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Commentary

Safety issues in pediatric patient-controlled analgesia by proxy

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Prior to the development of the concept of patient-controlled analgesia and the devices to support it, narcotics were administered as boluses by nurses, who had to respond to a patient's request, obtain and verify the narcotics dose, and then administer it, all while attending to needs of other patients. In my experience and that of others (M Yaster 2005, personal communication), this practice is inefficient. Patients would commonly wait substantial amounts of time for pain relief and experience frequent pain recurrences. Medications were often wasted. The safety and efficacy of patient-controlled analgesia (PCA) in adults, adolescents, and older children is now well documented (Berde et al., 1991; Lehr & BeVier, 2003). While many institutions have begun using PCA in younger children and allowing individuals other than the patient to control medication delivery (PCA by proxy), the safety and efficacy of these modifications are incompletely studied. This article will discuss recent safety concerns and the current evidence supporting the use of PCA by proxy.

In 2004, the US Joint Commission on Accreditation of Healthcare Organizations raised safety issues regarding the use of patient-controlled analgesia by proxy (JCAHO, 2004). Information submitted to the US Pharmacopeia databases revealed 15 errors that were related directly to the use of a proxy. Based on their review, the Joint Commission recommended establishing the following practices (adapted here from JCAHO, 2004):

1. Develop criteria for selecting appropriate patients to receive PCA and nurse-controlled analgesia…. Some patients may not be appropriate candidates to receive PCA because of their age (infants and young children are not appropriate candidates).
2. Carefully monitor patients.
3. Teach patients and family members about the proper use of PCA and the dangers of others pressing the button for the patient. Provide written instructions to family members that instruct them NOT to administer PCA doses.
4. Alert staff to the dangers of administering a dose for the patient outside of a nurse-controlled analgesia protocol.

Cohen and Smetzer (2005) detail an extended set of safety recommendations for PCA use. While I support many of their recommendations, I believe that two of their views should be challenged. First, their policy of limiting proxy PCA to nurse administration alone fails to acknowledge that several institutions have extended experience in safely engaging a variety of surrogates as proxies. The Children's Hospital of Wisconsin has been doing so for seven years (SJ Weisman 2005, personal communication). The articles discussed below document similar experiences (Gureno & Reisinger, 1991; Monitto et al., 2000; Weldon et al., 1993). Second, the use of age alone for patient

selection is inadequate, as the capacity for a child to understand the need for pain relief and the mechanism for obtaining it correlate best with developmental age and psychosocial factors (Gerik, 2005).

Three studies address safety and efficacy issues in PCA by proxy. Monitto et al. (2000) elected to treat 212 children less than six years of age (including developmentally delayed patients) with a low-dose continuous opioid infusion, supplemented by low-dose boluses. Both parents and nurses were allowed to administer bolus doses. Oxygen saturations were monitored continuously for the first 24 hours and with every dose increase thereafter. Maximum pain scores no greater than 3/10 were found for 81-95% of patients on all days of the study. On day 1, 25% of the unintubated patients required oxygen supplementation to maintain saturations greater than 94%. Many of these children had medical conditions that could have caused the oxygen requirement. It was therefore impossible to distinguish those patients whose hypoxemia was caused solely by the use of a proxy. Four patients (1.7%) required naloxone to treat narcotic-induced apnea or desaturation. No specific risk factor correlated with naloxone administration. The authors support the concept that respiratory compromise may be unrelated to the use of a proxy, but agree that treatment protocols should be established to monitor and treat this and other adverse effects. They strongly advocate against limiting PCA by proxy use to "low-risk" patients, which would deny highly effective treatment to many children. The authors feel that it should be used only when adequate resources are available to monitor patients and manage complications as they arise.

Gureno and Reisinger (1991) studied eight pediatric surgical patients aged 3 to 5 years whose parent or nurse activated the PCA bolus in cooperation with the patient. The authors document their protocol for medication administration and safety monitoring. All the patients had good pain control, with scores of 1/5 72% and 2/5 18 % of the time. No respiratory depression or other potentially serious side effects were noted.

Weldon et.al. (1993) included an assessment of the safety and efficacy of nurse-controlled analgesia (NCA) in their study of pain control in children and adolescents undergoing major operations in a pediatric ICU setting. The authors note that their "data suggest that ICU nurses can safely and efficiently control the PCA device for pediatric patients who are unable to operate the device for themselves…. no difficulties or complications were encountered during nearly 1,000 patient hours of NCA therapy." More than 90% of the nurses were highly satisfied with this delivery technique.

The JCAHO recommendations, if adopted as policy, would severely compromise our ability to provide maximal pain control for pediatric patients by limiting the use of proxies. We now have the ability to formulate a better policy in this area. I suggest we consider the following steps:

1. Any center that offers pain control to children should develop an institutional policy for providing that service. A committee should be established that includes representatives from involved disciplines, such as anesthesia, pediatrics, ethics, administration, etc. Local resources should be evaluated and safety issues analyzed. The article by Cohen and Smetzer (2005) is an excellent resource and should be consulted. I suggest that all patients less than six years of age receive PCA by proxy; this recommendation is supported by literature (Gureno & Reisinger, 1991; Monitto et al., 2000). I suggest that patients six years of age and older may be considered for PCA without a proxy. Gureno and Reisinger (1991) support this view, and Berde et al. (1991) support it for patients at least 7 years of age. However, my literature search and the article by Lehr and BeVier (2003) show no standards for making this decision. I propose that if any doubt exists about a patient's capacity to use the PCA device solely, PCA by proxy should be chosen. Further research is needed to clarify this issue. If a proxy is used, to maximize safety consider adopting a strict policy of prohibiting dosing when the patient is asleep. Allow for the possibility that patients near the end of life may appropriately choose to receive maximal doses of narcotics to relieve pain, accepting consequences of any adverse effects that may occur.

2. Develop education programs for staff, patients, and proxies. Require that staff engaged in direct care of a patient receiving PCA or PCA by proxy have documented understanding of the program material. Staff must also document that patients and proxies understand their information and are competent to use the PCA device. Consider the use of a form that lists criteria for competency.
3. Monitor efficacy and safety, and adjust practice accordingly. Consider publishing data to provide support for the formation of institutional and national policies.

Leading institutions have formulated policies that support the use of PCA by proxy, allowing it to provide maximal patient benefit while maintaining high standards of safety (Gureno & Reisinger 1991; Monitto et al. 2000; Weldon et al., 1993; SJ Weisman 2005, personal communication). I encourage other institutions to use this experience to provide this service to their pediatric patients to the extent their resources allow. It is hoped that PCA by proxy and the protocols that guard its safety will become standard medical practice, serving a greatly increased number of children.

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