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Patient Controlled Analgesia and an Alternative Protocol: A Comparison of Outcomes After Thoracic and Lumbar Surgery

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ABSTRACT

Introduction. Patient controlled analgesia (PCA) is a common form of pain management after spine surgeries, in which patients get custom control of their opioid dose. PCA has been demonstrated as a safe form of analgesia; however, use of PCA comes with risks that can be mitigated by opting for alternative pain management. This study aimed to compare the outcomes of patients using PCA to those with an alternative analgesia protocol that does not involve PCA.

Methods. A retrospective chart review from January 2017 to July 2018 was conducted. Patients included in this study were those 18 or older who were admitted to a large midwestern tertiary medical center in Wichita, Kansas, and underwent thoracic or lumbar spinal surgery from a single spine surgeon. Data from patient demographics, comorbidities, and type of procedure were collected and compared to control for possible confounding variables. Patients were divided into two groups: patients receiving a PCA pain protocol post-operatively and those receiving a non-PCA protocol. Statistical analyses were performed and all tests with $p < 0.05$ were considered significant.

Results. This study found patients in the PCA protocol had similar outcomes to those in the alternative analgesia protocol. This was true for both primary and secondary outcomes. The primary outcome was patient length of stay after the operation. Secondary outcomes included readmission rates, frequency of naloxone rescue, transfers to higher levels of care, and total opioid consumption.

Conclusions. This study supported that a non-PCA protocol for post-operative pain management yields similar outcomes to a PCA protocol in the setting of thoracic and lumbar surgery.

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INTRODUCTION

More than 238 million opioids were prescribed in the U.S. in 2011[1], with opioid abuse costing $78.5 billion in healthcare and criminal justice expenditures.[2] In response to an epidemic of opioid-overdoses, government regulations have been tightened, proposals have been made to reduce opioid manufacturing, and there have been manufacturing problems in several pharmaceutical companies.[3] This has resulted in an abrupt shortage of three of the most commonly used parenteral opioids, including hydromorphone (i.e., Dilaudid®).[4]

The sudden shortage required physicians to adjust their opioid prescribing and find alternative ways to manage patient pain. The Enhanced Recovery After Surgery (ERAS) guideline recommendations urged multimodal analgesia to reduce opioid use post-operatively.[5] The best alternatives, non-steroidal anti-inflammatory drugs (NSAIDs), are a known impedance to bone and ligamentous healing[6] and prevents spinal fusions, which is problematic in the context of spine surgery. A recent study has shown little effect on bone healing in using NSAIDs in the short term.[7] Spine protocols have been slow to add multimodal analgesia, but Cozowicz et al.[7] noted that adding NSAIDS/COX-2 inhibitor to opioids was associated with reduction in opioid prescriptions, cost, and length of hospitalization, and there was an increased use of naloxone by 50% when gabapentinoid was used.

Effective opioid analgesia administration is a difficult balancing act, challenging physicians to ensure proper stewardship of these drugs.[8] On one hand, a large portion of those who become opioid dependent are first exposed in the perioperative period.[7] Conversely, inadequate perioperative analgesia is a risk factor for developing chronic pain, which itself contributes to opioid abuse.[9]

One way to administer opioids in the hospital is by patient-controlled analgesia (PCA). PCA involves patient self-administration (by pushing a button) of small doses of opioids intravenously by means of a programmable pump.[10] Though PCA generally is characterized as being safe,[11,12] potential problems arise, like pump programming errors,[13] activation of the PCA pump by others (i.e., family members),[14,15] and equipment failure, resulting in spontaneous activation of drug delivery.[16]

Although studies have demonstrated the risks and benefits of PCA opioid administration, the literature was lacking information comparing patient outcomes between PCA protocols to non-PCA protocols within spine surgery. Specifically, there was limited information comparing the effectiveness of using different administration modalities of opioids post-operatively.

This was a retrospective study to compare patient outcomes from thoracic and lumbar surgeries between patients using a PCA pain control protocol and patients using a non-PCA pain control protocol. The primary outcome used to assess the differences in analgesia was patient length of stay in the hospital. Secondary outcomes included total opioid consumption and the proportion of patients who were readmitted, required naloxone rescue, and transferred to higher levels of care.

METHODS

Participants. Patients included in this study were those 18 years or older who were admitted to a large midwestern tertiary medical center in Wichita, Kansas that performs more than 500 thoracic and lumbar procedures annually. These patients underwent thoracic or lumbar spinal surgery between September 1, 2016 and July 31, 2018. Patients who underwent a thoracic or lumbar procedure between September 1, 2016 and November 16, 2017 used PCA for pain control post-operatively. Patients who underwent a similar procedure between

November 30, 2017 and July 31, 2018 predominantly were given oral analgesia (non-PCA) to control pain post-operatively. Patients with the non-PCA protocol could receive parenteral morphine for pain that was not controlled sufficiently on oral analgesia, but this morphine was not administered via PCA. Patients with kidney disease (defined as a glomerular filtration rate less than 60 mL/min) required restricted opioid use, so these patients were excluded from the study.

Opioid Protocols. The non-PCA pain management protocol was standardized to the patient taking 1-2 tablets orally every 4-6 hours PRN of hydrocodone 10/325 mg for pain on a scale of 1-5. If the patient still had pain, the hydrocodone 10/325 mg could be switched with 1-2 tablets orally every 4-6 hours PRN of oxycodone (Percocet®) 10/325 mg, for pain on a scale of 1-5. Intravenous (IV) pain medications included 2-4 mg of morphine every hour PRN for pain on a scale of 6-10. However, if pain continued, then the morphine could be switched out with 0.2-0.5 mg every hour PRN of hydromorphone for pain on a scale of 6-10. Lastly, a cyclobenzaprine, or muscle relaxer, was added for the patient to take 10 mg orally every 8 hours to help with muscle spasms.

The PCA pain management protocol was standardized to allow the patient to self-administer IV opioid analgesics via pump and was used as the basis of protocol for this research. There was no loading dose or continuous IV fusion used. The patient was able to self-administer 0.1-0.4 mg of hydromorphone at a range of 5-15 minutes. With PCA, 0.5-2 mg of morphine at a range of 5-15 minutes was a rare substitute for hydromorphone.

Data Collection. The abstracted data included patient characteristics such as age, sex, race, and body mass index (BMI); the type of procedure performed; comorbidities (smoking, diabetes, hypertension); and the method of analgesia used post-operatively. Outcome data included: patient length of stay (from surgery to discharge), unplanned hospital readmission within 30 days after discharge, requirement of pain management from the emergency department of one facility within 30 days of the procedure, transfer to a high level of care (intensive care unit, ICU) post-operatively, post-operative naloxone use, and total opioid consumption.

Six different narcotic drugs were abstracted. Four of the narcotics administered were given orally (hydrocodone/Norco®, oxycodone/Percocet®, tramadol, and oxycodone as single formulation), and two were given intravenously (hydromorphone and morphine).

Procedures. This project was approved by the Wichita Medical Research and Education Foundation's Institutional Review Board and the Human Subjects Committee at the University of Kansas School of Medicine-Wichita. Data were collected through a retrospective chart review of eligible patients' electronic medical records and entered into Research Electronic Data Capture (REDCap®)[17] hosted at University of Kansas School of Medicine-Wichita.

Statistical Analysis. Descriptive statistics were summarized using frequencies (percentages) and means (standard deviations). Differences in study variables were compared according to the method of analgesia used post-operatively and analyzed using Pearson's chi-square, likelihood ratio chi-square, and Fisher`s exact tests, as appropriate. Mean comparisons were conducted using independent t-test, Mann-Whitney U test, and one-way ANOVA was used to compare the means differences as appropriate. Least-squares means (to estimate the marginal means over a balanced population) were used for pairwise comparisons of groups by Tukey test using Kramer adjustment. All statistical tests at $p < 0.05$ were considered to be significant. SAS version 9.4 was used for data analysis (SAS Int. Inc., Cary, NC).

RESULTS

Of the 269 patients who met the inclusion criteria, 18 had kidney disease due to the interference with drug metabolism and were excluded. The remaining 251 patients were included in the study analysis: 48.2% (n = 121) in the PCA protocol group and 51.8% (n = 130) in the non-PCA protocol group.

Most patients were Caucasian (92%, n = 231) and female (62%, n = 155), and the average age was 62 years (SD = 13; Table 1). There were no significant differences between the two groups. Other patient characteristics (type of procedure performed, BMI, smoking, diabetes, and hypertension status) were also similar between groups.

The amount of orally administered drugs was similar between the two groups (Table 2), whereas the amount of intravenously administered drugs differed between groups. Those on the PCA protocol received more hydromorphone and less morphine than those on the non-PCA protocol ($p < 0.0001$).

The average length of stay was 3.66 (95% CI: 3.39-3.93) days for those on the PCA protocol and 3.41 (95% CI: 3.18-3.63) days for those on the non-PCA protocol ($p = 0.15$). The proportion of 30-day emergency department visits for pain, 30-day inpatient readmission, transfers to the ICU, and naloxone use were not significantly different between the two groups (Table 3).

DISCUSSION

The purpose of this study was to compare outcomes between patients using a PCA pain control protocol versus patients using a non-PCA pain control protocol. Findings revealed there were no differences in patient lengths of stay, readmission rates, transfers to higher levels of care, and frequency of naloxone rescue between patients on the PCA and non-PCA protocols. The average amount of narcotic received between the two groups was also similar, except for morphine and hydromorphone. Patients on the PCA protocol received more hydromorphone than patients on the non-PCA protocol due to the hydromorphone shortage; those on the non-PCA protocol received more morphine than those on the PCA protocol since morphine was the parenteral drug used in place of hydromorphone.

There are some advantages of a non-PCA protocol versus a PCA protocol. Although PCA pumps generally are regarded as safe and effective,[10,11] there have been PCA pump mishaps that have led to patient harm.[13,15,16,18] Though these instances were relatively rare, their risk of occurring was null by removing the PCA pump altogether. Another possible advantage of a non-PCA protocol is a reduced cost compared to using a PCA protocol. By not using the PCA pump, this infers a lower cost compared to a non-PCA alternative because the cost of the pump is avoided. Furthermore, the cost of the drugs between the

Table 1. Demographics and clinical characteristics of sample population.

	Total (n = 251)	PCA (n = 121; 48%)	Non-PCA (n = 130; 52%)	p Value
Demographics				
Mean age, years; (SD)	62 (13)	62 (12)	61 (14)	0.65
Age, range (years)	19-86	22-86	19-83	
Sex, female (%)	155 (62)	73 (60)	82 (63)	0.65
Race (%)				0.59
White	231 (92)	113 (93)	118 (91)	
Other	20 (8)	8 (7)	12 (9)	
Body Mass Index (%)				0.12
Underweight (< 18.5)	5 (2)	2 (2)	3 (2)	
Normal weight (18.5-25)	29 (12)	12 (10)	17 (13)	
Overweight (25-30)	64 (25)	24 (20)	40 (31)	
Obese (> 30)	153 (61)	83 (68)	70 (54)	
Clinical Characteristics				
Diabetic (%)	61 (24)	33 (27)	28 (22)	0.29
Hypertension (%)	160 (64)	81 (67)	79 (61)	0.31
Smoking Status (%)				0.17
Never smoked	134 (54)	72 (60)	62 (48)	
Former smoker	81 (32)	34 (28)	47 (36)	
Current smoker	36 (14)	15 (12)	21 (16)	
Procedure Type (%)				0.8
Non-fusion	50 (20)	26 (21)	24 (18)	
1-2 level fusion	159 (63)	76 (63)	83 (64)	
3+ level fusion	42 (17)	19 (16)	23 (18)	

Table 2. Comparison of narcotics used between PCA and non-PCA groups.

	PCA	Non-PCA	MME	p Value
Oral				
Hydrocodone (Norco®)	99.86 (80.06-119.70)	101.90 (83.21-120.60)	40-120	0.86
Oxycodone (Percocet®)	51.90 (35.28-68.52)	52.00 (34.30-69.70)	60-180	0.99
Tramadol	5.38 (-2.32-13.08)	16.73 (4.78-28.68)		0.12
Oxycodone (single formulation)	5.08 (-0.50-10.67)	0.58 (-0.56-1.72)	60-180	0.12
Intravenous				
Hydromorphone (Dilaudid®)	6.59 (5.08-8.09)	1.01 (0.50-1.51)	19.2-48	< 0.0001
Morphine	0.08 (-0.08-0.25)	4.63 (2.82-6.44)	48-96	< 0.0001

Note: All values presented in means and 95% Confidence Intervals; all narcotic values in milligrams. MME stands for Morphine Milligram Equivalence. The Opioid Conversion Calculator from Oregon Pain Guidance was used to calculate the MME per day.

Table 3. Outcomes of primary and secondary endpoints.

	Total (n = 251)	PCA (n = 121; 48%)	Non-PCA (n = 130; 52%)	p Value
Outcomes				
Mean Hospital Length of Stay (days), (SD)	3.53 (1.40)	3.66 (1.49)	3.41 (1.29)	0.15
Naloxone Use (%)	6 (2)	3 (2)	3 (2)	0.92
Transfer to ICU (%)	5 (2)	4 (3)	1 (1)	0.15
30-day ED visit for pain (%)	6 (2)	4 (3)	2 (2)	0.36
30-day Readmission (%)	9 (4)	3 (2)	6 (5)	0.36

two protocols was similar due to each group using a similar amount of narcotics. However, the PCA protocol used more hydromorphone, the non-PCA protocol used more morphine. Morphine is a significantly cheaper opioid than hydromorphone (at this institution, 4 mg of morphine cost $1.67 and 4 mg of hydromorphone cost $7.32); it was also a less potent sedative.[19] Hydromorphone delivers 4 morphine milligram equivalents (MME).[20] This means hydromorphone is four times as potent as morphine, therefore, the PCA protocol received a higher dosage of narcotic overall. The PCA protocol received 26.36 MMEs in hydromorphone, compared to 4.04 MMEs in the non-PCA protocol, making morphine both a cheaper and safer[20] option in comparison to hydromorphone.

An advantage to using a PCA instead of a non-PCA protocol is patient satisfaction. Patients generally are satisfied with the PCA and the feeling of autonomy it provides.[10]

A disadvantage of a non-PCA protocol is an increased burden on the nursing staff caring for these patients. Since patients without a PCA pump can receive their pain medications only when they are administered by a nursing staff member, an assumption can be made that nursing workloads would increase. Further studies could test this assumption. However, patients on PCA or non-PCA protocols still required routine monitoring.

Decreasing length of stay has been identified as an important measure for increasing hospital efficiency and reducing iatrogenic morbidity and mortality and was a leading factor in the development of current Enhanced Recovery After Surgery (ERAS) guidelines.[9,21] Our study found no difference in the length of stay between a PCA and non-PCA protocol, adding to previous studies that suggested there was no difference in length of stay between patients on PCA and non-PCA protocols.[10,22]

Limitations. Some limitations of the current study included sample size. For a difference of 0.25 days in hospital length of stay to be statistically significant, 500 patients' data would have to be abstracted (power = 0.80). Adequacy of analgesia in the acute period after surgery is especially important to prevent chronic pain in the context of the current opioid crisis,[5] however, our study was not designed to assess this. The current study also failed to distinguish between those patients who were opioid naïve and those who had significant prior exposure. Stratifying according to opioid naïveté versus tolerance would have allowed for elimination of this as a cofounder.

CONCLUSIONS

This study suggested a non-PCA analgesia protocol can result in similar outcomes to a PCA protocol among patients undergoing thoracic or lumbar surgery. A surgeon considering avoiding PCA postoperatively can do so with similar outcomes.

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