

# The Traditional Method of Oral As-Needed Pain Medication Delivery Compared to an Oral Patient-Controlled Analgesia Device Following Total Knee Arthroplasty

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As-needed (PRN) oral pain medication is an essential part of multimodal pain therapy. Medication delivery is often delayed because of multiple demands upon nursing time in a busy postoperative nursing unit. Postoperative pain control was compared using either the manual delivery of PRN oral pain medication or a bedside oral patient-controlled analgesia device. Thirty patients in each group completed a survey on the day of discharge, and additional data were collected by chart reviews. Device patients had significantly better pain scores than the usual care group on postoperative Day 2 and within the last 24 hours prior to discharge. The device group reported statistically less pain interference overall with general activity, mood, physical therapy, sleep, and appetite. Use of an oral patient-controlled analgesia device may improve pain management and patient function following total knee arthroplasty compared to the traditional delivery of oral PRN pain medication.

## Background

Multimodal pain management for surgical joint procedures combines anesthesia techniques with various medications to optimize pain management and patient outcomes (Gandhi & Viscusi, 2009; Lewis, Gunta, Mitchell, & Bobay, 2012; Meftah et al., 2012; Parvizi & Bloomfield, 2013). Multimodal approaches for pain management vary in acute care hospitals, and no “gold standard” combination is deployed across all inpatient orthopaedic surgery programs. All patients, however, are eventually converted onto oral as-needed (PRN) pain medications prior to discharge in preparation for pain management at home or in a rehabilitation facility.

The traditional delivery of oral PRN pain medications by nursing staff can result in inefficient, time-consuming, repetitive tasks throughout the work shift. A time study in an inpatient orthopaedic unit reported a minimal mean of 10.9 minutes of nursing time for each manual delivery of oral pain medication (Pizzi, Chelly, & Marlin, 2013). This time reflects only the nursing time required and does not reflect the actual patient

wait time following the request for PRN oral pain medication.

Each patient request is an unscheduled interruption of an ongoing task, which requires completion before proceeding with the delivery of an oral PRN pain medication. The delayed delivery of oral pain medication results in patient anxiety and frustration and often inadequate medication dosing depending upon the duration of the time delay. The frequent interruption of nursing attention to deliver as-needed oral pain medications reduces nursing efficiency and contributes to mental distractions that may lead to patient care errors. Although the “quiet zone” and “sterile cockpit principle” are being adopted to protect nursing against interruptions for the delivery of scheduled medications, this approach does not apply to the delivery of unscheduled PRN medication delivery (Cornell & Riordan, 2011; Fore, Sculli, Albee, & Neily, 2013; Klejka, 2012; Westbrook, Woods, Rob, Dunsmuir, & Day, 2010).

Oral patient-controlled analgesia (PCA) protocols using a small number of predelivered pain tablets directly to a patient-worn Velcro wristband pouch or in a bedside container have reported better pain control and increased patient satisfaction as compared to the usual approach for pain management (Pasero & McCaffery, 2011; Riordan, Beam, & Okabe-Yamamura, 2004).

A Canadian group reported good pain control by providing a single contained dose of pain medication in advance at the bedside with the patients keeping their

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own diaries for the numeric pain score and time of medication self-administration. More than 90% of patients were satisfied with the PCA process although some preferred not to keep their own documentation diary and often nursing was delayed in the delivery of the single dose to the patient ahead of the time available for use (Kastanias, Snaith, & Robinson, 2006). However, current U.S. federal and many state pharmacy regulations discourage unprotected bedside opioids without a secure device and a means to track and document medication delivery to ensure patient safety and prevent diversion.

Oncology inpatients using secure electronic oral PCA  $\beta$ -prototypes reported better pain control as opposed to the manual delivery of PRN oral pain medications. Nurses agreed that the device saved nursing time and appeared to improve patient satisfaction with pain management (Rosati et al., 2007). The current study deployed these commercial devices for the delivery of oral PRN pain medications in a group of orthopaedic patients following total knee arthroplasty (TKA).

## Purpose

The frequent delay in the delivery of oral PRN pain medication in a busy inpatient orthopaedic unit was identified as a probable contributor to (1) elevated patient-reported numeric pain scores (NPS) at the time of oral medication delivery and (2) the need for frequent intravenous rescue opioids in addition to oral pain medication. The hypothesis of this research was that an electronic bedside oral PCA device would prevent the delay in the delivery of oral PRN pain medications and thereby improve patient-reported pain scores resulting in an overall patient-reported improvement in functional parameters during the hospital stay.

Patients receiving oral PRN pain medication after TKA were divided into two groups. One group would use an electronic oral PCA device for medication delivery (Group 1—device group), and a second group (Group 2—usual care) would receive oral PRN pain medication in the traditional manner directly from the nursing staff. The following measured endpoints would be collected and compared to test the hypothesis:

1. Acceptable patient postoperative pain score goals
2. Hospital lengths of stay
3. Pain scores collected prior to PRN medication delivery
4. Differences in any intravenous rescue medications required
5. Patient-reported pain interference with functional performance measures

## Methods

### RESEARCH DESIGN

This was a quantitative comparative study with data collected from both patient groups. All participating patients completed written questionnaires regarding their pain management on the day of discharge. Additional data were obtained from chart reviews.

### STUDY PROTOCOL

The study protocol was approved by the hospital institutional review board. Patients were educated about the study design and enrollment requirements in the optional preoperative educational classes prior to elective admission for TKA. Following the class, interested patients were allowed to enroll as either Group 1 patients using the device or Group 2 patients receiving PRN oral pain medication delivered manually by nursing. The education session enabled a detailed explanation of the study protocol and a demonstration of the oral PCA device.

All patients enrolled during the educational classes signed informed consent prior to surgery. Additional Group 2 patients receiving traditional care were offered enrollment in the study postoperatively and were consented on postoperative day 1. All patients agreed to complete a one-page questionnaire on the day of discharge. Thirty patients were enrolled into each group. For Group 1 patients, the initiation of the oral PCA device use and data collection was begun on either postoperative day 1 or postoperative day 2, depending upon the patient clinical status and nurse research staffing. Eleven device patients were begun on postoperative day 1 and 19 patients on postoperative day 2. Four staff orthopaedic surgeons referred patients to the study.

All patients met eligibility criteria for enrollment that included minimum age of 18 years, elective surgical procedure for TKA, no evidence of pathologic fracture, ability to understand and sign informed consent, not pregnant or on hemodialysis, no anticipated need for intensive care admission following surgery, agreement to complete a one-page questionnaire on the day of discharge, and no known allergy to morphine, hydrocodone, oxycodone, or hydromorphone.

Additional eligibility requirements for device patients included no history of drug abuse or previous treatment for drug abuse, agreement to use the device exclusively for their own use and to maintain device security, no difficulty with swallowing or physical disability to prevent safe use of the device for self-administration of medication. Each patient was required to demonstrate the ability to obtain the first dose of medication from the device by using the radiofrequency identification (RFID) wristband registered to the device with the nurse observing.

All staff nurses completed the device competency training. Patients in both groups received either Percocet (oxycodone, 5 mg with 325 mg acetaminophen) or Lortab 7.5 (hydrocodone, 7.5 mg with acetaminophen 325 mg) with a specified time interval between dosing of either every 3 hours or every 4 hours (see Table 1). Device patients started the device use and data collection on postoperative Day 1 or Day 2, depending upon the patient clinical status. Device patients were provided up to three additional single “now” or bolus doses of oral pain medication from their devices for pain not relieved by the patient-administered dose or prior to physical therapy by nursing staff using their RFID nurse cards to activate devices.

Device medication trays containing eight doses of medication were filled, labeled, barcoded, sealed by central pharmacy, and stored in the automated

**TABLE 1. MULTIMODAL REGIMEN FOR PAIN MANAGEMENT FOLLOWING TOTAL KNEE ARTHROPLASTY****Preoperative analgesia in the surgical holding area**

Femoral catheter placed for regional nerve block

**Intraoperative anesthesia and analgesia**

General anesthesia

Additional medications per anesthesiology with no consistent regimen

**Postoperative anesthesia (postanesthesia care unit)**

Continuous femoral nerve catheter with ropivacaine 0.2% in 0.9% saline (2 mg/ml) at a continuous infusion rate of 4 ml/hr (8 mg/hr) with a PCA dose of 4 ml with a 15-minute lockout. Other intravenous opioids as needed for pain control per anesthesia first 24 hours following surgery.

**Postoperative analgesia (patient care unit)**

Within the first 8 hours after transfer to the inpatient nursing unit, a one-time bolus from the nerve block infusion pump of 10 ml (20 mg) for a numeric pain score  $\geq 5$  and an increase in the infusion rate to 6 ml/hr (12 mg) with a dose escalation for breakthrough pain by numeric pain score by physician orders not to exceed 10 ml/hr (20 mg/hr). The continuous peripheral nerve catheter is discontinued per the anesthesia physician discretion either on postoperative day 1 or day 2 for most patients (see Table 3).

**Multimodal Pain regimen postoperative**

Nonopioid medications:

Ketorolac 15 mg every 6 hours IV  $\times$  4 doses then every 6 hours PRN pain

Pregabalin 50 mg oral BID  $\times$  3 days

Celebrex (celecoxib) 400 mg PO  $\times$  1 then 200 mg PO BID

Opioid PRN IV rescue medication:

IV rescue opioid analgesic hydromorphone 0.5 or 1 mg every 2 hours PRN pain

Device patients—Group 1—oral analgesics:

Oxycodone/acetaminophen 5 mg/325 mg or hydrocodone/acetaminophen 7.5 mg/325 mg with first dose now and q 3 hours PRN or 4 hours PRN per the device clinician order. The nurse was able to administer a “now” single dose directly from the device on call to physical therapy or for pain not relieved after a minimum time of 1 hour from self-administration of the oral pain medication up to 3 times within a 24-hour period. Devices delivered a single dose (tab) of medication after each lockout interval.

Usual Care—Group 2—oral analgesics:

Oxycodone/acetaminophen (5 mg/325 mg) 1–2 tabs every 4 hours PRN pain or hydrocodone/acetaminophen (7.5 mg/325 mg) 1–2 tabs every 4 hours PRN pain

dispensing pharmacy unit on the inpatient unit. Nurses loaded the devices with the appropriate medication tray as part of the device programming steps. Each device was programmed by accessing the device software loaded into the nursing computer workstations via a USB (universal serial bus) connection between the device and the computer workstation.

Each device patient wore a unique RFID wristband registered exclusively to their device for the patient's access only. Patients were alerted that the required lockout interval in hours between doses had passed, signaling that a dose of medication was available, when a green ready light was illuminated on the front of the device. Patients were allowed to self-administer medication from the device, depending upon their need for medication at any time interval after the green light illuminated.

To obtain a single tab of medication, the patient was required to register the level of pain on the NPS display on the device from 0 to 10. Registering the pain score activated the RFID reader within the device. If the reader recognized the registered RFID patient wristband, the device tray turned to expose a single dose of medication for the patient to remove and self-administer.

Early study discontinuation was possible for failure to be compliant with the patient responsibility agreement for Group 1 patients, admission to the intensive care unit, patient confusion or disorientation during the study, any evidence of drug diversion by a patient, or an inability to tolerate oral pain medication. All patients were able to complete the study.

No patients were allowed to cross over into the other study group. All patients were provided intravenous rescue pain medications for pain control not adequately treated by oral pain medication. No adverse patient events related to pain management were reported during the study. No patients using devices for medication administration were removed from the device use due to noncompliance or diversion.

**MULTIMODAL PAIN MANAGEMENT PLAN**

All patients received femoral nerve block catheters for ropivacaine infusion placed preoperatively as part of their multimodal pain management plan (see Table 1). Ropivacaine was continued without interruption postoperatively with the ability of nursing staff to deliver additional bolus infusions as needed for adequate pain management. The day of surgery, that is, day 0, patient pain management was per anesthesiology and the

**TABLE 2. PATIENT DATA SUMMARY**

	Sex	Age (Years)	Length of Stay (Hours)	Tolerable Pain Score	
Device Group (N = 30)	M (16) 53%	63.7 ± 9.3	Median 71	3.17 ± 0.91	
	F (14) 47%		LQ 68 UQ 76		
			IQR 8		
Usual Care Group (N = 30)	M (11) 37%	64.7 ± 9.6	Median 72	3.23 ± 0.77	
Usual Care Group (N = 30)	F (19) 63%		LQ 70, UQ 74		
			IQR 4		

Note. From outlier analysis using interquartile ranges (IQR) upper (UQ) and lower (LQ) quartiles are shown. Observations outside 1.5 IQR + UQ are longer stay outliers.

attending physician. All patients received education regarding the use of the numeric pain scale (NPS) to express their pain status during the hospital stay. Device patients began oral pain medication per the device use on either postoperative day 1 or day 2, depending upon their clinical and pain control status.

Patients receiving the traditional delivery of oral PRN pain medication by nursing staff reported their NPS at the time of medication delivery. Reassessment of pain was done within an hour of the manual medication delivery. Device patients were required to enter a pain score on the device as part of the request for medication prior to the removal and self-administration of the pain medication. Pain reassessment times for device patients were accomplished using the same protocol as used with IV-PCA device patients with the initial pain reassessment at 1 hour, then every 2 hours times 2, and then every 4 hours. No patients in the study used IV PCA devices.

### DATA COLLECTION

Collected patient data included patient questionnaires completed on the day of discharge, length of stay (LOS), recorded pain scores at the time of medication administration, and the amount of oral and intravenous pain medications received by each group during the patient stay. Length of stay was measured from the time the patient was admitted to the inpatient unit until the time the patient departed from the unit on the day of discharge. All collected data were entered into Survey Monkey (<http://www.surveymonkey.com>) for data summaries and analysis.

### STATISTICAL ANALYSIS

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

percentages. Lengths of stay for the two groups were calculated as median and interquartile range. Comparisons between groups on continuous measures were carried out using two-sample two-sided *t* tests or Wilcoxon rank sum tests for the case of nonnormally distributed data. Chi-square analysis was used to analyze differences between pain scores and percentages of pain interference across each of the five measures of patient functions to determine statistical differences. All analyses were carried out using SAS Version 9.2 (SAS Institute, Cary, NC) and used a *p* < .05 to denote statistical significance. Statistical analysis was done by Alex Kiss, PhD, Department of Research Design and Biostatistics, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada.

## Results

More men were enrolled in the device group as compared to the usual care group (53% vs. 37%), although there were no significant differences in ages between the two groups (see Table 2). Median LOSs were not significantly different at 71 and 72 hours between the two groups. Extended stay outliers were identified for both groups using interquartile ranges. Reasons for patients' requiring more prolonged hospitalizations equal to or greater than the upper quartile ranges were not pain related as verified by patient chart reviews. As part of the inpatient unit admission, patients were asked what pain score would be tolerable and acceptable to them during the hospital stay, acknowledging that attention to pain management would be essential to maintain a tolerable pain level. Both groups reported a target tolerable pain score of 3.

All daily routes of pain management are summarized in Table 3. Any use of PRN oral pain medication or rescue intravenous pain medications, regardless of the number of doses, was scored as a positive use for each patient. By postoperative Day 2, more than 70% of

**TABLE 3. PERCENTAGES OF PATIENTS USING PAIN MODALITIES**

Postoperative day	Nerve Block			Intravenous PRN Rescue Meds			Oral PRN Pain Meds		
	1	2	3	1	2	3	1	2	3
Device (N = 30)	96.7	26.7	4.0	60.0	43.3	28.0	100	96.7	96.0
Usual care (N = 30)	90.7	20.7	14.3	70.0	48.3	19.0	83.3	89.7	95.2



**TABLE 4. ORAL PRN PAIN MEDICATION**

Groups	Oral Medication	Total Number of PRN Oral Doses (Tabs) Pain Meds			
		Postoperative Day 1	Postoperative Day 2	Postoperative Day 3	Total
Device group (N = 30)	Oxycodone/acetaminophen 5/325 mg	148	121	68	337
	Hydrocodone/acetaminophen 7.5/325	27	19	3	49
Usual care (N = 30)	Oxycodone/acetaminophen 5/325 mg	90	117	40	247
	Hydrocodone/acetaminophen 7.5/325	23	21	4	48

patients had nerve block catheters removed. The most frequent approach for pain management was PRN oral pain medication with intravenous rescue doses available as needed. More device patients deployed PRN oral pain medication during the three postoperative days ( $97.7\% \pm 2.1$ ) compared with the usual care group ( $89.3\% \pm 5.9$ ). The use of intravenous rescue medication was reduced each day as would be expected for each day following surgery.

Device patients received more total pain tabs of oxycodone/acetaminophen than the usual care group (see Table 4). Patients within both groups received essentially the same number of hydrocodone/acetaminophen tabs, which comprised less than 17% of the oral tabs obtained for each patient group.

Collected NPS for each group were compared at the time of oral medication delivery (see Table 5). Reassessment scores were not compared, as they were done at different time intervals after oral pain medication delivery. Cumulated average pain scores for both groups were compared from postoperative Day 2. The device group had a lesser percentage of pain scores of 5 or greater as compared to the control group ( $55.2\%$  vs.  $74.6\%$ ,  $p = .0007$ ). On the day of discharge, each patient completed a questionnaire that asked patients to record the worst pain score each had experienced within the last 24 hours prior to discharge. The percentage of the device group reporting the worst pain of 5 or greater was less than that of the control group at  $63.3\%$  versus  $86.7\%$  ( $p = .04$ ).

The patient questionnaire asked how pain had interfered with various functional parameters on a scale of 0–10 during the last 24 hours prior to discharge with zero meaning *no interference from pain* and 10 meaning *maximum interference* (see Table 6). A chi-square analysis was run to compare the percentage of scores of 5 or greater between groups looking across all five measures including general activity, mood, physical therapy, sleep, and appetite. Across all the categories, the differences were significant ( $p = .02$ ) with the device

group having 31.5% of observations showing interference and the usual care group 43.5%.

Patients in the device group who started the device use on postoperative day 1 as compared with postoperative Day 2 had a longer period of time using devices prior to discharge. The group with the longer time of use reported less interference from pain as opposed to those starting on postoperative Day 2, but a chi-square analysis comparing the two groups did not meet statistical significance.

## Discussion

Patients in the two study groups had the same acceptable postoperative pain score goals at a numeric pain score of 3, and there was no significant difference in the LOS between the two groups. However, the percentages of pain scores recorded at 5 or greater at the time of medication delivery on postoperative Day 2 were significantly better in the device group than in the usual care group. Postoperative Day 2 was considered the best day to obtain these data since all patients had been enrolled into the two groups by postoperative Day 2. When patients were asked to report the worst pain experienced during the last 24 hours prior to discharge, the device group reported a significantly smaller percentage of pain equal to or greater than 5 as compared to the control group.

As-needed oral pain medication was used consistently by both groups on postoperative days 1–3. Device patients received more oxycodone/acetaminophen pain tabs over postoperative days 1–3 as compared to the control group during this time. This difference could be due to easier access to medication from the bedside device as opposed to the usual approach, which requires a request to the nurse followed by a wait time prior to medication delivery. These data are of particular interest since device patients could only access one tab at a time whereas the usual care patients were provided one or two tabs, depending upon the nurse assessment of pain at the time of delivery.

Pain interference with function measures are gauged as predictors of recovery and may impact long-term performance outcomes and in some cases the development of chronic pain (Theunissen, Peters, Bruce, Gramke, & Marcus, 2012). Patients in the device group reported overall less interference from pain with general activity, mood, physical therapy, sleep, and appetite with statistically significant differences including all parameters. These results may factor in better pain control with some contribution from reduced stress and anxiety since the device group did not have to wait on pain

**TABLE 5. PAIN SCORES**

Group	Percentage Pain Score Distribution $\geq 5$	
	Postoperative Day 2	Last 24 Hours Prior to Discharge
Device	55.2%	63.3%
Usual Care	74.6%	86.7%
<i>p</i>	.0007	.04

**TABLE 6. PERCENTAGE OF PATIENTS REPORTING PAIN INTERFERENCE RELATING TO FUNCTIONAL MEASURES**

Group	General Activity	Mood	Physical Therapy	Sleep	Appetite
Device group total (N = 30)	43.3%	30%	34.4%	40.0%	10.0%
Device group <sup>a</sup> (N = 11)	36.4%	27.3%	18.2%	27.3%	9.1%
Started device postoperative day 1					
Device group (N = 19)	47.5%	31.5%	44.6%	36.8%	10.6%
Started device postoperative day 2					
Usual care group (N = 30)	60.1%	30.8%	46.6%	50.0%	30.1%

Note. Interference recorded on a scale of 0–10 with 10 being *maximum interference*. Percentages reported are the percentages of patients who reported interference 5 or more.

medication once the prescribed time interval between doses was reached.

Postoperative pain perception is subjective and influenced by demographic and psychological factors in addition to the nociceptive pain signals from the surgical site. Identified predictors of enhanced postsurgical pain include preoperative and postoperative anxiety, postsurgical stress, and catastrophizing defined as an exaggerated negative response to pain (Pinto, McIntyre, Ferrero, Almeida & Araujo-Soares, 2013; Khan et al., 2011). Some orthopaedic postsurgical pain studies have suggested that gender differences may also influence postoperative pain with women tending to report higher pain scores than men after TKA (Liu et al., 2012). The development of postoperative chronic pain has been related to the extent of pain control on postoperative day 2 for patients after TKA (Masselin-Dubois et al., 2013).

The ability to control medication delivery for the device patients may have contributed to a reduction in anxiety and stress, thereby improving the NPS reporting of pain. This is an assumption since psychological parameters were not formally evaluated as part of this study. However, many device patients volunteered written comments on their discharge questionnaires regarding their satisfaction from not needing to wait on nursing staff for medication and their ability to control when they obtained their medication within the prescribed lockout parameters on the device.

## STUDY LIMITATIONS

Limitations of the study included the small number of enrolled patients in each group and the inability to prospectively randomize patients due to limited research staffing. More men were enrolled in the device group from lack of randomization. Gender differences within the two groups may have contributed some bias to the results, although there were no differences in the average ages of the two groups and both groups reported the same ideal target pain score during the hospitalization. Four surgeons referred patients to the study, which may have reflected some differences in surgical techniques contributing to different pain experiences from the surgical site.

## Conclusion

Significantly better pain scores were reported following TKA on postoperative day 2 in patients using an

electronic oral PCA device compared to patients receiving oral PRN pain medication from nursing staff. Device patients also reported significantly less maximum pain experienced during the last 24 hours prior to discharge. Measured functional parameters, including general activity, mood, physical therapy, sleep, and appetite, were overall significantly better in the device group than in the control group. In spite of the better pain scores from the device group, pain scores at the time of medication delivery were higher than expected or acceptable for both groups. Since completion of this study, additional modifications have been added to the multimodal pain regimen for observed improvements in pain scores.

Upon review of the study data, devices were adopted for the delivery of PRN oral pain medications for patients undergoing joint surgery. Device time parameters have been changed from a 3-hour to a 2-hour lock-out interval to provide an equivalent number of tabs within a 4-hour time span as compared to the previous traditional manual order for one to two tabs every 4 hours for manual delivery. These changes have continued to improve patient pain scores and satisfaction as measured by institutional surveys.

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