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Parent-Controlled PCA for Pain Management in Pediatric Oncology: Is it Safe?

Doralina L. Anghelescu, MD [Member, Division of Anesthesiology, Director, Pain Management Service], Lane G. Faughnan, BSN [Clinical Research Associate], Linda L. Oakes, MSN [Clinical Nurse Specialist], Kelley B. Windsor, MSN [Clinical Nurse Special], and Deqing Pei, MS [Biostatistician]

St. Jude Children's Research Hospital

Laura L. Burgoyne, BM BS [Clinical Senior Lecturer]

University of Adelaide and Department of Children's Anaesthesia, Women's and Children's Hospital, North Adelaide, Australia

Abstract

Patient-controlled analgesia offers safe and effective pain control for children who can self-administer medication. Some children may not be candidates for PCA unless a proxy can administer doses. The safety of proxy-administered PCA has been studied, but the safety of parent-administered PCA in children with cancer has not been reported. In this study we compare the rate of complications in PCA by parent proxy versus PCA by clinician (nurse) proxy and self-administered PCA. Our pediatric institution's quality improvement database was reviewed for adverse events associated with PCA from 2004 through 2010. Each PCA day was categorized according to patient or proxy authorization. Data from 6,151 PCA observation days were included; 61.3% of these days were standard PCA, 23.5% were parent-proxy PCA, and 15.2% were clinician-proxy PCA days. Mean duration of PCA use was 12.1 days, and mean patient age was 12.3 years. Mean patient age was lower in the clinician-proxy (9.4 years) and parent-proxy (5.1 years) groups, respectively. The complication rate was lowest in the parent proxy group (0.62%). We found that proxy administration of PCA by authorized parents is as safe as clinician administered and standard PCA at our pediatric institution.

Keywords

Patient-controlled analgesia; pain; opioids; pediatric oncology

Introduction

Patient controlled analgesia (PCA) for children is widely available and commonly used; its safety and efficacy are well established.^{1,2} It offers the advantages of flexibility, rapid

Corresponding Author: Doralina L. Anghelescu, MD St. Jude Children's Research Hospital 262 Danny Thomas Pl Memphis, TN 38105 Phone: 901-595-4032 FAX: 901-595-4061 doralina.anghelescu@stjude.org.

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titration in response to pain or anticipated painful events,³ and high patient satisfaction.² However, very young or very ill children and those with developmental disabilities may lack the cognitive or physical ability to appropriately self-administer medication. The use of PCA by proxy provides a solution to this problem by authorizing a nurse or parent to “push the button.”^{4–8} This practice persists in pediatric institutions despite cautionary statements from the Joint Commissions.¹ It provides a convenient and effective method of analgesia for a group of patients who would otherwise receive less reliable pain control, and there is evidence that when proxies are carefully selected and adequately trained, PCA by proxy is as safe as conventional PCA.^{4,8} In 2007, the American Society of Pain Management Nurses published a position statement outlining the recommended process for authorizing family members and nurses to provide PCA doses when the patient cannot do so.⁹

Nurses are the most commonly designated proxies for pediatric PCA, but many institutions allow parents to serve in this capacity.¹ Our organization allows both nurses and parents to act as proxies with specific education and authorization. Nurses are trained to administer PCA by proxy at the time of employment, and they review the principles of providing safe proxy doses (by nurse and/or parent) annually through institutional educational programs. By policy, parents are taught to provide bolus doses for their child through institutional instructional material, and this education is to be documented in the medical record. In our clinical practice, as well as others, when a parent is authorized to provide PCA, a nurse is usually authorized to do so as well, as the parent cannot be present continually.⁶ This arrangement is appropriately termed parent/nurse controlled-analgesia.⁵ It remains unknown whether the risk of PCA by proxy is increased when the parent serves as proxy.

Our safety study of PCA by proxy, in which proxy categories (parent and clinician) were analyzed together (*Anesthesia & Analgesia*, 2005) found a frequency of adverse events similar to that of traditional PCA.⁴ Others have since reported on the safety and efficacy of this technique in specific patient groups.^{5–8} More recently, we demonstrated that the rate of complications of PCA by proxy remains low at our institution despite a 4-fold increase in its use.¹⁰ Here we compare the rate of complications in PCA by parent proxy, PCA by clinician (nurse) proxy PCA, and standard (self-administered) PCA to examine the safety of PCA when parents are given authorization to provide doses.

Methods

Setting, patients, and patient data

This retrospective study of quality improvement data was approved by the St. Jude Children's Research Hospital (St. Jude) Institutional Review Board, which waived the requirement for informed consent. St. Jude is a tertiary care institution for children with cancer and other life-threatening diseases. The institution has 60 inpatient beds: 36 for hematology and oncology, 8 for intensive care, and 16 for bone marrow transplantation. Patients range in age from newborns to young adults.

One to three days of each week between January 2004 and December 2010 were audited in the charts of all inpatients who had received opioid analgesia by PCA during the previous 24 hours, as indicated by pharmacy records. The medical and nursing record (including the specific PCA record sheet) were reviewed for any data indicating respiratory (decreased respiratory rate or amplitude, decreased oxygen saturation) or neurological (confusion, decreased arousability, hallucinations) complications, the use of naloxone, or death. Dates of intubation, extubation, and the authorized PCA proxies (the patient, parent, nurse, or parent and nurse) for each patient PCA day were also obtained. We excluded from analysis all PCA days during which the patient was intubated. Data for adverse events were obtained from the pain management service's quality improvement database and were reviewed for accuracy

by comparison with the medical record. Some patients included in the database may have received PCA treatment more than once during the review period.

PCA administration

Standard PCA was defined as PCA administered only by the patient, and PCA by proxy was defined as PCA administered by a nurse and/or parent. We defined PCA by parent proxy as PCA for which a specific family caregiver (often the parent) was authorized to administer boost doses, alone or in addition to the nurse and/or the patient. PCA by clinician (nurse) proxy was defined as PCA for which the nurse was authorized to administer boost doses, alone or in addition to the patient. We compared the frequency of adverse events when PCA was delivered by parents to that when PCA was delivered by patients and/or nurses. The drugs, doses, equipment, and procedures used for standard PCA and PCA by proxy were identical.

At St. Jude, physicians, physician assistants and nurse practitioners can order PCA without consultation with the Pain Management Service. During the time reviewed, PCA was administered via a CADD-Prizm Variable Infusion Profile Ambulatory Infusion Pump, Model 6101 (Smiths Medical MD Inc., St. Paul, MN). The standard starting bolus doses of opioids are posted on the hospital's intranet site: morphine, 0.02 mg/kg; hydromorphone, 0.004 mg/kg; and fentanyl, 0.5 mcg/kg, with a 15-minute lockout interval. If a background infusion is indicated, the recommended starting dose per hour is equivalent to the bolus dose. Doses are titrated as required until adequate analgesia is achieved or dose escalation is limited by uncontrollable side effects (there is no maximum dose limit). Vital signs (blood pressure, heart rate, respiratory rate, and temperature) are monitored every 4 hours on the oncology units and every 2 hours in the intensive care unit. Pulse oximetry is performed as appropriate for the clinical condition at the discretion of the clinicians. PCA-specific monitoring consists of assessing pain intensity and level of consciousness every 4 hours. Pain intensity is assessed by using the Faces, Legs, Activity, Cry, Consolability (FLACC) scale,¹¹ the Wong-Baker FACES scale,¹² or the numerical rating scale,¹³ depending on the patient's age and clinical condition. The patient's level of consciousness is documented as alert, drowsy, confused, asleep, or unarousable.

Statistical analysis

Descriptive statistics are reported for the study group and subgroups. Complication rates among the three PCA user groups were analyzed by using the exact Pearson chi-square test. Mean age in the three groups was compared by using the Kruskal-Wallis test. Two-sided *p* values are reported.

Results

Data were collected for 791 of 2,548 days (mean, 2.2 days per week) between January 2004 and December 2010. A total of 1,541 PCA orders were written for 929 patients, yielding 7,383 PCA observation days. After exclusion of data from intubated patients (46 patients, 101 PCA orders, and 1,232 PCA observation days), data for analysis comprised 883 patients, 1,440 PCA orders, and 6,151 PCA observation days. Figure 1 shows the distribution of PCA days in the standard (self-administered), parent-proxy, and clinician-proxy categories and in subgroups within these categories. Table 1 shows the distribution of complications in each group. Of 6,151 PCA days, 2,382 (38.7%) included proxy authorization (clinician proxy, 936 days, 15.2%; parent proxy, 1,446 days, 23.5%) and 3,769 (61.3%) were standard PCA days. A high percentage of the total PCA days (6,060/6,151, 98.52%) were complication-free. In the proxy groups, rates of complication were not only consistently low (0.96%; [95% CI, 0.44%–1.82%] in the clinician-proxy group and 0.62%

[95% CI, 0.29%–1.18%] in the parent-proxy group) but were lower than the complication rate in the standard PCA group (1.94%; 95% CI, 1.52%–2.43%) ($p = 0.0008$). We found that naloxone was administered on 3 of 6,151 PCA days, two in the standard PCA category (2 of 3,769 standard PCA days) and one in the clinician (nurse) PCA category (1 of 936 clinician PCA days); naloxone was not administered in the parent PCA category. There were no deaths from complications of the use of PCA in the entire study cohort; we identified 71 of 883 (8.0%) patients who were using PCAs at the time of death, and no complications were noted in this subgroup.

Table 2 shows the age distribution and duration of PCA use in all groups. The mean ages in the standard, clinician-proxy, and parent-proxy groups were 15.1 years, 9.4 years, and 5.1 years, respectively ($p < 0.0001$). The mean duration of PCA use was 11.5 days, 13.4 days, and 13.3 days in the standard, clinician proxy, and parent proxy groups, respectively.

Discussion

This study compared the safety profiles of PCA delivered by parent proxy, clinician (nurse) proxy, and patients in a pediatric population. It should be noted that this study excluded all PCA days for intubated patients to allow an accurate comparison of PCA-related respiratory and neurological complications. The lowest rate of complications (0.62%) occurred in the parent proxy PCA group and the highest (1.94%) occurred in the standard PCA group.

Comparison of PCA complication rates in the literature is difficult because of the inconsistent manner in which complications are defined and reported. Even the frequency of naloxone administration cannot be directly compared, as some groups report these data per patient and others report it per treatment day.^{4,5,7} Further, it must be kept in mind that the selection of standard PCA vs. clinician-proxy PCA vs. parent-proxy PCA is not randomized, and thus selection bias is a confounding factor.

In our study and others,⁸ patients receiving PCA by proxy were younger and often had more comorbidities than patients receiving standard PCA. A recent study of young children receiving PCA by parent proxy showed a neurological and respiratory depression rate of 0.9% per day during the first 2 days and 0% during subsequent days.⁶ Our rate of complications in the parent proxy group of 0.62% is comparable, but our study patients in this group had a mean age of 5.1 years, compared to only 19.6 months in that study. A report from the same institution stated that 2.8% of children with developmental delay who received PCA by parent proxy required naloxone to treat significant sedation or respiratory depression. Another study found an even higher rate of naloxone administration (4%) in children less than 6 years of age.⁷ Although it is intuitive that a parent, having less clinical knowledge than a clinician, should be a “less competent” proxy and incur a higher risk of complications, we found the overall rate of complications in the parent PCA group (0.62%) to be less than that in the clinician PCA group (0.96%), despite the substantially younger patient age in the parent proxy group (mean, 5.1 years vs. 9.4 years), which poses a higher risk of complications.

We found only one study other than our previously reported study⁴ that compared standard PCA to PCA by proxy; it evaluated the use of nurse proxy PCA in post-operative pediatric patients.⁸ That study followed patients for 3 days and found that 7.6% of those in the nurse proxy group required “rescue events” (airway support or naloxone administration). The frequency of naloxone administration was 1.7% in the nurse proxy group, in contrast to our one case of naloxone administration in the nurse proxy group (1 of 936 clinician PCA days) and none in the parent proxy group. Although the groups were not found to differ significantly in the frequency of adverse events, patients in the nurse proxy group had a

higher frequency of adverse events requiring intervention. The authors commented that the patients in this group were younger and had more comorbidities. Our study also had younger patients in the proxy groups, but we found a lower rate of complications in the proxy groups than in the standard PCA group. A study of postoperative PCA by nurse proxy³ with no standard PCA control group reported that 4.5% of patients were over-sedated or had respiratory depression, compared to an overall complication rate of only 0.96% in the nurse proxy group in our study. Also, the mean patient age (4 years) was younger than the mean age (9.4 years) for clinician proxy PCA in our study. Further, that study analyzed complications for two days on average (the entire PCA administration period for each patient), while our analyses were based 24-hour periods in which PCA was used.

We attribute our low complication rates to several factors, including institutional standards and guidelines, caregiver education, the availability of nurses to make frequent bedside assessments, and case mix. Our nurse-to-patient ratio (usually 1:2 and never less than 1:3) is relatively high, and nursing education is well regulated, with mandatory yearly training in patient selection for proxy PCA and the use of PCA by proxy. Our policy for use of parent proxy PCA is to educate parents to provide PCA by proxy with written and/or video materials, and this education is to be documented by the nursing staff before the parent is authorized as a proxy. The quality improvement process rigorously evaluates safety outcomes and compliance with policies and includes quarterly reports to the institutional Pain Committee. All of our patients are undergoing treatment for cancer or chronic hematological diseases, both of which tend to require long-term management. Consequently, the parents are medically sophisticated and are accustomed to monitoring the medical status of their child. This factor may contribute to the lower rate of complications reported at our center. In addition, our patients are less likely than most pediatric inpatients to be opioid-naïve.

Both this study and our previous study⁴ showed a lower complication rate for PCA by proxy than for standard PCA. Our finding of lower complication rates in both proxy groups (clinician-proxy and parent-proxy) than in the standard PCA group should be interpreted with caution in view of inherent differences between proxy assessments of pain versus self-assessment of pain, which is the gold standard of pain assessment. Additionally, patients in the standard PCA group were older than in the proxy groups and therefore more capable to make decisions regarding their pain control. It is possible that proxies administer PCA doses more cautiously than do the patients themselves.

The limitations of this study include the lack of data on actual opioid usage and the corresponding analgesic efficacy; therefore, we are able to report on the risks but not the analgesic benefits of standard, parent-proxy, and clinician-proxy PCA. Further, our patients differ from the usual pediatric surgical inpatient, and their parents are likely to be more medically sophisticated than most other parents. Also for those patients for whom both parents and nurses could provide boosts, we could not determine the proportion of boosts delivered by the parent vs. the nurse.

One area of further investigation is the use of PCA by proxy in the context of palliative care at the end of life in children with cancer. Specifically, the risks and benefits associated for those patients with proxy-provided doses should be explored in the inpatient and outpatient settings at the end of life.

We have demonstrated that parent-controlled PCA is safe at our institution, where policies and strategies are in place to sustain the safety of PCA by parent proxy.

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Figure 1.
Distribution of PCA days in the standard, parent proxy, and clinician proxy PCA groups.

Table 1

Complications Associated with Standard PCA, Clinician-Proxy PCA, and Parent-Proxy PCA in a Pediatric Hematology/Oncology Hospital

Proxy Type	Observation days n (% total)	No complications n (% proxy type)	Overall Complications n (% proxy type) [95% CI]	Respiratory complications n (% proxy type) [95% CI]	Neurologic complications n (% proxy type) [95% CI]	Concurrent neurologic and respiratory complication n (% proxy type) [95% CI]
Standard PCA	3769 (61.3)	3696 (98.06)	73 (1.94) [1.52–2.43]	11 (0.29) [0.15–0.52]	49 (1.30) [0.96–1.72]	13 (0.34) [0.18–0.59]
Clinician proxy	936 (15.2)	927 (99.04)	9 (0.96) [0.44–1.82]	2 (0.21) [0.026–0.77]	6 (0.64) [0.24–1.39]	1 (0.11) [0.003–0.59]
Parent proxy	1446 (23.5)	1437 (99.38)	9 (0.62) [0.29–1.18]	2 (0.14) [0.01–0.50]	7 (0.48) [0.20–0.99]	0 (0) [0–0.25]
All PCA	6151 (100)	6060 (98.52)	91 (1.48)	15 (0.24)	62 (1.01)	14 (0.23)
P value ^a	NA	NA	0.0008	0.6229	0.0135	0.03648

PCA: Patient-controlled analgesia; NA: not analyzed

^aPearson chi-square test

Table 2

Age Distribution and Duration of PCA Use

	All PCA	Standard	Clinician	Parent
n (PCA)	1365	910	160	295
Age (years)				
Mean ^a	12.3	15.1	9.4	5.1
SD	6.6	5.0	6.7	4.5
Duration (days)				
Mean	12.1	11.5	13.4	13.3
SD	17.1	16.1	23.3	16.0

Some patients had more than one PCA day during the study period.

Age was calculated at the time of each new PCA order.

Standard: self-administered PCA; Clinician: nurse-administered PCA; Parent: parent-administered PCA

^ap<0.0001 across the 3 groups (Krusal-Wallis test)