in number of prescribed opioids was paralleled by a dramatic increase in the number of opioid-related deaths (National Institute of Health, 2014, Figure 1).

One common reason for opioid prescription is to treat post-operative pain. Historically, surgical intervention was considered an invasive treatment option, resulting in significant pain, extended recovery time, and residual scarring. Development of laparoscopes and other sophisticated surgical devices, however, have provided means for less-invasive surgical

techniques. Gallbladder removal, one of the most frequently performed surgeries in the U.S., was once considered a major surgery, requiring a very large incision to open the abdomen and days spent in the hospital post-operatively. The laparoscopic approach to gallbladder removal (laparoscopic cholecystectomy) has now become the gold standard as it results in significantly shorter recovery time, minimal scarring, and less post-operative pain (Soper & Malladi, 2016). Most patients who undergo laparoscopic cholecystectomy are discharged home on the same day.

While the reality and severity of pain and the need for adequate treatment should be recognized, it is well documented that opioids are often over prescribed following invasive procedures. In 2011, a study examining post-operative opioid use following urological surgery, found 67% of patients were prescribed an excessive number of opioid pills post-operatively (Bates, Laciak, Southwick, & Bishoff, 2011). In a more recently published study examining opioid use after outpatient orthopedic surgery, Kumar et al. (2017), found health care providers were prescribing up to 75% more opioids than the patient used. “Prescribing more medication than the amount likely to be needed can make unused medication available for misuse and abuse” (U.S. Department of Health and Human Services, Centers of Disease Control and Prevention, 2010, p. 156).

Multi-modal approaches to pain management are often reported to manage pain, thus resulting in a decreased need for opioids. The American Society of Anesthesiologists (ASA) (2011) strongly supports multi-modal pain management therapy- including use of acetaminophen, non-steroidal anti-inflammatory medications (NSAIDs) and calcium channel alpha-2 antagonists, such as gabapentin or Pregabalin to augment opioid effectiveness. However, “despite years of advances in pain management, the mainstay of post-operative pain therapy in many settings is still opioids” (Garimella & Cellini, 2013, p. 192).

Opioids are effective analgesics, not by removing the pain stimulus or potentiating tissue healing, but by decreasing the central nervous system's (CNS) perception of pain stimuli, thus increasing a patient's tolerance for pain (National Institute of Health, 2016). The euphoria associated with opioid use is a primary reason why opioids are highly addictive and, as a result, have high potential for misuse and abuse. Jones, Paulozzi, and Mack (2014) found those who abused opioids on a short-term basis identified their supply sources as family and friends who had leftover medication. "One area for public health action is to [educate] patients to properly dispose of leftover medication. Disposing of leftover medication will prevent accidental use by children, pets, or anyone else as well as prevent theft for misuse" (U.S. Department of Health and Human Services, Centers of Disease Control and Prevention, 2010, p. 156). Both Bates, et al. (2011) and Kumar, et al. (2017) found education regarding proper disposal of leftover opioid prescription medication was lacking. Therefore, the purpose of this descriptive research study is to examine providers' opioid prescriptive practices and patients' pain levels and behavior following uncomplicated laparoscopic cholecystectomy.

Research Questions

1. How do patients describe their pain level and pain management approximately 1 week following uncomplicated laparoscopic cholecystectomy?
2. What are the patient perceptions of the amount of prescribed pain medication following uncomplicated laparoscopic cholecystectomy?
3. What is the patients' reported knowledge of how to dispose of unused opioids?

Methods

Sample and Setting

Following Institutional Review Board approval, a convenience sample of 42 patients scheduled for elective laparoscopic cholecystectomy were enrolled in the study. Surgeries were performed in a tertiary care hospital's same-day-surgery department between November 2016 and February 2017. Designated pre-operative nursing staff obtained informed consent pre-operatively. A descriptive study design was used including chart reviews and structured telephone interviews conducted with patients who underwent a scheduled uncomplicated laparoscopic cholecystectomy approximately 1 week previously. Inclusion criteria were defined as patients scheduled for a non-emergent, uncomplicated laparoscopic cholecystectomy who spoke English, were aged 18-65 years, and were determined by their physician to be competent. Exclusion criteria included persons currently treated for chronic pain, unplanned in-patient admission post-operatively, self-disclosed history of narcotic or illicit drug abuse, and a surgical procedure complicated by biliary duct obstruction requiring endoscopic retrograde cholangiopancreatography (ERCP).

Patients were recruited for the study upon check-in pre-operatively by designated pre-operative nursing staff prior to administration of any medication. Written consent was obtained after explaining the study and answering any questions the patients had. During the consent process, the patient provided a phone number for contact approximately 1 week post-operatively.

The researcher reviewed the operative report to determine if the patient met inclusion criteria. The researcher also transcribed, from the electronic record onto a hard copy data collection form, the patients' demographic information (age, ethnicity, gender, date of surgery), and the number of opioid medication pills prescribed by the health care provider upon discharge.

In addition to the chart review, the researcher interviewed each patient, by phone, 6-10 days post-operatively. Notes from the interviews were transcribed electronically. A maximum of three attempts were made to contact enrolled participants before being eliminated from the study. Pain scores were measured using a 10-point numeric rating scale, with zero being no pain, and 10 being the worst pain.

Instrument

There were no validated instruments measuring opioid prescription practices after same day surgery. The instrument consisted of a structured questionnaire developed by the researchers based upon literature review and expert opinion. The questionnaire included 11 questions plus demographic information (age, gender, ethnicity, date of surgery, surgeon). Questions included self-rated pain levels with and without activity, the number of prescribed opioid pills following surgery, the number of opioid pills taken up until the time of the interview, other medications used for pain control, side effects experienced, a rating of the amount of narcotics prescribed (too few, just right, or too many) and whether the patient had received instructions about disposal of unused opioids.

Data Analysis

Data were transcribed and entered into an Excel spreadsheet and was then entered into SPSS version 22 for analysis. A descriptive analysis was completed for quantitative variables including mean, standard deviation, range and distribution of the data. Because of the small sample size and the fact that the data were not normally distributed, a Spearman Rho correlation was used to assess the relationship between age, pain and the number of opioid pills used.

Results

A total of 42 participants were enrolled in the study pre-operatively. Three patients were excluded due to complications following surgery and five patients did not answer follow-up phone calls. The final sample included 34 patients (response rate = 80%). Participants were mostly white (97%), female (91%) and an average age of 36.8 years (range = 20-65 years). A total of 10 different health care providers prescribed opioids for study participants post-operatively.

Pain Level and Pain Management

Patients reported their average pain on a 10-point Likert type scale with and without activity at the time of the follow-up phone call. With no activity patients' mean reported pain was 2.0 (SD = 1.8). With activity, patients reported average pain score was 4.1 (SD = 2.3). Patients reported using both prescribed opioid and over the counter analgesics to manage their post-operative pain. A total of 58.8% (n = 20) of patients used a multi-modal approach with ibuprofen or acetaminophen taken in conjunction with opioids. The average number of days of opioid use following surgery was 4.2 with 71% (n = 29) of patients using opioids for five or fewer days. At the time of the follow-up phone call, patients reported having taken a total of about 11 opioids to control their pain (M= 10.9; SD = 8.2; Range 0-26). In addition, about 8% (n=3) of the patients in this study reported using no opioids after the day of surgery.

Opioids Prescribed Following Surgery

Health care providers prescribed the subjects in this study between 12-50 opioid pills following their uncomplicated laparoscopic cholecystectomy (Mean = 27; SD = 8). At the time of the follow-up phone call, patients reported having between 0-42 pills left over (Mean = 14; SD = 11.7).

Patients were asked if they felt they were prescribed too few, just right, or too many opioid pills following surgery. A total of 47% of patients ($n = 16$) felt they were prescribed 'too many' while only 11.8% ($n = 4$) indicated they were prescribed 'too few' opioids with 41% ($n = 14$) indicating the amount of opioids prescribed was 'just right'. Of the participants who rated the prescribed quantity as "just right," eleven participants had anywhere from 2-19 opioid pills left over ($M = 8.1$). There was no relationship between age and the number of days needing opioids ($p = .8$; $r = .025$) and pain level with or without activity ($p = 0.7 - 0.8$; $r = -0.06 - 0.027$). There was a small significant positive correlation with age and the number of pills left over ($p = 0.026$; $r = 0.387$).

A majority (64%; $n = 22$) of patients reported side effects resulting from opioid administration and half of all participants agreed that medication side effects influenced the number of opioid pills they used to treat their pain.

Knowledge of Disposal

A total of 88% ($n = 30$) reported that they were not informed how to dispose of unused opioids. A few ($n = 2$) reported not being instructed personally by either a health care provider or nursing staff, but instead referred to state-sponsored programs focused on medication safety, stating, "I've seen the billboards." A small number of participants volunteered what they thought was the proper way to dispose of surplus supply, stating it was appropriate to "flush them" ($n = 5$), "take them somewhere" ($n = 1$), and "use a drop box/takeback facility" ($n = 6$). Others ($n = 20$) in the study indicated they had no knowledge of how to appropriately dispose of unused opioid pills. One participant indicated plans to keep the remaining opioids in the home, stating, "I feel safer with a few left-over."

Discussion

In this study, we identified three key findings: Some providers continue to use opioids as the primary treatment for pain management post-operatively instead of recommending patients use a multi-modal approach, the quantity of opioid pills prescribed is often more than necessary, and patients are not routinely provided with adequate education on safe disposal of unused medications. These findings are important because the same behaviors, which have been shown to contribute to opioid abuse, continue in spite of recommendations and guidelines commissioned by the American Pain Society (APS), the American Academy of Pain Medicine (AAPM), and the American Medical Association (AMA) (Thorson et al., 2014; Chou et al., 2009; American Medical Association, 2017).

A multi-modal approach for analgesia is recommended by pain management experts for many different types of pain, including post-operative pain (National Pharmaceutical Council, 2001). The ASA (2011) encourages an around-the-clock regimen of NSAID, cyclooxygenase-2 inhibitors (COXIB), or acetaminophen as primary coverage for pain management, with opioids used as adjunct therapy for breakthrough pain. In fact, solely non-opioid approaches have been shown to provide comparable pain relief when used in some post-operative situations, such as after tonsillectomy in children (Baugh et al., 2010) and after carpal tunnel release in adults (Chapman, Kim, Maltenfort, & Ilyas, 2017). Similarly, some of our study participants (11.8%) found adequate pain relief using only NSAIDs or acetaminophen for pain control after surgery, without any opioids. Our data suggests that in spite of multi-modal therapy recommendations by numerous pain management experts (i.e. ASA, American Pain Society, etc.), the primary method of treatment for pain after laparoscopic cholecystectomy continues to be opioids.

Many of our study participants indicated being prescribed too many opioid pills after laparoscopic cholecystectomy. Our data are supported by a much larger study conducted by Hill, McMahon, Stucke, and Barth (2016), who found wide variation of and over-prescribing of opioids after common surgeries. Surgeon General Vivek Murthy (2016) suggests one reason why physicians may still over-prescribe opioids: He recalls being in medical school nearly 2 decades ago, when medical students were taught to aggressively treat pain with opioids— without adequate training, support, or accurate information about the addictive potential of opioids. Further, Stanek, Renslow, and Kalliainen (2015) suggest non-specific, generalized opioid prescription recommendations currently available are insufficient to provide meaningful counsel for prescribers. Our study findings suggest prescribing 19 opioid pills after laparoscopic cholecystectomy would be adequate for 81% of participants. Similarly, Hill et al. (2016) recommend prescribing only 15 opioid pills after laparoscopic cholecystectomy, which would satisfy the opioid demand of 80% of post-operative patients in their study.

Over-prescribing opioids for post-operative pain management results in an excess of unused medication. Patients are then left with a decision to either dispose or store the remaining opioid medication. In this study, 88% of our participants indicated they did not recall receiving any information about how to dispose of unused medication appropriately, and while we did not specifically ask what they intended to do with excess opioid pills, many patients stated they would be storing the medication for future use. This is consistent with findings from Bates et al. (2011), who determined 92% of their study participants recalled no disposal instructions and 90% of their study participants indicated they planned to keep excess opioid pills.

Several U.S. states help fund campaigns to educate consumers on proper use and disposal of opioids, including Georgia's 'Generation Rx Project,' Ohio's 'Prescription for prevention,'

Wisconsin's 'Good Drugs Gone Bad,' and Utah's 'Use Only As Directed.' These media campaigns aim to educate and encourage the public to help fight the misuse of opioids by appropriately using and then disposing of medications (Substance Abuse and Mental Health Services Administration, 2017). Our data suggest that opioid-related media campaigns are somewhat effective in their goal to educate about proper opioid medication disposal, as evidenced by unscripted responses from study participants. However, more direct and personalized instruction from health care providers is lacking.

Implications

Using a variety of medications to manage pain will minimize the number of needed opioids after cholecystectomy. "Multimodal analgesia allows for the use of lower doses of medications, yet potentially provides greater pain relief and fewer analgesic adverse effects than can be achieved with monomodal (i.e., single medication or modality) therapy" (ManWarren, 2015, p. 309). Congruent with the ASA guidelines, providers should implement evidence-based best practice protocols and prescribe an around-the-clock regimen of a NSAIDs (i.e. ibuprofen) and acetaminophen as the primary analgesics after laparoscopic cholecystectomy (if not contraindicated), and decrease the total number of opioid pills prescribed to only 15-19 pills. A multi-modal pain management regimen will help decrease the need for opioids while still achieving adequate analgesia for patients after laparoscopic cholecystectomy.

Over-prescribing opioid medications could be prevented with accurate data and proper education for health care providers. Different approaches have been proposed to guide more appropriate opioid prescribing. Some researchers are trying to determine the appropriate opioid regimen for use after each type of surgery. For example, Kim et al. (2016) provides a general guideline for post-operative opioid prescription quantity based on surgical type and anatomic

location. Stanek, et al. (2015) suggests a simple educational-assist device, in addition to changing post-operative order sets, may be an alternative pathway in affecting over-prescribing habits. Others are examining genetic profiles which then offer individualized pain management plans (ManWorren, 2015). Regardless of what technique is used to determine appropriate dosing, Murthy (2016) pleads with providers to help decrease surplus opioid supplies and contribute to the fight against opioid abuse by educating themselves about how to treat pain both safely and effectively, screening for opioid misuse, and recognizing and treating opioid abuse as a chronic illness. Considering Murthy's call for action, as well as the direct relationship between pain management accreditation requirements adopted in 2001 and the simultaneous rise in opioid prescription and use, regulatory agencies should re-examine their accreditation requirements. Prescribers have been manipulated into using opioids for pain management in a vain attempt to increase patient satisfaction scores which are included in regulatory measurements of quality.

Professional standards for physicians include educating patients on "how to appropriately use and properly dispose of any unused controlled substance" (Kentucky Legislative Research Commission, 2017, Section 3: #6). Sadly, however, fewer than 20% of patients are educated on proper disposal (Seehusen & Edwards, 2006). One barrier to effective education is the inconsistency between state laws and regulations regarding appropriate disposal of opioids (Herring, Shah, Shah, & Gupta, 2008). The Food and Drug Administration (2017) recommends using Drug Enforcement Agency (DEA) sponsored Take-Back programs and facilities as the ideal method of opioid medication disposal. Nevertheless, Take-Back programs and safe drop-boxes for unused medication were not widely available until 2014, when the DEA expanded authorization for take-back facilities to include hospitals and pharmacies (United States Department of Justice, Office of Public Affairs, 2014). Because the DEA only recently expanded

programs, health care providers, including physicians, nurses, and pharmacists may not be knowledgeable of what disposal facilities are now available in their own communities. Health systems and individual health care providers need to be aware of available Take-Back facilities and resources in the community they serve so that patients can be accurately educated. In addition, instructing patients on how to properly dispose of left over opioids needs to become a routine part of prescribing any opioid medication.

Limitations

Apriori power analysis indicated 100 subjects would be needed to reach statistical significance. Therefore, the limitations of this study include an insufficiently small sample size, as well as a homogenous sample from one hospital. Most of the study participants were Caucasian females. Additionally, the type and concentration of prescribed opioid medication was not collected (i.e. oxycodone 5 mg vs hydrocodone 7.5 mg). Another limitation of our study is the lack of adjustment for participant co-morbidities such as anxiety, depression, or other health concerns that have been shown to influence the perception of pain (Craven, Cinar, & Madsen, 2012).

Recommendations for Future Research

While there are many assumptions and opinions about why health care providers continue to over-prescribe opioid medication, additional research is needed to understand the rationale and the barriers influencing over-prescribing practices. It would also be useful to investigate the knowledge and attitudes of health care providers about proper medication disposal. Lastly, as medication disposal programs and state-sponsored campaigns continue to expand, additional research is needed to analyze the effectiveness of the Take-Back program and public education.

Conclusion

Pain management is an ethical responsibility for health care providers. This study investigated the prescribing pattern of opioids following laparoscopic cholecystectomy. We found a lack of a multi-modal approach for treatment of post-operative pain, as well as overprescribing, and low rates of adequate education given to patients regarding proper disposal of unused opioids. Information from this study should be used to change prescribing practices and inform future research.

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Table 1: Opioid use following laparoscopic cholecystectomy (N=34)

	N	%
Number of Opioids Used		
Opioid use only	12	35.3
Opioid plus over the counter analgesics	20	58.8
No opioid use	2	5.8
Total number opioids prescribed		
Not reported	2	5.8
12-23	5	14.7
24-30	24	70.5
30+	3	8.8
Number of pills remaining at time of interview		
Not reported	2	5.8
0-9	16	47
10-19	4	11.7
20-29	8	23.5
30+	4	11.7

Figure 1: Graph re-created using data from NIDA, obtained from www.drugabuse.com

