A Prospective Randomized Trial of an Oral Patient-Controlled Analgesia Device Versus Usual Care Following Total Hip Arthroplasty

Lois J. Pizzi ▼ Madalyn Bates ▼ Jacques E. Chelly ▼ Carlyn J. Goodrich

BACKGROUND: Multimodal pain management for surgery patients may include the use of a combination of scheduled oral pain medications with as-needed (PRN) oral opioids. Multiple concurrent time demands on nursing staff frequently cause delays in the delivery of oral PRN pain medication compromising pain management.

PURPOSE: Postoperative pain control was compared using a wireless oral patient-controlled analgesia device for the delivery of oxycodone with a control group receiving PRN oxycodone from nursing staff.

METHODS: Thirty patients were prospectively randomized into each of 2 groups after total hip arthroplasty. Patient demographics, pain scores, drug dose data, and physical therapy data were collected from chart reviews. Additional data were obtained from patient and nursing surveys.

RESULTS: Device patients recorded statistically lower pain scores while taking lower doses of oxycodone on postoperative Day 1 as compared with the control group. Patient surveys indicated that those in the device group reported lower pain scores 24 hours prior to discharge, albeit not statistically different from the control group. Men in the device group reported statistically lower pain scores with physical therapy than men in the control group. Findings from the nursing survey indicate that nurses favored the device over nurse-administered PRN.

CONCLUSION: Patients using the wireless patient-controlled analgesia (PCA) (oral) device had less pain at rest and with activity (men) while taking lower doses of oxycodone with each dose. Nursing surveys indicated that nursing staff in this orthopedic postoperative unit found the device easy to use, reliable, and efficient. They also recommended its adoption for those capable of using it.

Background

Adequate pain management in the surgical patient is a crucial factor that affects immediate postoperative recovery and, in some cases, chronic pain and long-term morbidity after surgery (Gan, 2017). Recent guidelines on the management of postoperative pain strongly support a multimodal approach for pain management (Apfelbaum, Ashburn, & Connis, 2012; Chou et al., 2016). This approach utilizes multiple classes of medications, both opioids and nonopioids, that act at different pain receptor sites in the central and peripheral nervous systems to block the pain signal. This combination allows for smaller doses of each class of medication, resulting in fewer side effects from each (Golladay, Balch, Dalury, Satpathy, & Jiranek, 2017; Parvizi & Bloomfield, 2013). The expansion and improvement of multimodal pain regimens have improved pain control while reducing the total amount of needed opioids (Buvanendran et al., 2015).

In reference to the opioid component of the multimodal pain regimen, many multimodal analgesic pain models and surgical expedited recovery protocols (Scott et al., 2017) recommend oral analgesics because patients experience fewer side effects as compared with parenteral opioids (Rajpal et al., 2010). A number of researchers have found that oral opioids can be as effective as parenteral opioids for postoperative pain

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management (Davis, Esposito, & Meyer, 2006; Pearl et al., 2002; Rajpal et al., 2010; Rothwell et al., 2011; Ruetzler et al., 2014).

An ideal approach for the PRN (as-needed) administration of oral pain medication would be a patient-controlled analgesia (PCA) (oral) device (see Figure 1). Previous reports of this concept included patient's access to a pill bottle at the patient's bedside, which contained a dose of pain medication; another was a Velcro wrist pouch worn by the patient that contained one or two doses of opioid pain medications (Kastanias, Snaith, & Robinson, 2006; Riordan, Beam, & Okabe-Yamamura, 2004). Patients utilized PRN self-dosing methods in these instances and would alert the nurse when the medication was taken so that it could be replaced.

A recent French study compared PCA with nurse-controlled parenteral analgesia after cesarean delivery (Bonnal et al., 2016). The PCA group received oral pain regimen with oral morphine in bedside pillboxes with instructions for use. This study showed equivalent pain scores within the two groups and a patient preference for PCA over parenteral opioids because of the convenience for medication access compared with nurse-administered parenteral pain medication. However, in U.S. healthcare systems, barriers including required security of all administered medications prevent the previously described PCA approaches.

An electronic, wireless PCA device called the MOD for Medication on Demand, now available, meets U.S. pharmacy and regulatory requirements for the safe delivery of oral pain medication. A study in total knee arthroplasty (TKA) patients showed significantly better numeric pain scores in patients using this device as compared with patients receiving the same oral opioids administered on a PRN basis from nurses (Lambert & Cata, 2014).

The study described here after total hip arthroplasty (THA) was designed to further explore the use of this wireless device in another population of joint patients to assess the reproducibility of previous high patient satisfaction data and to explore any changes in nurse acceptance of the wireless technology as a useful tool for pain management.

A difference in device technology for this study was the capability of the MOD to connect wirelessly to a server network. In two published studies that used the MOD, the device required a universal serial bus (USB) connection to the computer workstation to access the programming platform. Without the wireless technology, previous devices were more difficult for nurses to program and use despite consistent high patient satisfaction with the device (Lambert & Cata, 2014; Riemondy, Gonzalez, Gosik, Ricords, & Schirm, 2016). A nursing survey was included in our THA study to monitor nursing attitudes towards adoption of the wireless devices.

A problem with nurse administration of PRN pain medications is the inherent time delay from the patient request to the time of medication delivery by busy nursing staff. A study to determine the amount of time needed to administer a single PRN dose of oral pain medication was undertaken in the same postoperative, orthopaedic unit as the site for this research (Pizzi, Chelly, & Marlin, 2014). The time needed to administer a PRN medication includes the actual administration task time but does not account for any interruptions or delays in initiating the task due to workload. Patient self-administration of medication eliminates that wait time. Patient anxiety, exacerbated by waiting for a requested pain medication, can escalate the pain experience (Pinto, McIntyre, Ferrero, Almeida, & Araujo-Soares, 2013). This may explain the improved pain scores previously noted when the device was used as compared with nursing administration of PRN oral pain medication. In addition, there was no pressure to record higher scores to receive more medication because the dose of the drug from the device was always the same.

FIGURE 1. Medication on Demand (MOD) device.

Purpose

This quantitative prospective randomized study was designed to compare pain management outcomes using the wireless PCA device to nurse administration of PRN oral opioids by nursing staff in postoperative THA patients. Multiple parameters were measured to gauge any differences in pain control and patient's satisfaction in the two groups by comparing patient-reported pain scores on Postoperative Day 1 (POD1) at three points: at discharge, at rest, and during physical therapy. Because this was new technology for nursing staff, a nursing survey was also used to obtain feedback on impressions of device use as a tool for pain management.

The hypotheses of this research study were as follows:

1. The use of a PCA device would result in better pain management because it can deliver smaller doses of medication more frequently on patient demand as compared with the nurse-administered pain medication given less frequently and governed by a patient-reported pain score.

2. Nursing staff would report a positive experience using the device: its ease of use, reliability, and perceived saved nursing time in comparison to the findings of previous surveys of nurses who had used the non-wireless device (Riemondy et al., 2016).

This project exemplifies the Self-Care Deficit Theory of Dorothea Orem. Self-care comprises the activities that an individual can independently perform to promote and maintain personal well-being. A self-care deficit comes about when the person can no longer carry out these activities. Nursing-administered opioid pain medication takes away the activity of self-medicating for pain. According to Orem, when self-care is disrupted, in this case by the patient's environment, self-care deficits occur. Orem's Self-Care Deficit Nursing Theory supports the overall concept of implementing a system that allows patients who are eligible to safely self-administer their own oral pain medications (Hartweg, 2015).

Methods

Study Protocol

This prospective randomized study protocol was approved by an independent institutional review board. Based on a power analysis, we estimated that a minimum of 30 patients in each group would yield meaningful data and detect any differences in the mean pain scores between the two groups. A checklist was used to determine patient eligibility for participation in the study. Eligible patients were contacted and offered an opportunity to participate. Informed consent was obtained at a separate baseline visit prior to the planned primary THA.

The informed consent included a description of the study, study goals, risks and benefits, and an agreement to be randomized to either a device group (Group 1) or the usual care control group (Group 2) on the day of the surgical procedure designated as Postoperative Day 0 (POD0). Eligibility for enrollment included: at least 18 years of age, scheduled for elective primary THA, able to understand and sign an informed consent form, able to pass a mini-mental status test, and no evidence of opioid tolerance as per a review of prior pain medications. No evidence of opioid tolerance was defined as not receiving for the past 1 week or longer, at least 60-mg oral morphine per day, or 25-μg transdermal Fentanyl per hour, or 30-mg oral oxycodone per day, or 60-mg oral hydrocodone per day, or 8-mg oral hydromorphone per day, or 25-mg oral oxymorphone per day (U.S. Food & Drug Administration 2017). In addition, patients were not included if they had a history of substance abuse or any physical limitation that would interfere with device use. Once consent was obtained, patients were assigned to either of two groups according to a randomization program provided by the statistician. All patients were educated on the numeric rating scale (from 0 to 10) for recording their level of pain following surgery.

Nurses provided each patient assigned to the device group education on how to use the device; they then asked the patient to demonstrate its use to confirm understanding. All devices were locked onto an IV pole with a proprietary wrench for security. The mobility of the IV pole allowed for easy access to the device by the patients if they were in a bed or a chair. Patients were given a wristband that contained a radio frequency identification (RFID) chip unique to the device they would be using as part of device security. To obtain a dose of medication, patients would enter their numeric pain score by pushing the appropriate numbered button and then holding their RFID wristband to the front of the device, triggering it to turn and expose a single dose of medication to be self-administered by the patient. The device was set to allow access to a dose of medication every 2 hours. A green light on the front of the device indicated that a dose was ready for dispensing; the green light would remain on until the patient removed a dose of medication. If a red light was illuminated, it meant that it was not yet time for the next dose. Once a dose was removed and self-administered, the device timer would begin again, and the green light would not illuminate again until the 2-hour lockout had passed. Patients included in the device group were required to sign an agreement that defined their responsibility to not share medications with anyone and would access the device to obtain medications for themselves only.

All nurses on the unit completed training on the device by the vendor educator prior to the study initiation. Training included one-on-one nurse training with a requirement to demonstrate competency after each training session. Nurses accessed the device programming platform by signing into the device site on their computer workstations. To set up a device, each programming segment was composed of a simple wizard program that guided the nurse through registration of the RFID wristband to be used with that device, selection of the medication and dose, entry of the lockout time interval in hours between doses, and the medication tray loading steps, which had to be witnessed and documented by a second nurse. Additional tray reloading programs and removal from the device programs were also included in the training. Training manuals were provided for the nursing staff and the vendor maintained a 24-hour 7-day phone helpline. All research staff were also educated on the device use as additional support for the nursing staff.

Pharmacy and Informatics Study Roles

Prior to study initiation, project work groups were established with representatives from the systemwide informatics department and systemwide pharmacy information technology (IT) group. The two hospital groups worked with the vendor IT team to ensure that the wireless Wi-Fi device met all IT security requirements and protocols including patient data security. Once this was completed, the device was tested for all functionality prior to deployment on the inpatient unit. The IT work groups, vendor IT team, physicians, and lead nurses collaborated to create the parameters of an electronic order set for use in the electronic health record (EHR) to enable order entry for patients randomized to the device group.

The central pharmacy group was trained by the device vendor and then tasked to assemble, load, and label the medication trays needed for use in the devices. Pharmacy then managed the automated dispensing cabinets on the unit with device trays. The clinical informatics pharmacist participated in the development of the device order set to ensure that pharmacy security measures and accurate pill counts were available from the device databases. The clinical informatics pharmacist is an expert in human factors, patient safety, and the use of technology to optimize care delivery processes and effectively communicate patient care activity.

Postoperative Pain Management

Upon discharge from the postanesthesia care unit and arrival at the orthopaedic postoperative unit, patients in both groups received oral 5-mg oxycodone for a pain score of 6 or less or oxycodone 10 mg for a pain score of 7 or greater. To ensure patients met a minimum level of mental functioning, an abbreviated mental test (AMT) was administered to each patient (Hodkinson, 1972; Ni Chonchubhair, Valacio, Kelly, & O'Keefe, 1995; Swain & Nightingale, 1997). This test has been widely used in patients to identify delirium in postoperative patients. This measure was included to ensure that patients would be able to either comprehend the teaching on the use of the device or request pain medication from the nurse and complete a survey about their pain experience upon discharge. All patients passed the AMT.

Overall Multimodal Pain Management Plan

Table 1 describes the multimodal pain management plan for preoperative and postoperative medications. All patients had a continuous lumbar plexus catheter infusion with bupivacaine and additional available bolus doses if needed.

Patients assigned to the device group (Group 1) had access to 5-mg oxycodone at 2-hour lockout intervals, whereas patients in the control group (Group 2) could receive 5 or 10 mg of oxycodone every 4 hours with numeric pain score parameters as described in Table 1. Patients in both groups had an additional one-time dose of 5-mg oxycodone available 30 minutes prior to physical therapy, as needed. The device group was administered this dose using a nurse-controlled override function on the device and the control group received the medication by the nurse via usual orders. The maximum dose of oxycodone available to patients in both groups was 15-mg oxycodone in a 4-hour period.

For patients in the device group, regular nursing pain assessment was undertaken every four hours and

Table 1. Perioperative Multimodal Regimen for Pain Management: Primary Total Hip Arthroplasty

Preoperative analgesia in the surgical holding area
Lumbar plexus catheter placed for regional block initial injection of local anesthetics, followed by an infusion postoperatively.
Patients younger than 65 years: oral oxymorphone hydrochloride ER 10 mg, gabapentin 600 mg, celecoxib 400 mg, acetaminophen 1,000 mg.
Patients older than 65 years: oral oxymorphone hydrochloride ER 5 mg, gabapentin 300 mg, celecoxib 200 mg, acetaminophen 1,000 mg
Intraoperative anesthesia and analgesia
Spinal anesthesia—Additional medications per anesthesiologist with no consistent regimen.
Postoperative analgesia (postanesthesia care unit)
Continuous lumbar plexus catheter infusion with bupivacaine 0.0625% in normal saline 250 ml at 7 ml/hour
Bolus bupivacaine 0.0625% via lumbar plexus catheter every 30 minutes as needed for breakthrough pain ×2 doses of ketorolac 7.5 mg iv once PRN breakthrough pain.
Multimodal pain management regimen postoperative care unit
Nonopioid medications:
Acetaminophen 1,000 mg every 6 hours by mouth.
Ketorolac 7.5 mg iv every 6 hours x 48 hours to start on POD1.
Gabapentin 300 mg by mouth, daily, at bedtime.
Continuous lumbar plexus catheter infusion with bupivacaine 0.0625% at 7ml/hour continuous rate.
Lumbar plexus catheter bolus bupivacaine 0.0625% every hour for a maximum of two doses for pain (pain score of 5–10).
Opioid medications:
Device patients—Group 1
Oxycodone 5 mg with a lockout of 2 hours PRN
Usual care control group—Group 2
For mild to moderate pain (pain score of 4–6), oxycodone 5 mg by mouth every 4 hours as needed and an additional dose 30 minutes prior to physical therapy. For severe pain (pain score of 7–10), oxycodone 10 mg by mouth every 4 hours as needed.
Groups 1 and 2
Rescue pain medication not controlled by other medications—hydromorphone 0.3 mg iv bolus every 30 minutes as needed, not to exceed a total of 3 bolus doses per breakthrough pain episode. Notify Pain Service if pain is not controlled.

recorded in the EHR. The pain assessment task included documentation of the patient's numeric pain score using the numeric rating scale from zero to 10, quality descriptors of the pain, sedation level, and any other observations regarding pain or needs. Pain data from patients in the device group were pulled from pain scores entered by patients on the device when medication was requested.

Times of patient doses, pain scores, and reassessment pain scores for the device group could be viewed on and printed from the workstation computer. The device had an electronic voice that would prompt the patient to enter their pain score on the device keypad 60 minutes after the medication was dispensed. Device dosing, however, was independent of pain score and occurred no less than every 2 hours.

Patients in the control group were assessed prior to and reassessed 60 minutes after a dose of oxycodone was administered by the nurse, per usual care standards. An "alert" marked "pain response" would pop up on the electronic medication record to remind the nurse to enter the results of her reassessment.

If a patient's pain in either group was not able to be controlled by the available medications, a nurse could deliver a single dose of 0.3-mg hydromorphone intravenously as detailed in Table 1. For pain not adequately controlled by this approach, the nursing staff could notify the Acute Interventional Perioperative Pain Service for further orders. Any rescue doses of administered parenteral opioids were accounted for by chart review. The total milligrams used in rescue dosing were converted to an equivalent oral dose of oxycodone for comparison, which allowed for the calculation of the mean dose of oxycodone used by each group. Peripheral nerve block boluses with bupivacaine were available for patients in both groups and were accounted for by chart review.

Data Collection

Patient demographics, length of hospital stay, pain intensity scores, total oral opioid consumption, and physical therapy data were obtained by electronic chart review.

A patient survey was administered on the day of discharge. Sections I and II of this patient survey were based on questions from the brief pain inventory (BPI) about pain levels during the 24 hours prior to discharge and how pain had interfered with performance parameters that might impact recovery. The BPI has been shown to be a valid pain inventory for use in patients with noncancer pain with a reliability coefficient greater than 0.70 (Keller et al., 2004). Section III was derived from the Patient Global Assessment of the Method of Pain Control (Rothman, Vallow, Damaraju, & Hewitt, 2009). Responses to the patient survey were compared with a previous publication that reported patient experience with the same device after TKA (Lambert & Cata, 2014).

The inpatient physical therapy department was apprised of the study prior to its launch. Physical therapy (PT) staff were already routinely documenting in the patient EHR, numeric pain scores at rest and during activity; these data were extracted by chart review for comparisons between the control and device groups. Most patients were able to participate in two PT sessions each day. For PT, no special distinction was made between the two groups. Patient physical performance was not evaluated prior to surgery.

All patient self-report and PT data were analyzed by group (device group vs. control group) and gender (within each group and between groups) to detect any significant differences. The PT data were the only data that revealed any significant gender differences.

On (patient's) POD2 or at discharge (whichever came first), the day shift nurses completed an eight-question survey to rate their experience with patients assigned to the device group (see Table 2). If the nurse did not interact with a device programming step during that shift time, the nurse could respond that the question as not applicable (i.e., N/A). The N/A responses were not included in the response calculations. Data were reported as percentage of respondents who gave each of the four possible responses (Strongly Disagree, Disagree, Agree, and Strongly Agree). The sum of all responses indicated that nursing staff were

Table 2. Nursing Survey Responses Regarding the Device Use

	Percentages Reported				
Question	Strongly Disagree	Disagree	Agree	Strongly Agree	Favorable Agree + Strongly A
Patient understands how to use the device ($N = 30$)	3.3	3.3	20	73	93
The patient can easily use the device ($N = 29$)	3.4	3.4	14	79	93
The device was easy to set up and program ($N = 18$)	0	0	56	44	100
The device was easy to program for the time interval required between medication doses ($N = 17$)	0	0	53	47	100
The device was easy to query to obtain charting data ($N = 27$)	3.7	0	52	44	96
The device functions reliably ($N = 28$)	3.5	0	29	68	97
The device saves nursing time ($N = 30$)	3.3	3.3	40	53	93
I would like to use the device for my patients who are capable of using it ($N = 29$)	3.4	0	45	52	97

Table 3. Patient Demographic Summary

	Device Group ($N = 30$)	Control Group ($N = 30$)	p
Age: Years, *M* (*SD*)	61.5 (9.49)	61.4 (9.36)	.98
	Minimum 41 to Maximum 79	Minimum 43 to Maximum 79	
Sex			
Male	21 (70%)	18 (60%)	.42
Female	9 (30%)	12 (40%)	
Race			
African American	3 (10%)	2 (7%)	.64
Caucasian	27 (90%)	28 (93%)	
Length of stay			
Hours, *M* (*SD*)	47.7 (12.9)	52.2 (15.6)	.46

highly favorable on all questions regarding their own experience with the device and their perception of patients' experience with the device.

Because there are few validated tools available that measure nursing satisfaction around managing pain for patients, a previous survey was used that exhibited a Cronbach's α reliability measure of 0.79 in a previous device evaluation (Rosati et al., 2007).

Statistical Analyses

Descriptive statistics were calculated for all variables of interest. Continuous variables were summarized using means and standard deviations whereas categorical variables were summarized using counts and percentages.

Demographic variables were compared between groups (device group vs. control group) using two sample *t* tests for continuous variables such as age, χ^2 statistics for categorical variables such as sex, and Wilcoxon rank sum tests for nonnormally distributed variables such as length of stay. A repeated measures analysis of variance (ANOVA) was used to compare groups for pain scores, oxycodone consumption, and physical therapy data, as multiple data points were collected for each patient. For those outcomes that were nonnormally distributed, the nonparametric approach was used (Brunner, Domhof, & Langer, 2002). Patient pain questionnaires were compared using a χ^2 test.

All statistical analyses were carried out using SAS Version 9.4 (SAS Institute, Inc., Cary, North Carolina) and used a *P* value of .05 or less to indicate statistical significance. Statistical analysis was done through the faculty of the Department of Research Design and Biostatistics, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada.

Results

Patient demographics are shown in Table 3. The average ages of the two groups were 61.5 and 61.4 years, respectively; there were no differences by *t* test or standard deviations. Chi-square analysis showed no significant differences in gender or racial distributions. There were no significant differences in length of stay in hours: 47.7 for the device group and 52.2 for the control group. The length of stay was calculated starting with the time the patient arrived on the inpatient unit until the time the patient was discharged from the unit.

Table 4 includes the mean pain scores and mean oxycodone doses of both groups as recorded on POD1. Pain score and physical therapy data were analyzed for POD1 because all patients were present in the inpatient unit during that entire 24-hour period. Patients arrived at the inpatient unit at different times on POD0 and some patients were discharged on POD2; therefore, POD1 was used for pain score comparisons.

The nurse administration of PRN oxycodone was available every 4 hours with 5 to 10 mg of oxycodone depending upon patients' reported numeric pain score from 1 to 10. The PCA device was programmed with a 2-hour lockout between 5-mg doses of oxycodone, which is in keeping with the logic of PCA devices—smaller doses of medication provided more frequently as needed. The control group reported significantly higher pain scores (mean numeric score of 6.0) while taking higher average doses of oxycodone (8.2 mg) as compared with the device group with a mean pain score of 4.7 using an average of 5.1-mg oxycodone per dose. A repeated ANOVA was run to compare the two groups as multiple pain scores were recorded during POD1. This calculation showed a highly significant difference

Table 4. Pain Data Postoperative Day 1

	Device Group ($N = 30$)	Control Group ($N = 30$)	p
Pain scores, *M* (*SD*)	4.7 (1.8)	6.0 (2.2)	<.0001
Dose of oxycodone, *M* (*SD*), mg	5.1 (1.2)	8.2 (3.6)	<.0001
Total oxycodone, *M* (*SD*), mg	37.6 (20.3)	32.1 (21.8)	.40
Total bolus bupivacaine, *M* (*SD*), mg	32.9 (32.4)	40.9 (38.0)	.49

Table 5. Pain Score Distribution 24 Hours Prior to Discharge

	Percentages of Pain Scores Distribution of ≥5	
	Worst Pain 24 Hours Prior to Discharge	Least Pain 24 Hours Prior to Discharge
Device group	70%	3.3 %
Control group	83%	13%
p	.22	.35

between the two groups with the device group having a 1.3 lower pain score on average than the control group. For any additional rescue opioids given other than oral oxycodone, those doses were converted into equivalent oral oxycodone using the opioid conversion calculator based on multiple recommendations in the literature (Kane, 2017). There were no significant differences between the two groups on POD1 in the total mean dose of oxycodone taken during that 24-hour period or the milligrams of bolus bupivacaine given in the peripheral nerve blocks.

Patient surveys were obtained on the day of discharge. Question I from the BPI asked patients to record their numeric level of pain at its worst and least in the 24 hours prior to discharge by circling the appropriate number using a linear numeric pain scale (see Table 5). Seventy percent of the device group reported pain at its worst as 5 or greater, whereas 83% of the control group reported their worst pain as 5 or greater during the 24 hours prior to discharge. When asked to record a pain score indicating the least amount of pain experienced during the 24 hours prior to discharge, 3.3% of the device group recorded a pain score of 5 or greater and 13% of the control group recorded a score of 5 or greater. Although the trend was better pain control in the device group, the data did not reach statistical significance according to *p* values using χ^2 analysis.

Questions II A through E asked patients to report how pain had interfered with general activity, mood, walking ability, sleep, and appetite during the 24 hours prior to discharge. Interference was recorded by circling numbers on a linear scale from zero to 10 for each question, with zero representing no interference and 10 maximum interference. Results are shown in Table 6 for the percentage of responses representing interference of 5 or greater. No statistical differences from pain interference with specific activities were seen between the two groups. The largest difference was seen for interference with appetite: 13% (in the device group) versus 23% in the control group.

Question III on the patient survey asked, "Please rate the delivery method of your as-needed oral pain medication either by your nurse or by the MOD device during your stay." Answer options included Poor, Fair, Good, or Excellent. The device group reported 97% Good and Excellent, whereas the control group reported Good and Excellent 93% of the time. Although the device group was slightly higher in the response, it was not statistically significant with a *p* value of .62.

In the PT report (in patient charts), the physical therapists recorded the distance walked in feet and patient-reported numeric pain scores from zero to 10 at rest and with activity for each session (see Table 7). There were no overall significant differences in the mean distances walked between the device group and the control group. When the data were analyzed by gender, women walked shorter distances than men; there were no differences within the same gender when compared between the two groups. Pain scores at rest and during activity are shown for both groups including gender-specific data. The only significant differences were in men during PT session: Male patients in the device group reported significantly lower pain scores than men in the control group ($p = .03$). These data were analyzed using nonparametric analyses, as nonnormal distributions were found.

Discussion

A multimodal pain regimen was used preoperatively and postoperatively in a prospective randomized study that deployed nonopioid scheduled pain medications, PRN oral oxycodone, and a continuous lumbar plexus regional nerve block with bolus doses of bupivacaine PRN per the patient's request. Thirty postoperative THA patients were provided with PRN oxycodone using a wireless PCA device and another thirty received PRN oxycodone from nursing staff.

An advantage of a PCA device is that it administers smaller doses of medication, available more frequently (every 2 hours) to achieve better pain control as previously validated with IV PCA technology (McNicol, Ferguson, & Hudcova, 2015). Table 4 is a validation of the PCA device, which resulted in significantly lower pain scores per dose (as entered into the device by the patient) in comparison with the control group. Smaller doses of opioid more frequently can better achieve a steady plasma analgesic concentration as compared

Table 6. Percentages of Patients Reporting Pain Interference Relating to Functional Measures[a]

Group	General Activity	Mood	Walking Ability	Sleep	Appetite
Device group, *N* = 30	47%	30%	47%	33%	13%
Control group, *N* = 30	43%	23%	50%	27%	23%
p	.80	.55	.79	.57	.31

[a]Interference recorded on a scale of 0 to 10 being maximum interference. Percentages reported are the percentages of patients who reported interference of 5 or more.

Table 7. Physical Therapy Data From Postoperative Day 1

	Device Group (N = 30/57[a])	Control Group (N = 30/59)	p
Distance walked in feet, *M* (*SD*)	155 (92.7)	131 (86.3)	.21
Men only	173 (95.0)	146 (78.0)	.24
Women only	113 (74.0)	109 (94.7)	.91
Pain score at rest, *M* (*SD*)	4.00 (2.24)	3.57 (1.9)	.38
Men only	3.56 (2.57)	3.53 (1.68)	.92
Women only	4.80 (1.23)	3.63 (2.45)	.14
Pain score during activity, *M* (*SD*)	4.57 (2.00)	5.02 (2.50)	.23
Men only	4.24 (1.83)	5.22 (2.31)	.03
Women only	5.46 (2.22)	4.69 (2.85)	.46

[a]*N*: Total number of observations for data calculations including both groups.

with the peaks and troughs of larger doses given less frequently (Conley & Cassano, 2015).

Patient surveys provided information for pain score distribution 24 hours prior to discharge and percentages of patients reporting pain interference relating to functional measures (see Tables 5 and 6). This shows a trend for less pain perceived in the device group as compared with the control group during the 24 hours prior to discharge, although the data were not statistically significantly different. No significant differences were found between the control and device groups when asked about pain interference with activities including general activity, mood, walking ability, sleep, and appetite during the 24 hours prior to discharge. The largest differences, although not significant, were in interference with appetite: 13% in the device group versus 23% in the control group reported five or more instances of interference. For comparison, in a similar study after TKA with a control group and a device group, both groups were asked the same questions as in this study regarding pain interference with general activity, mood, walking ability, physical therapy, sleep, and appetite during the 24 hours prior to discharge. In the TKA study, the device group overall reported significantly less interference from pain across all measures (Lambert & Cata, 2014). Of note in the TKA study, the largest difference was found between appetite interference—10% in the device group versus 30% in the control group. One possible explanation regarding the differences between the device and control groups in the TKA groups as compared with the THA groups reported here is that the THA group may have had less overall pain with a shorter hospital stay as compared with the TKA group. Considering this comparison, this study may have been underpowered to reveal any small significant differences between patient reports although trends in general seen in Tables 4 and 5 suggested better pain control in the device group.

There were also no significant differences in reported satisfaction with pain management, whether nurse- or device-administered. Because this could not be a blinded study, there may be a possible bias to consider in patient responses to opinion surveys. Both patient groups acknowledged their excellent nursing care as shown in patient notes at the end of their surveys. Patient satisfaction with pain management in one institutional study has been directly correlated with the perception that caregivers did everything they could to control pain rather than the pain being well-controlled (Hanna, Gonzalez-Fernandez, Barrett, Williams, & Pronovost, 2012). The excellent nursing environment on this unit encouraged quick response to patients requesting pain medications in general; this may have contributed to less significant differences in the patient survey when comparing satisfaction with pain control between the control and device groups (see Table 4). This identification may have influenced the favorable management of the control patient group.

Physical therapy data for the two groups showed a larger distance walked by the device group, albeit not significantly different (see Table 7). Reviewing pain scores at rest overall and within the genders showed no significant differences. The only significant difference was a lower pain score with activity reported by men in the device group as compared with men in the control group (p = .03). Of note, these data were evaluated using nonparametric calculations because there were nonnormal distributions. There were no other significant differences between gender groups.

The nursing survey questions (see Table 2) reflected the nursing staff's impression of the patient ease of use of the device, the ability of the device to save their time, and the ability of the nurses to program and gather data from the device. Survey responses were more than 90% favorable for the device use, with a 97% favorable response to use the device for future patients. A previous nursing survey at a different hospital, with an earlier version of this device technology, was less positive (Riemondy et al., 2016). It is important to note that the device used in the 2016 report was not yet a wireless device and was more complex for nursing staff to program and use than the device used in this study.

Study Limitations

Because this could not be a blinded study, there may be a possible bias to consider in patient responses to opinion surveys. This identification may have influenced the favorable management of the control patient group.

The statistical significance of our findings (as in Table 4) indicates that our sample size of 30 per group

was sufficient to detect differences in our primary outcome of mean pain scores between groups; however, a larger number of patients would have allowed us to better define differences in responses between the two groups. Other secondary outcomes in Tables 4 and 5 are shown to be trending favorably in the direction of the device group but are not statistically significant due to a lack of statistical power, which would have required a minimum of 124 per group to detect the largest differences.

To standardize the multimodal pain management approach and surgical technique, more than 95% of patients enrolled in the study had a single surgeon for the operative procedure. This tactic slowed patient accrual limiting the number of enrolled subjects in the study. Slow study enrollment may have presented a barrier to the nursing staff achieving full familiarity with the device, perhaps influencing patient responses.

Patient self-administration of oral medication is a change in the usual process that is allowed in The Joint Commission Standards under Medication Management (The Joint Commission [2018], Standard MM.06.01.03). Some nurses initially expressed concern regarding possible patient medication diversion, although this was not experienced. Involving nurses in creating and setting standards for patient and family education and device monitoring could allay nurses' concerns around this issue (Sawhney & Maeda, 2013). Medication administration by patients using the device was an adjustment for nursing, who would need continual education if the device becomes standard.

Conclusion

The first hypothesis of the study has been supported, that is, the use of a PCA would result in better pain management as shown in the statistically significant differences between the pain scores recorded in the device group versus the control group. The advantage of the PCA is its ability to deliver smaller doses of medication more frequently on patient demand.

The second study hypothesis was related to the nurses' perception of patient device use, ease of use by nursing in setting up and maintaining the device, reliability, efficiency, and a preference to use the device for future patients. Our findings indicate that nursing staff were highly favorable about the devices used in the study and overwhelmingly wanted to use the device in the future for patients capable of using it.

Orthopaedic nursing practice continues to challenge nursing to meet the concurrent unpredictable demands that occur with PRN medications causing workflow interruptions that may compromise patient care and, in this case, pain management (Cornell, Riordan, Townsend-Gervis, & Mobley, 2011). The fast-paced environment of orthopaedic postoperative care and the rigors of keeping patients on track with PT sessions and recovery activities are a constant challenge. The adoption of new technology, such a PCA device, could improve postoperative pain management in a more patient-centered environment while saving valuable nursing time (Bolton, Gassert, & Cipriano, 2008).

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