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ORIGINAL RESEARCH

A Single Center Exploratory Survey of Patients and Nurses on post-Surgical Oral Opioid Delivery Through Patient-Controlled Analgesia

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Background: The most common route of opioid delivery is nurse-administered pills. However, there are numerous challenges such as nursing burden, opioid diversion, medication delay, and patient dissatisfaction. In this study, we conducted two surveys, first to assess patients' and nurses' opinions on the current administration of opioids in pill form, followed by their attitudes towards an innovative concept of oral medication delivery based on a medical device currently undergoing research and development within the University, patient-controlled dispenser and deactivator (PCDD) that allows patients to self-administer liquid oral opioids on demand based on physician prescription.

Methods: Questionnaires were developed, verified and deployed to assess nurse and post-surgical patient opinions on the current administration of opioids in pill form, as well as the proposed new concept of patient -controlled administration of oral liquid medication via an illustration of PCDD, from September 2022 through July 2023 at a major academic tertiary care center. Quantitative and qualitative data were collected from postoperative patients and nurses from surgical specialties including General Surgery, Surgical Oncology, Trauma Surgery, Orthopedics, and Neurosurgery.

Results: Forty-three patients and 53 nurses were interviewed. Seventy percent of patients frequently called nurses for pain medication post-surgery 1–4 times daily, and 32% of patients were told each day by nurses that they could not receive medication because they were not due yet. Medication delay caused 24% of patients to worry about nursing availability for medication delivery. Likewise, nurses reported that half of patients receive delayed medication (22 minutes median delay time) and half of nursing time was spent administering pain medication. Nurses expressed moderate satisfaction with their current delivery of medication (median satisfaction score 6.5 out of 10). When being introduced to the concept of PCDD via a product illustration, 15% of patients said that they prefer liquid medication and 51% said they prefer PCDD or were interested in trying it.

Conclusion: Nurse-administered pills are a common but suboptimal method for postoperative pain management. Based on patient and nurse feedback, patient controlled self-administered liquid oral opioid delivery is conceptually innovative, practically viable and potentially a preferred alternative for timely and less nurse-exhaustive pain management.

Keywords: pain management, opioid, survey, nursing, patient-controlled analgesia pump

Introduction

Of the approximately 330 million surgeries performed globally each year,[1] about 80% of patients experience acute pain after surgery, with 47% reporting severe or extreme pain.[2] Despite advances in perioperative early recovery after surgery, suboptimal pain control remains a constant issue with long term sequelae such as persistent postsurgical pain and chronic

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opioid use.[3] As part of a multimodal pain management regimen, two of the most common forms of opioid administration are patient-controlled intravenous analgesia (PCIA) and oral pills.

PCIA pumps are considered the gold standard to deliver systemic opioids that provide patients with timely pain management and a greater sense of control and satisfaction,[4] but invasive, restrict patient mobility,[5] and patients eventually need to transition to an oral medication for discharge, which often increases their hospital length of stay.

Opioid pill administration is time-consuming for nurses, who must physically deliver the medications to patients, watch them take the medication, and properly dispose of leftover medication in a special waste receptacle with another healthcare worker present as witness.[6] Because one in 10 American healthcare professionals have some form of substance use disorder and many have easier access to controlled substances than the general population, diversion of controlled substances among healthcare workers is a significant national problem.[7,8] Opioid pill administration also poses issues for patients. Due to low staffing requirements, the current regimen at hospitals is to administer opioids at long intervals (every 3–6 hours), which can lead to medication delays, prolonged hospital stays, and decreased patient satisfaction.[9]

Given the current status of pain medication administered by the nurses in pill form and by PCIA, our research team at Yale University are the first to propose an alternative patient-controlled oral administration (PCOA) of liquid opioids, and designed a liquid oral medication dispenser (illustration shown in Figure 1) which is protected under a US utility patent (Supplemental File 1). The device, manufactured by Realief, is named Patient-Controlled Dispenser and Deactivator (PCDD), and allows patients to self-administer liquid oral pain medication on demand.[10] The device extends the well-known benefits of PCIA to a non-invasive oral format with safety features to limit diversion and misuse, provides estimation of discharge opioid requirements, and deactivates leftover opioids.

This study aimed to investigate nursing and patient opinions on current opioid delivery in the hospital and their perception of our proposed new model of PCOA. We hypothesized that the primary outcome is patients face significant medication delay for nurse-administered opioid pills and are dissatisfied with current opioid administration. We also hypothesized secondary outcomes that patients are inclined to try liquid oral opioid medication and the PCDD as an alternative. The PCDD device was not trialed on any patients, rather the concept of the device was presented to patients and nurses via an illustration during the study. The study was not sponsored by any company. This research project has not received any funding external to the University, and there is no industry sponsorship.

Methods

Questionnaires were developed by investigators (DW, JL, and CS), in collaboration with the patient advisory council and senior surgical nurses at Yale New Haven Hospital (YNHH), who provided feedback on readability and design (Tables 1 and 2). The Yale University institutional review board approved the study with exempt from written consent. Verbal consent was deemed sufficient because neither investigational intervention was involved in this survey study, nor was identifiable study subject information collected from any study participants. Verbal consents were obtained from all study participants and documented in

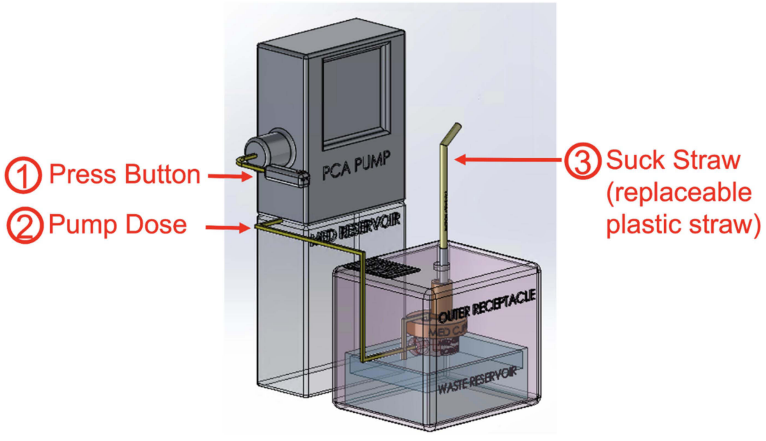

Figure 1 An illustration of the patient-controlled dispenser and deactivator device (this illustration was presented to patients and nurses when surveyed).

Table 1 Summary of Patient Survey Data

Question	Answer	Overall (n=43)
Ethnicity	Not indicated	8 (18.6%)
	White	30 (69.8%)
	Black	4 (9.3%)
	Asian	1 (2.3%)
Age	Mean (SD)	52.6 (18.0)
Sex	Male	22 (51.2%)
	Female	21 (48.8%)
Surgery Type	Missing	1
	Orthopedic Surgery	20 (47.6%)
	Surgical Oncology	10 (23.8%)
	General Surgery	12 (28.6%)
Length of Stay (Days)	Missing	1
	Mean (SD)	11.3 (28.5)
	Median (IQR)	3 (2–7)
Duration of Opioid Use Post Surgery (Days)	Missing	4
	Mean (SD)	13.5 (34.6)
	Median (IQR)	3.0 (1.0, 7.0)
Morphine Milligram Equivalents Consumed by Patients Daily (MME)	Missing	28
	Mean (SD)	256.7 (663.0)
	Median IQR	60.0 (38.5, 142.5)
Are you still taking any opioid pain medications now?	Missing	2
	No	12 (29.2%)
	Yes	29 (70.7%)
Concerns about nurse unavailability or delay in pain medication delivery	Missing	1
	Not at all	26 (61.9%)
	Not really	6 (14.3%)
	Somewhat	8 (19.0%)
	Very much	2 (4.8%)
Concern about developing opioid addiction	Missing	1
	Not at all	31 (73.8%)
	Not really	5 (11.9%)
	Undecided	2 (4.8%)
	Somewhat	1 (2.4%)
	Very much	3 (7.1%)

(*Continued*)

Table 1 (Continued).

Question	Answer	Overall (n=43)
Concern about medication diversion within hospital	Missing	1
	Yes, I am concerned	40 (95.2%)
	No, I am not concerned	2 (4.8%)
Concern about medication diversion within home	Missing	1
	Yes, I am concerned	42 (100.0%)
Satisfaction with current method of pain medication administration	Missing	1
	Completely dissatisfied	3 (7.1%)
	Dissatisfied	3 (7.1%)
	Neutral	11 (26.2%)
	Satisfied	12 (28.6%)
	Completely satisfied	13 (31.0%)
Patient experienced side effects from opioid use	None	20 (46.5%)
	Constipation	17 (39.5%)
	Sleepiness/fatigue	3 (7.0%)
	Inability to concentrate or focus	1 (2.3%)
	Nausea/vomiting	1 (2.3%)
	Other	1 (2.3%)
Patient preference of PCDD device or nurse given pills	Missing	1
	I will only take pills from a nurse	5 (11.9%)
	I prefer to take pills from a nurse	11 (26.2%)
	It makes no difference to me	4 (9.5%)
	I am interested in this self-administered pain medication option and would try it	14 (33.3%)
	I prefer to use this device to self-administer pain medication	8 (19.0%)
Reasons preventing patient from using PCDD device	None	25 (58.1%)
	I am worried about my own safety (ie the risk that I will overdose)	8 (18.6%)
	I need a nurse to be with me and assess me	4 (9.3%)
	I am worried about the cost, will insurance cover it?	2 (4.7%)
	I am not familiar with the device	1 (2.3%)
	I need to be trained before I use the device	1 (2.3%)
	I do not know how much opioid I have taken	1 (2.3%)
	I am worried about ingesting medication in liquid form	1 (2.3%)

(*Continued*)

Table 1 (Continued).

Question	Answer	Overall (n=43)
Patient suggestions to improve PCDD device	None	36 (83.7%)
	The patient is an automation engineer and says he knows how to defeat automation.	1 (2.3%)
	Mobility issues	1 (2.3%)
	"Know yourself, PCDD device usage should only be allowed for certain patients".	1 (2.3%)
	Add flavor (eg cherry, pineapple).	1 (2.3%)
	Being "double subscribed" – acquiring one device from one healthcare provider and an additional device from a different provider	1 (2.3%)
	Long, flexible straw - patient's inability to move very much after surgery	1 (2.3%)
	Monitor patterns of use – "Is the patient taking medication the moment they can? Are they developing an addiction?"	1 (2.3%)
	Only use device within hospital setting	1 (2.3%)
	Missing	1
Patient likelihood to choose surgeon due to device	It definitely will not	12 (28.6%)
	Very unlikely it would	10 (23.8%)
	Neutral, it could go either way	12 (28.6%)
	Very likely it will	5 (11.9%)
	It definitely will	3 (7.1%)
	Missing	1
Patient likelihood to choose hospital due to device	It definitely will not	14 (33.3%)
	Very unlikely it would	11 (26.2%)
	Neutral, it could go either way	10 (23.8%)
	Very likely it will	4 (9.5%)
	It definitely will	3 (7.1%)

Abbreviations: POD, Postoperative Day; PCDD, Patient-Controlled Dispenser and Deactivator; IQR, Interquartile Range; SD, Standard Deviation.

survey questionnaires. Investigators (CS, DM, LZ, IP, and MH) conducted in-person interviews from September 2022 through July 2023. The nurses and patients were introduced to the concept of patient-controlled oral administration of medications with an illustration of a medical device PCDD (Figure 1).

Quantitative and qualitative data were collected from patients undergoing surgeries which required an inpatient stay and from nurses specializing in surgical specialties at the General Surgery, Surgical Oncology, Trauma Surgery, Orthopedics, Neurosurgery, and Medical Units of YNHH.

Patient inclusion criteria were hospitalized postoperative patients who were prescribed oral opioid analgesics for acute pain control. Patient exclusion criteria were patient refusal and mental status change or psychiatric disorders that

Table 2 Summary of Nurse Survey Data

Question	Answer	Overall (n=52)
Nurse specialty	Missing	8
	Orthopedics and Neurosurgery	6 (13.6%)
	Oncology	21 (47.7%)
	Medical Surgery	10 (22.7%)
	General	1 (2.3%)
	Other	6 (13.6%)
What type of patients do you typically take care of?	Missing	13
	Orthopedics	6 (15.4%)
	Oncology	21 (53.8%)
	Post-Operation	6 (15.4%)
	General	4 (10.3%)
	Other	2 (5.1%)
For your typical patients, what percent of your time with them is due to pain control, delivering pain medication, managing pain medication side effects?	Missing	2
	Median (SD)	54.5 (22.5)
	Median (IQR)	50.0 (33.5, 75.0)
What percent of patients receive delayed pain medications because there are more important pressing issues on the floor that are a higher priority?	Missing	5
	Median (SD)	51.0 (27.6)
	Median (IQR)	50.0 (25.0, 75.0)
What is the estimated average time delay (mins) in patients receiving pain medication? (ie 10/30/60 mins, etc.)	Missing	5
	Mean (SD)	22.2 (13.3)
	Median (IQR)	15.0 (10.0, 30.0)
What percent of patients are overly sedated due to oral opioid medication (eg require naloxone [Narcan], rapid response team called, minimally responsive, or code called)?	Missing	6
	1 every month	3 (6.5%)
	1 every 3 months	9 (19.6%)
	1 every 6 months	20 (43.5%)
	Extremely rarely	14 (30.4%)
Are you concerned about diversion of oral opioids in the hospital due to nurses?	Missing	0
	Yes, I am concerned about opioid diversion due to other nurses	1 (1.9%)
	No, I am not concerned about opioid diversion due to other nurses	51 (98.1%)

(*Continued*)

Table 2 (Continued).

Question	Answer	Overall (n=52)
Are you concerned about diversion of oral opioids in the hospital due to patients?	Missing	0
	Yes, I am concerned about opioid diversion due to other patients	9 (17.3%)
	No, I am not concerned about opioid diversion due to other patients	43 (82.7%)
How satisfied are you with the current oral pain medication delivery system? (Scale of 0–10: 1 extremely dissatisfied, 10 extremely satisfied)	Missing	2
	Mean (SD)	6.7 (1.2)
	Median (IQR)	6.5 (6.0, 7.4)
How would you rank the concept of patient controlled liquid oral opioid administration as compared to the usual care of nurse-administered PRN pills, and why?	Missing	2
	Mean (SD)	6.2 (1.8)
	Median (IQR)	6.0 (5.0, 7.0)
Do you have any suggestions for a patient-controlled analgesia dispenser and deactivator to improve its function and safety?	Missing	7
	No suggestion	24 (53.3%)
	Structural integrity	3 (6.7%)
	Security	8 (17.8%)
	Supervision	5 (11.3%)
	Other	5 (11.1%)
What would be the ideal oral opioid delivery for inpatients?	Missing	16
	Oral	4 (11.1%)
	Pills	20 (55.6%)
	IV	2 (5.6%)
	PCDD device	10 (27.8%)
What would be the ideal oral opioid delivery for outpatients?	Missing	17
	Oral	3 (8.6%)
	Pills	24 (68.6%)
	IV	8 (22.9%)

Abbreviations: PCDD, Patient-Controlled Dispenser and Deactivator; IQR, Interquartile Range; SD, Standard Deviation; IV, Intravenous.

prevented patients from providing verbal consent and/or answering survey questions. All nurses in YNHH postoperative care settings were eligible for our study.

The patient survey included questions on basic demographic information, types of surgery, methods of opioid pain medication, and satisfaction with the current pain delivery system. After being introduced to PCDD, patients were asked about their preference for pills or liquid medication, concerns about the device, and whether they would prioritize a hospital or surgeon if the device is available (Table 1). Pain medication doses were recorded as a total of milligram amounts of brand-specific, oral opioid medication consumed per day and then converted into and reported as daily morphine milligram equivalents (MME).

The nurse survey included questions such as nurse specialty, type of patients, quantitative measures of nurses' pain management regime, suggestions to improve the functions of PCDD, and ideal outpatient and inpatient opioid delivery method for patients (Table 2).

Continuous data were presented as mean (standard deviation [SD]), categorical data were presented as the number of survey respondents (percentage). All data were immediately de-identified once the initial data collection was complete to maintain patient data confidentiality and compliance with the Declaration of Helsinki.

Results

A total of 43 patients were interviewed, of which 22 (51.2%) self-identified as female and 21 (48.8%) male. Among patients, the average age Mean (SD) was 52.6 ±18.0 years old. The majority of patients self-identified as White (30 [69.8%]), along with Black (4 [9.3%]) and Asian (1 [2.3%]). The patients interviewed had undergone a variety of surgeries, with an even spread between orthopedics, surgical oncology, and general surgery (Table 1).

A total of 52 nurses were included in this study from various surgical specialties. A majority of nurses specialized in surgical oncology (21 [47.7%]), some in general surgery (10 [22.7%]), and a few in orthopedics and neurosurgery (6 [13.6%]) (Table 2).

According to the patient interviews, patients often experienced intense pain episodes, hence requiring more frequent pain medication deliveries from nurses. About 74% of patients reported experiencing at least one severe pain episode on postoperative day (POD) 1 after surgery, with as many as 45% experiencing greater than 3 severe episodes. The mean (SD) frequency of severe pain on POD 1 was 2.6 (1.5) times per day. This continued into POD 2, with 29% of patients experiencing pain episodes 1–2 times per day and 43% experiencing greater than 3 severe episodes (Figure 2). Patients frequently called nurses for pain medications post-surgery on POD 1 (0 times: 24%, 1–2 times: 50%, 3–4 times: 20%) (Figure 3).

However, the high demand for pain management from patients was not adequately met by nurses, leading to decreased patient satisfaction. According to the survey, 32% of patients were told by the nurses per day that they could not receive the pain medications because they were not due yet, meaning their prescription required a longer duration between administration of each dose than what the patient was requesting (Figure 4). The delay in pain medications caused concern among patients, with 24% of them reporting being worried that their nurses would not be available or delayed in providing pain medication. This corresponds with nurses' estimation from survey results that 50% of patients receiving delayed medications with an average time delay of 22 minutes.

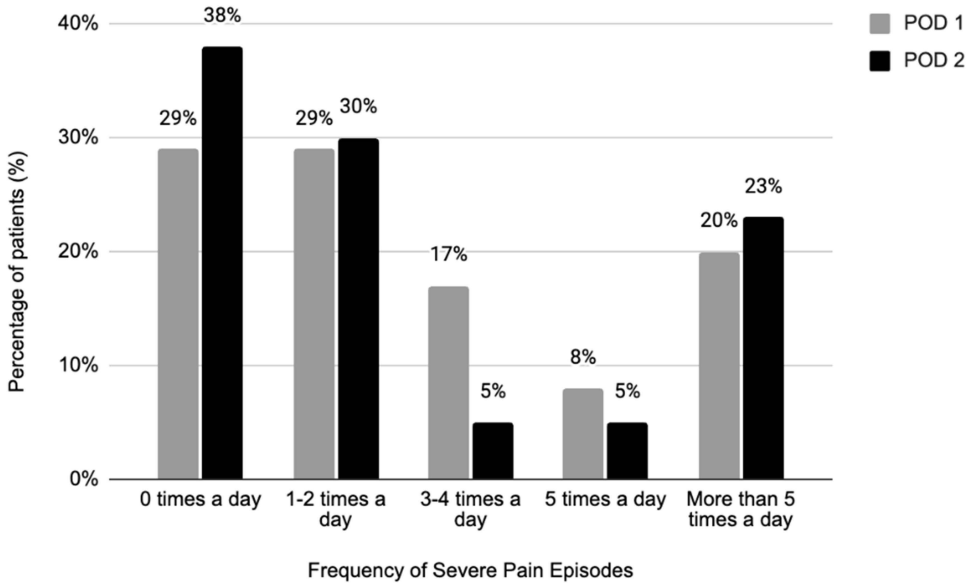

Figure 2 Patient Reported Severe Pain Episodes on Postoperative day 1–2.
Abbreviation: POD, Post-Operative Day.

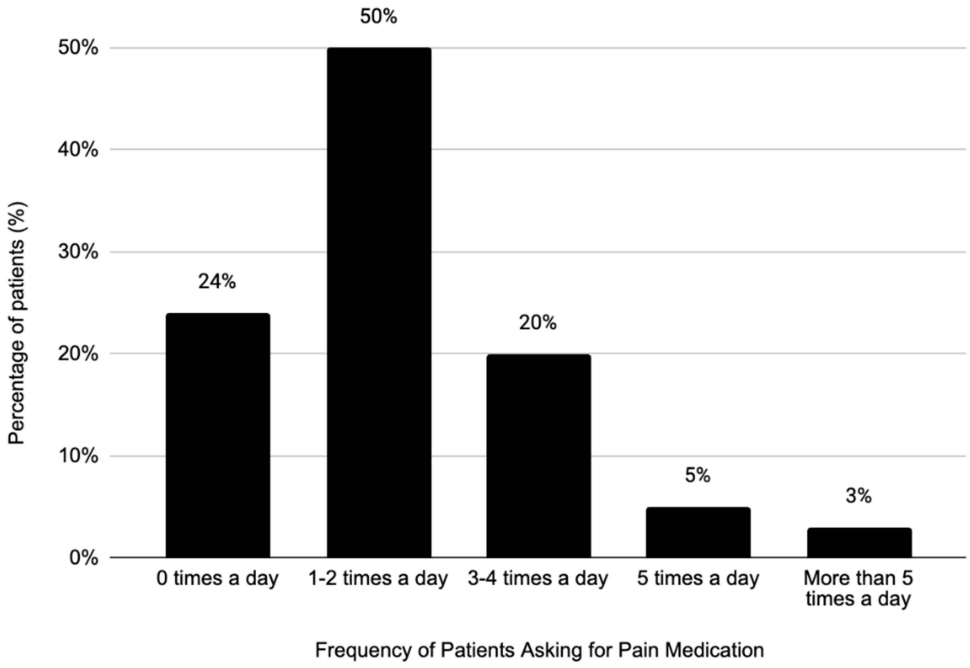

Figure 3 Daily Frequency of Patients Asking for Pain Medication.

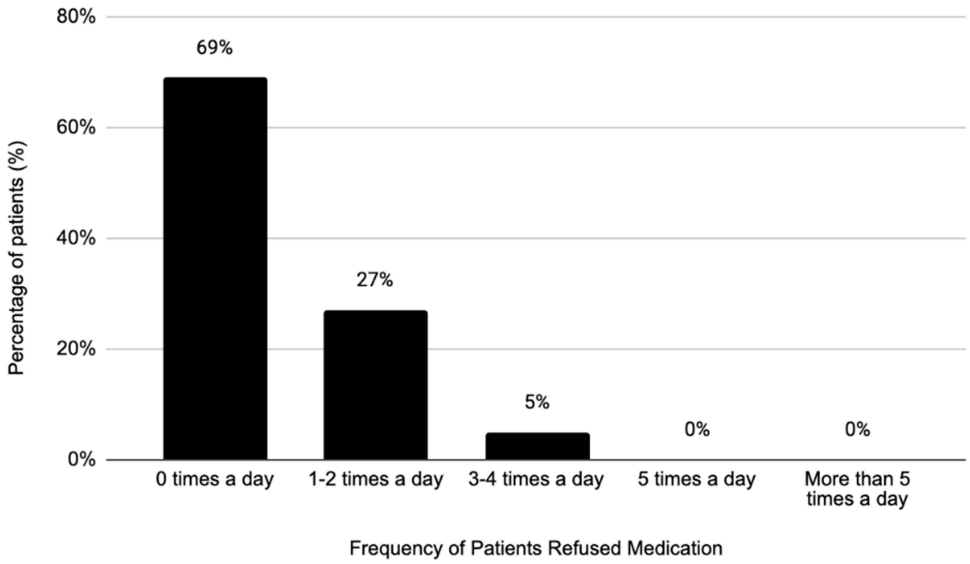

Figure 4 Percentage of Patients Refused Medication Because It was not Time Yet for Their Next Dose.

Failures in pain management were not restricted simply to severe pain episodes. Problems such as oversedation also occurred as nurses reported that oversedation of patients (defined as requiring naloxone [Narcan], rapid response team called, minimally responsive, or code called) occurred approximately once every 6 months in the patient care units they worked in. Like patients, nurses were not overwhelmingly happy with the current oral pain medication delivery system, reporting a median satisfaction score of 6.5 out of 10.

After the patients were introduced to PCDD, their opinions on liquid versus pill forms of pain medication were assessed, showing promising indications of patients' preferences for liquid pain medication. About 25% said they prefer pills, 23% were interested in or prefer liquid medications, and 38% said it makes no difference to them (Figure 5). When

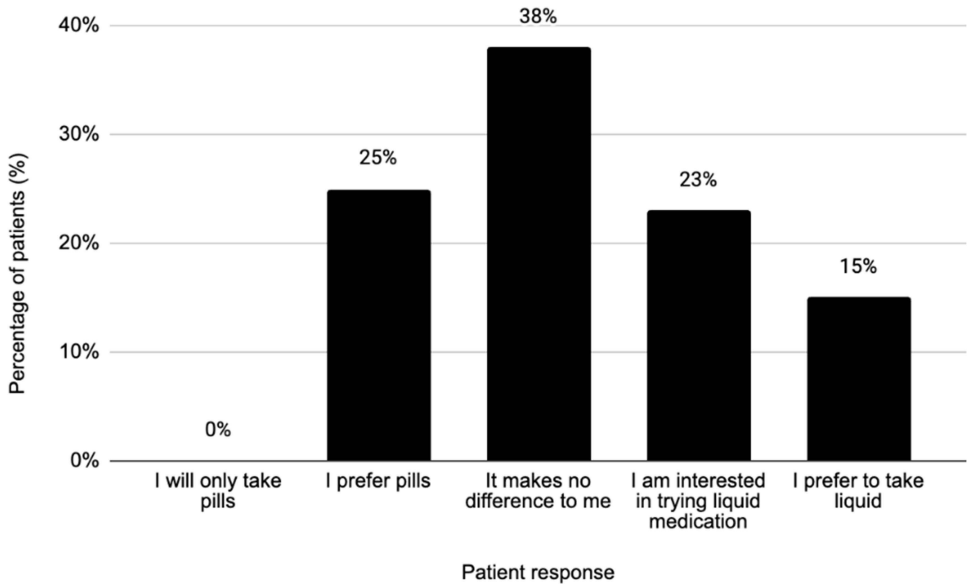

Figure 5 Percentage of Patients Who Prefer Liquid Versus Pill Pain Medication.

providing PCDD as an alternative means of pain medication delivery, 33% of patients said that they were interested in PCDD and would try it, with 18% even saying that they prefer to use PCDD over nurse-administered pills.

With respect to whether PCDD will affect the patients' opinions on choosing a surgeon or hospital for an elective surgery, patient opinions were divided. Twenty-four percent of patients said that the device would make them more likely to choose a specific surgeon, and 17% said the device would make them choose a specific hospital. However, a majority of patients said that the device would not make them choose a surgeon and would not make them choose a hospital (57% and 64% respectively). Separately, a majority (57%) of nurses rated PCDD higher than nurse-administered pills, though most still said that pill was their ideal oral opioid delivery for inpatient and outpatient.

When being asked for concerns that would prevent them from using the device, 69% of patients said none, 16% said they are not sure they understand how to use it properly, 7% said they are worried about safety and overdose, 2% said they are worried about cost, 2% said they do not trust that they will have the mental capacity to utilize it, and 2% said they need a nurse to be with them and assess them. Other anticipated problems with PCDD raised by patients were bad flavor, lack of supervision, overdose risk, device diversion, device structural integrity, machine cost, and risk of aspiration. Some suggestions from both patients and nurses to improve the function of the device included adding flavor to the liquid medication to make it more palatable, monitoring medication use patterns to ensure no diversion of the device, having more flexible straws (from which patients will suck medication out of the PCDD) to accommodate those with limited mobility post-surgery, incorporating remote monitoring features and safety mechanisms such as fingerprint recognition, connecting the device to vitals before taking medication, targeting a specific patient population, and having a small medication reservoir to prevent oversedation.

Discussion

This single center prospective survey study demonstrates that significant unmet need with the current pain medication delivery system of nurse-administered pills, resulting in medication delay and dissatisfaction among both patients and nurses.

To the best of our knowledge, our study is the first to investigate adult inpatient and nurse preference for liquid versus pill opioid medication. It is also the first study to assess patients' and nurses' opinion on a patented patient-controlled liquid medication administration device, with a majority of patients (51%) and nurses (55%) demonstrating interest to try liquid oral pain medication delivered in a patient-controlled format by the PCDD.

The World Health Organization (WHO) and International Association for the Study of Pain (IASP) have identified pain relief as a human right.[11] Poorly managed postoperative pain can lead to complications and prolonged rehabilitation, which can lead to development of chronic pain with reduction in quality of life.[12] According to a review of quality

improvement monitoring in pain management, patient pain intensity ratings remained high over 10 years of data collection, highlighting the continual need for pain quality improvement.[13]

Proper pain management post-surgery is important and necessary for patient satisfaction and wellbeing, as a fifth of patients experienced severe pain on day 1 and 2 after surgery in our study. However, there are many causes of unsatisfactory postoperative pain control, including insufficient education, fear of side effects associated with opioids, poor pain assessment, and inadequate staffing.[14] In 2017, it was estimated that postoperative pain was not well addressed in over 80% of patients in the US and was associated with increased morbidity, functional and quality-of-life impairment, delayed recovery time, prolonged duration of opioid use, and higher healthcare costs.[15] These statistics align with findings from our study that about half of patients called nurses for pain medications 1–2 times each day, but 32% of patients were told on a daily basis they could not receive the medications because they were not due yet.

Our study results are also consistent with results from a national survey that took a random sample of 250 adults who had undergone surgical procedures in the US Approximately 80% of the surveyed patients experienced acute pain after surgery. Of these patients, 86% had moderate, severe, or extreme pain. About 25% of patients who received pain medications experienced adverse effects; however, almost 90% of them were satisfied with their pain medications.[2] The high percentages of pain reports from patients highlight the need for better postoperative pain control.

Similarly, nurse responses in this study evinced that pills delivered by nurses were leading to medication delay and more time spent managing pain. On average, about half of nurse time was spent on pain management, while 50% of patients receive delayed medication. The average time delay was 22 minutes. Similarly, in a 2010 German study that investigated nurses' and physicians' opinions on post-operative pain therapy, 10.7% of nurses reported time delays exceeding 6 hours between a request for pain medication and its administration.[15]

As an alternative to intravenous liquid medication administration, oral administration of liquids may be preferable for patients permitted to drink, which is typically within a few hours for non-gastric or intestinal surgeries or unless otherwise contraindicated.[16] Similar studies have demonstrated that liquid oral analgesia has good bioavailability and can be digested by patients.[17] In fact, PCOA has been successfully implemented in a unique program at the Toronto Western Hospital, one of 3 sites comprising the University Health Network in Canada.[18]

By using a PCIA pump to deliver liquid oral medication, PCDD provides a novel non-invasive way for patients to self-administer liquid pain medication upon demand within one safe and tamper-proof device. The high percentage (51%) of patients interested in liquid medication further highlights the potential to introduce PCDD into the existing pain management system. Nurse and patient feedback also reflected their interest in trying the device. About 35% of patients were interested in or preferred liquid medications, 15% preferred liquid, and 33% were interested in the PCDD device and would try it. Most nurses rated PCDD's function superior to that of nurse-administered pills.[4]

Our study is among the first to demonstrate the advent of PCOA for liquid opioids and patients' and nurses' opinions on its potential to improve pain management, but it is not without limitations. One limitation is that all patients and nurses were selected from a single tertiary care center, which may not be representative of the quality of care at all US hospitals. Of note, approximately 10 out of 43 patients stated that other hospitals were comparatively understaffed, leading to delays, while their experiences at YNHH were far more positive. Additionally, 16% of patients said they are not sure how to use the device, which may indicate that the interviewers were not able to explain the device clearly. Future directions include survey studies at a larger scale and randomized control trials adopting the new concept of patient controlled oral liquid medication delivery by utilizing PCDD.

Conclusion

This survey study is among the first to demonstrate patient and nurse opinions on liquid versus pill pain medication and proposed a new patient-controlled liquid oral medication delivery method. Postoperative pain management through nurse-administered pills was found to be time-consuming for nurses and a cause of medication delay and dissatisfaction for patients. Both patients and nurses expressed interest in trying the liquid oral self-administration device, highlighting its potential to expand the future toolbox of pain management options.

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Disclosure

Daniel Wiznia, Jinlei Li, and Claudia See report a patent "Patient-controlled liquid oral medicine dispenser and deactivation system (US11857504B1)" issued. All authors report no other conflicts of interest relevant to this manuscript.

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