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Errors in Postoperative Administration of Intravenous Patient-Controlled Analgesia: A Retrospective Study

Findings indicate the need for standardized procedures and better provider and patient education.

First developed in the 1960s, intravenous patient-controlled analgesia (IV PCA) has become widely used in clinical settings as an effective method of postoperative pain management.[1,2] (PCA can refer to epidural or IV routes of delivery; this article focuses specifically on IV PCA.) Typically, IV PCA involves the use of an electronic infusion pump with a timer function; the patient can self-administer analgesia by pressing a button to release a preprogrammed dose.[1,3] An anesthesiologist, nurse anesthetist, pain management specialist, or other critical care prescriber writes an order for medication that includes the basal rate (the amount of drug given per hour as a continuous infusion), bolus dose (the amount of drug that can be given as a bolus at set intervals to boost the level of analgesia), lockout interval (the period of time between bolus doses that the device cannot deliver medication), and dose limits (the maximum amount of drug to be delivered per a set number of hours).[4,5] The nature of the drugs used and the rather convoluted processes and equipment associated with IV PCA are contributing factors to preventable errors.[6] Opioids—the most common analgesics used in IV PCA—are highly dangerous drugs that can lead to respiratory depression and even death.[7,8] When one also considers the various possibilities for IV PCA device malfunction, operator error, and patient error,[9,10] it's clear that IV PCA can pose significant risks to patients.

Several studies have indicated that IV PCA device malfunction and operator error, in particular, are among the most frequently occurring problems associated with IV PCA use. Hankin and colleagues examined all U.S. Food and Drug Administration Manufacturer and User Facility Device Experience reports of events involving IV PCA devices in a two-year period.[9] Of the 2,009 reported events, 79.1% involved "device safety" problems. Another 6.5% involved operator error, of which 81% involved misprogramming of the device.[6,9] A study by Paul and colleagues found that pump programming errors accounted for 33.9% of all errors associated with IV PCA use.[10] Moreover, findings from a study by Hicks and colleagues suggest that PCA-related errors are "more common than is generally assumed" and tend to cause greater harm than non-PCA-related errors.[11]

Technological innovations have led to the development of computerized "smart" infusion pumps, which can incorporate comprehensive drug libraries, set predetermined dosage and infusion rate limits, and

ABSTRACT

Background: Intravenous patient-controlled analgesia (IV PCA), which typically involves opioids, has become widely used in clinical settings as an effective method of pain management. Identifying errors in the administration of these drugs is essential to improving patient outcomes. This study sought to describe and analyze the errors associated with postoperative IV PCA.

Methods: Relevant data were collected from the medical records of all patients who received IV PCA at a large academic medical center in South Korea during a three-year period. The study sample comprised 45,104 patients who used one of four types of IV PCA delivery devices.

Results: Errors occurred in 406 cases (0.9%). Operator error was the most common type of error (54.7%), followed by device malfunction (32.3%), prescription error (12.3%), and patient error (0.7%). Of the 222 operator errors, the most frequent type was failure to begin IV PCA drug administration (28.8%), followed by programming errors by non-anesthesia providers who weren't authorized to program the device (24.8%) and wrong infusion rates set by anesthesia providers who were so authorized (24.8%).

Conclusions: The findings provide valuable information that can aid in the development of policy and procedures for safer, more effective postoperative administration of IV PCA. They also suggest that it's necessary not only to improve the operation of acute pain services teams, but also to ensure ongoing provider and patient education specific to IV PCA use.

Keywords: equipment failure, error, patient-controlled analgesia, postoperative pain, quality improvement

log alerts.[12, 13] Some studies have indicated that smart IV PCA pumps can help to reduce error,[14, 15] yet problems persist. In their comprehensive analysis, Hicks and colleagues found that "the influence of human factors on PCA errors was more evident than on non-PCA errors, suggesting that the PCA process is heavily dependent on individuals' executing sequential tasks successfully."[11] Furthermore, to our knowledge no studies have identified or analyzed problems in PCA administration by examining data entered into electronic health records (EHRs) by the clinicians involved.

Study purpose. The purpose of this study was to describe errors associated with IV PCA use by postoperative patients at a large medical center in Seoul, South Korea.

METHODS

Study design and sample. This was a retrospective descriptive study conducted in 2015. Approval from the medical center's institutional review board was obtained before the study began. Relevant data—including pain reports, PCA drug dosages and amounts, side effects, and device errors—were collected from the medical records of all patients who received PCA at a large academic medical center in South Korea during a three-year period between 2010 and 2013. All patient records were divided into three one-year groups, with each year defined as from June 1 through May 31.

Initially, we considered the records of 49,079 patients who used PCA devices for postoperative pain management during the three-year study period. We then excluded the 3,922 patients who used epidural PCA devices, because these devices have different error patterns. We included only patients who used IV PCA. We also excluded 53 patients whose records were insufficient or incomplete.

Data collection. We used a checklist for retrospective data collection. The checklist was developed based on a combination of categorization systems used by Hankin and colleagues[9] and Park and colleagues.[16] A team of two clinical nurse specialists (CNSs) (two of us, YL and MK) on the acute pain services team, one anesthesiologist, and one nursing professor (KK) compared these systems and set the scope of error-related data to be extracted from the patient records. The final error categories were IV PCA device malfunction, operator error, patient error, and prescription error. Two researchers (YL and KK) reviewed all of the study records, identified cases in which errors occurred, and documented the causes of the errors using the checklist.

The IV PCA administration process. Only those patients who consented before surgery to the use of IV PCA, based on the explanations provided by their physicians, were connected to IV PCA devices. An anesthesiologist prescribed the drugs to be used. An anesthesiologist and an anesthesiologist assistant then mixed the drugs and programmed and connected the devices to the patients under the supervision of an anesthesiologist.

The anesthesiologists wrote the orders for the drugs, basal rate, bolus dose, lockout interval, and dosage limits. Only fentanyl is prescribed for postoperative IV PCA in the hospital involved in our study.

A standard fentanyl dose for IV PCA was set at a basal rate of 1 to 2 mL (10 to 40 mcg) per hour, a bolus dose of 1 to 2 mL (10 to 40 mcg) with a 15-minute lockout interval, in a total volume of 50 to 250 mL, according to patient characteristics and type of surgery. Patients used their IV PCA device in the postoperative recovery room, ICU, and general unit until it was no longer needed.

The two CNSs on the acute pain services team and the unit nurses provided IV PCA training to the patients and their caregivers. Four types of IV PCA devices—AutoMed 3200 (Ace Medical Co, Ltd., Seoul), Anaplus (EWHA Biomedics, Seoul), Accufuser (Woo Young Medical, Seoul), and Accumate 1100 (Woo Young Medical, Seoul)—were used according to the anesthesiologist's prescription. All devices were monitored for any operative problems by the two CNSs and an anesthesiologist.

Any problems that arose were addressed immediately. Hospital policy was to suspend device usage until any associated problems were resolved. To ensure continuous availability of IV PCA for pain management, a variety of devices that could be substituted for each other were used. All providers who were responsible for prescribing IV PCA drugs or for programming, adjusting, or operating IV PCA devices underwent regular training sessions and received education on how to resolve issues related to IV PCA use.

Data analysis. The data were analyzed and descriptive statistics calculated using SPSS version 20 (IBM Corp.).

RESULTS

Sample. The final sample consisted of 45,104 patients who used IV PCA between June 1, 2010, and May 31, 2013.

Frequency of IV PCA errors. Errors occurred in 406 (0.9%) cases. When the entire sample was subdivided into one-year time spans, these errors were found to be distributed about equally across years, with errors ranging from 133 (0.97%) in year 1 to 137 (0.87%) in year 2 and 136 (0.88%) in year 3 (see Table 1).

Types of error. Operator errors were the most frequent type of IV PCA–associated error (222 cases, 54.7%), followed by device malfunction (131 cases, 32.3%), prescription errors (50 cases, 12.3%), and patient errors (3 cases, 0.7%) (see Table 2).

Table 1. Frequency of IV PCA Errors

Period	No. of Patients	No. (%) of Errors
Year 1	13,773	133 (0.97)
Year 2	15,814	137 (0.87)
Year 3	15,517	136 (0.88)
Total	45,104	406 (0.9)

Description of errors by type. Table 3 provides details about the different types of IV PCA–associated errors that occurred during the three-year study period. Of the 222 cases of operator error, 64 cases (28.8%) involved failure to start drug administration via an IV PCA device, 55 cases (24.8%) involved wrong infusion rates set by non-anesthesia providers, and another 55 cases (24.8%) involved wrong infusion rates set by anesthesia providers. Thirty cases (13.5%) involved improperly installed IV PCA lines. The remaining cases involved medication mixing errors and failures in equipment setup. Of the 131 cases of device malfunction, 50 cases (38.2%) were related to slow infusion, 34 cases (26%) involved fast infusion, 12 cases (9.2%) involved damage to the main body of the device, and 10 cases (7.6%) involved a defective bolus button. The remaining cases reflected various other equipment problems. Among the 50 cases of prescription error, 25 cases (50%) were related to mistakes in drug prescription records, 13 cases (26%) were related to lack of prescriptions of drug dosage, and 11 cases (22%) omitted a patient's personal information. The remaining case involved drug contraindications. Lastly, of the three cases of patient error, two (66.7%) involved patient manipulation (such as intentional tampering with device settings) and one (33.3%) involved caregiver manipulation.

DISCUSSION

This study aimed to elucidate the errors that occurred during IV PCA use by analyzing the problems reported among 45,104 cases of such use during a recent three-year period.

Errors occurred in 406 cases (0.9%) overall. This percentage was similar to that found in the aforementioned study by Hicks and colleagues, in which PCA errors occurred in 0.9% to 1.1% of patients annually during the five years of the study.[11] In our study, error rates did not differ significantly for each of the three one-year time spans.

Operator errors were the most frequent type of IV PCA error, accounting for 54.7% of all errors. Yet in the study by Hankin and colleagues, operator error accounted for a mere 6.5% of all errors.[9] In our study, contributing factors to operator error may have been the use of several different pump models and frequent operator changes. Despite health care providers being trained in managing IV PCA, there might have been cases of inappropriate device manipulations by those with less experience and skill.

Among the operator errors, 28.8% involved failure to start the drug administration process in a timely manner. In principle, an anesthesiologist should have started the IV PCA process in the operating room by writing the order and overseeing device programming and connection to the patient, but in some cases this did not happen. This type of error signifies that IV PCA was not available to some patients immediately

Table 2. Types of IV PCA Errors

Type	No. (%) of Errors			
	Year 1	Year 2	Year 3	Total
Operator errors	69 (51.9)	75 (54.7)	78 (57.4)	222 (54.7)
Device malfunctions	38 (28.6)	44 (32.1)	49 (36)	131 (32.3)
Prescription errors	25 (18.8)	17 (12.4)	8 (5.9)	50 (12.3)
Patient errors	1 (0.8)	1 (0.7)	1 (0.7)	3 (0.7)
Total	133 (100)	137 (100)	136 (100)	406 (100)

Note: Percentages may not sum to 100% because of rounding.

after surgery, at a time when postoperative pain was probably most severe. Another 24.8% of operator errors involved prescription of IV PCA drug dosages and manipulation of the device by non-anesthesia providers who lacked sufficient knowledge about IV PCA and narcotic analgesics. In these cases, physicians or unit nurses who were not anesthesiologists or acute pain services team CNSs, respectively, manipulated the PCA devices without authorization, performing actions such as changing programmed drug doses. These errors in turn led to several secondary problems, including the development of adverse effects caused by overdosing, the failure of pain management caused by underdosing, and IV PCA device failure. Another 24.8% of operator errors were related to incorrect settings of IV PCA doses. Similarly, Hicks and colleagues reported that inaccurate dosage of PCA drugs accounted for 38% of all errors.[11] In our study, these errors occurred because anesthesiologists inaccurately set the basal rates, bolus doses, and lockout intervals for devices (AutoMed, Accumate) that must be programmed before administration. In a study by Paul and colleagues, a multidisciplinary safety panel recommended instructing nurses to double-check device program settings, and errors were subsequently reduced.[10] In our study, because the health care providers changed frequently, operator errors occurred that could have been prevented had there been lower turnover, which would have allowed providers to gain greater experience, knowledge, and skills. (Indeed, in South Korea, the turnover rate of new nurses is reportedly as high as 31.2%.[17])

Device malfunctions. Different types of problems occurred in the four types of devices that were used, and device malfunctions accounted for 32.3% of all errors. The most common type of error caused by device malfunction was a too-slow rate of infusion, which led to underdosing and inadequate pain control. This problem was exacerbated by the fact that it wasn't easily detectable during the early stages of administration, because only low drug volumes were being administered and the patient showed no adverse effects.

The second most common type of error due to device malfunction was a too-fast rate of infusion, which led to overdosing. Unlike slow-infusion errors, fast-infusion errors can result in harm to patients. In such cases, PCA infusion is stopped immediately and follow-up occurs. (Fortunately, during the three-year study period, there were no critical events caused by such errors.) To avert fast-infusion errors, during their rounds the acute pain services CNSs regularly checked administration volumes and unit nurses checked IV PCA devices.

The third most common type of device malfunction error involved cases in which the main body of the IV PCA devices were damaged or broke apart. The degree of damage varied from extensive to minor; but in each case it was enough to cause malfunction.

Prescription errors included mistakes in drug prescription records, lack of an order for IV PCA, missing patient demographics on such orders, and IV PCA use by patients who were pregnant or had other contraindications (such as learning difficulties or confusion). In our study, prescription errors constituted 12.3% of all errors. Similarly, Polomano and colleagues have reported that prescription errors account for 9.2% of all PCA-related errors.[18] If an anesthesiologist records inaccurate prescription data, it's difficult for nurses to catch this, since they're checking device settings against that record.

Patient errors. Although IV PCA devices are designed to be operated by patients, and patient errors are relatively rare, in our study such errors accounted for 0.7% of all errors. Similarly, Hankin and colleagues reported that "patient-related events" such as "intentional tampering" accounted for 0.6% of all errors in their study.[9] To improve safety, an IV PCA device has a locking system designed to prevent unauthorized changes to the programmed basal rate, bolus dose, and other settings. However, in our study there were instances in which curious patients or caregivers adjusted the basal rate using various tools (such as scissors or knives) or changed the preset dosage through surreptitious use of the device's keyboard. These events occurred despite patients and caregivers being given preoperative education regarding the use of IV PCA devices.

Limitations. There are a few limitations to this study. First, we weren't able to compare data for any

one type of IV PCA device across the different one-year periods. In the hospital in which the study was conducted, it was necessary to use four types of devices because replacements were often required to resolve device-related problems. Furthermore, there were misleading increases in the number of device malfunction errors at certain times because the same problem occurred repeatedly until the malfunctioning device was replaced. Second, because this was a retrospective study, it was impossible to investigate every minor detail of how patients manipulated the devices. Third, the health care providers possessed different levels of knowledge and skill regarding IV PCA devices and procedures. Although the acute pain services CNSs remained the same throughout the study period, the unit nurses and physicians who were responsible for pre- and postoperative education of patients and caregivers changed frequently. Thus, there were differences in the level of training patients and caregivers received. Fourth, the patterns of errors seen during the study period were affected by the hospital's ongoing efforts to improve the quality of IV PCA administration during that time.

Table 3. Description of IV PCA Errors by Type

Type	Items	No. (%) of Errors
Operator errors	Failure to start IV PCA	64 (28.8)
	Wrong infusion rate set by non-anesthesia provider	55 (24.8)
	Wrong infusion rate set by anesthesia provider	55 (24.8)
	Improperly installed IV PCA line	30 (13.5)
	Medication mixing error	10 (4.5)
	IV line clamped	6 (2.7)
	Disconnected bolus dose button	2 (0.9)
	Total	222 (100)
Device malfunctions	Slow infusion	50 (38.2)
	Fast infusion	34 (26)
	Damage to main body of IV PCA device	12 (9.2)
	Defective bolus dose button	10 (7.6)
	Defective alert system	8 (6.1)
	Defective battery	7 (5.3)
	Defective line	4 (3.1)
	Defective panel	3 (2.3)
	Broken means of securement to IV pole	2 (1.5)
	Irregular infusion rate	1 (0.8)
	Total	131 (100)
Prescription errors	Mistakes in drug prescription record	25 (50)
	No order for IV PCA	13 (26)
	No patient demographics on IV PCA order	11 (22)
	Contraindications	1 (2)
	Total	50 (100)
Patient errors	Patient manipulation	2 (66.7)
	Caregiver manipulation	1 (33.3)
	Total	3 (100)

Note: Percentages may not sum to 100% because of rounding.

Nursing implications. The findings of this study can be used to improve the safety of IV PCA use. Nursing interventions might include

- providing improved patient and caregiver education.
- ensuring the proper display of warning labels to prevent device tampering.
- helping to develop stronger locking systems for IV PCA devices.
- performing rigorous checks of postoperative IV PCA start times.
- reinforcing the need for constant monitoring of the operative status of IV PCA devices.
- standardizing sign-off procedures.

Indeed, if standardized procedures for periodic checks, including ongoing updates to the EHR, were implemented, it's likely this would improve the safety of IV PCA considerably.

CONCLUSIONS

Since the end of the study period in 2013, there have been many technological changes. At the time of data collection, few IV PCA devices had alert functions; the next generation of smart IV pumps has such alerts, along with other features that may help prevent errors.[13] Moreover, continuous quality improvement efforts are being made at the study site. These include sending error-related feedback to device manufacturers so they can modify their products to reduce error potential. Better patient monitoring is also critical to reducing errors.[5] Yet acute pain services currently operate in only 46% of South Korean hospitals, and such services with monitoring nurses such as CNSs operate in only 21%.[19] In the United States, it's been reported that 74% of U.S. hospitals have acute pain services, but the role of RNs varies widely.[20]

Our findings provide valuable information that can aid in the development of policy and procedures for safer, more effective postoperative administration of IV PCA. They also suggest that it's necessary not only to improve the operation of acute pain services teams, but also to ensure ongoing provider and patient education specific to IV PCA use. We found that the overall incidence rate of IV PCA errors during the study period was less than 1%. But those errors still affected more than 400 patients, placing them at risk for harm. Efforts to reduce IV PCA–related error rates to zero should be considered a nursing priority. As Lawal and colleagues have pointed out,

IV PCA–related issues due to device problems or human error are mostly preventable.[21] We propose that future studies be conducted to investigate how improved education programs for both providers and patients, targeting common IV PCA–related errors, might affect IV PCA–related error rates. ▼

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