A Prospective Randomized Trial of an Oral Patient-Controlled Analgesia Device versus Usual Care for the Administration of As Needed (PRN) Oral Pain Medications Following Total Hip Arthroplasty

Lois J. Pizzi MSN, ACNS-BC, RN-BC, Madalyn Bates BS Pharm, Katie Vulakovich CCRP, Jacques E. Chelly MD, PhD, MBA

Background

Intravenous (IV) patient controlled analgesia (PCA) has become a standard in the hospital setting. However, oral PCA is a relatively new concept. This concept was tested in the hospital using a pill bottle with a dose of medication at the bedside; as well as using a Velcro wrist pouch worn by the patient that contained a dose or two of opioid medication. Patients utilized PRN (as needed) self-dosing with these methods.[1, 2, 3]

Recently, a mechanical oral PCA device called the "MOD"® (Medication on Demand), has been developed. A study in total knee replacement patients showed significantly better pain scores for patients using the MOD than those in the usual care group. [4]

This technology eliminates unsecured medications, allows for electronic tabulation, and can save nursing time. A previous study showed a mean time of 10.2 minutes per episode when administering oral PRN analgesics.[5]

Methods

After determining eligibility for the study and obtaining informed consent, 60 adults scheduled for primary total hip arthroplasty (THA) at UPMC Shadyside Hospital were randomized into the study. Patient demographics between the MOD device group and the control group where not different. (Table 1)

Table 1: Patient Data Summary

	Device Group N=30	Control Group N=30	p value
Age (years)	Mean 61.5 Min 41 – Max 79	Mean 61.4 Min 43 – Max 79	
Sex	Male 70% Female 30%	Male 60% Female 40%	0.42
Race/ethnicity	Afr. American 10% Caucasian 90%	Afr. American 7% Caucasian 93%	0.64
Length of Stay (hours)	47.7	52.2	0.46

Methods

Upon arrival to the inpatient unit, each patient was given a modified Mini Mental Status exam to ensure patients had appropriate mental functioning. Next, each patient received oxycodone either 5mg (pain score ≤6) or 10mg (pain score ≥7). Thereafter, each patient in the MOD device group was able to self-dose oxycodone 5mg every 2 hours PRN.

Patients in the control group could receive oxycodone 5mg-10mg every 4 hours PRN by requesting this from the nurse. An additional dose of oxycodone 5mg was available to patients in each group 30 minutes prior to physical therapy sessions.

Nurses completed reassessments of patients in the control group 60 minutes after patients received the PRN dose of medication. Patients self-dosing medication from the MOD device are reminded by the device to enter a pain score 60 minutes after a dose is removed from the MOD.

Patients in both study groups completed a "Patient Questionnaire". Questions for this tool were derived from validated pain assessment tools.

Each nurse filled out a questionnaire reflecting their experience with their patient on post-operative day #2. The questionnaire's objective was to evaluate the nurses' experience managing the patient's pain.

The study data presented is a mean (range). Statistical analysis preformed on patient demographics was via a Chi-square analysis.

Comparison of groups for length of stay was done with a Wilcoxon rank sum test.

A repeated measures ANOVA was used to compare groups for pain scores and oxycodone consumption.

Sponsored by Avancen MOD Corporation. PI: Lois J. Pizzi, MSN, RN-BC. The authors declare that they have no conflicts of interest.

Results

POD#1: Patients in the MOD device group experienced significantly less pain and used significantly less oxycodone per dose than the patients used in the control group. (Table 2)

Table 2: Post-Op Day 1 Data

Variable	Device Group	Control Group	p value
Mean Pain Scores	4.7	6.0	< 0.0001
Mean dose of oxycodone	5.1 mg	8.2 mg	< 0.0001
Mean total mg oxycodone taken	37.6 mg	32.1 mg	0.40
Mean total bolus dosing of bupivacaine in the peripheral nerve block	32.9 mg	40.9 mg	0.49

In males, pain was significantly less in the MOD device group. (Table 3)

Table 3: Physical Therapy Data from Post-Op Day 1
Pain scores as reported on a 10 point scale.

Variable	Device Group N = 57	Control Group N = 59	p value by ANOVA
Mean Distance Walked in feet	155	131	0.21
Pain Score at Rest	4.0	3.57	0.38
Pain Score During Activity	4.57 Males Only 4.24	5.02 Males Only 5.22	0.23 0.03

The results of the nurse questionnaire were favorable toward using the MOD device. (Table 4)

Table 4: Nursing Survey Responses Regarding the Oral Patient-Controlled Analgesia Device (Percentages)

Question	Strongly Disagree	Disagree	Agree	Strongly Agree	Favorable
The 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 between 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	3.4	0	45	52	97

Discussion

This is the first prospective randomized clinical trial comparing an oral PCA device to nurse administration of PRN oral opioids for the management of pain following primary total hip arthroplasty.

In our study, women reported higher pain scores suggesting that gender differences may influence post-operative pain, as suggested in a study by Liu in 2012.[6]

At UPMC, the results of the nursing questionnaire provided positive data to support the use of the MOD® device on this unit. A study by Riemondy showed that nursing found the device difficult to use, but patient satisfaction was high.[7] The MOD® used in this study was not wireless. For our study, the MOD® device had an upgrade to wireless functionality.

Conclusion

Our data suggests that patients undergoing THA using the MOD device were able to achieve better pain control. Thus, the patients in the MOD groups experienced less pain at rest, less pain during physical therapy (males) while using less oxycodone per dose.

The wireless upgrade of this device may have made it more user friendly.

References:

1. Kastanias, P., Snaith, K. E., & Robinson, S. (2006). Patient Controlled Oral Analgesia: A low tech solution in a high tech world. Pain Management Nursing, 7(3), 126-132.
2. Pasero, C., Quinn T.E.,Portenoy, R.K., McCaffery, M. & Rizos, A. (2011). Opioid Analgesics. In C. Pasero & M. McCaffery (Eds.), Pain Assessment and Pharmacologic Management. Pain: Clinical Manual (Pp. 318-322). St. Louis: Mosby.
3. Riordan, S. W., Beam, K., & Okabe-Yamamura, T. (2004). Introducing patient-controlled oral analgesia. Nursing, 34(9), 20.
4. Lambert, T, & Cata, D.M. (2014). The traditional method of oral as-needed pain medication delivery compared to an oral patient-controlled analgesia device following total knee arthroplasty. Orthopedic Nursing 33(4), 217-222.
5. Pizzi, L. J., Chelly, J. E., & Marlin, V. (2014, September). Nursing Time Study for the Administration of a PRN Oral Analgesic on an Orthopedic Postoperative Unit. Pain Management Nursing, 15(3), 603-608.
6. Liu, S., Buvanendran, A., Rathmell, J., Sawhney, M., Bae, J., Moric, M…, & Sculco, T. P. (2012). Predictors for moderate to severe acute postoperative pain after total hip and knee replacement. International Orthopaedics, 36(11), 2261-2267.
7. Riemondy, S., Gonzales, L., Gosik, K., Ricords, A., & Schirm, V. (2016, April). Nurses perceptions and attitudes toward use of oral patient-controlled analgesia. Pain Management Nursing, 17(2), 132-139.