Device-Related Error in Patient-Controlled Analgesia: Analysis of 82,698 Patients in a Tertiary Hospital

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BACKGROUND: Patient-controlled analgesia (PCA) is one of the most popular and effective methods for managing postoperative pain. Various types of continuous infusion pumps are available for the safe and accurate administration of analgesic drugs. Here we report the causes and clinical outcomes of device-related errors in PCA.

METHODS: Clinical records from January 1, 2011 to December 31, 2014 were collected by acute pain service team nurses in a 2715-bed tertiary hospital. Devices for all types of PCA, including intravenous PCA, epidural PCA, and nerve block PCA, were included for analysis. The following 4 types of infusion pumps were used during the study period: elastomeric balloon infusers, carbon dioxide-driven infusers, semielectronic disposable pumps, and electronic programmable pumps. We categorized PCA device-related errors based on the error mechanism and clinical features.

RESULTS: Among 82,698 surgical patients using PCA, 610 cases (0.74%) were reported as human error, and 155 cases (0.19%) of device-related errors were noted during the 4-year study period. The most common type of device-related error was underflow, which was observed in 47 cases (30.3%). The electronic programmable pump exhibited the high incidence of errors in PCA (70 of 15,052 patients; 0.47%; 95% confidence interval, 0.36–0.59) among the 4 types of devices, and 96 of 152 (63%) patients experienced some type of adverse outcome, ranging from minor symptoms to respiratory arrest.

CONCLUSIONS: The incidence of PCA device-related errors was <0.2% and significantly differed according to the infusion pump type. A total of 63% of patients with PCA device-related errors suffered from adverse clinical outcomes, with no mortality. Recent technological advances may contribute to reducing the incidence and severity of PCA errors. Nonetheless, the results of this study can be used to improve patient safety and ensure quality care. (Anesth Analg XXX;XXX:00–00)

KEY POINTS

- **Question:** How often does device-related PCA error occur and does it really harm the patient?
- **Findings:** The incidence of PCA device-related error was 0.19%; 63% of those patients suffered from any kind of adverse clinical outcome.
- **Meaning:** Even though advanced technology has enabled us to improve safety of PCA devices, meticulous monitoring is always required.

Acute pain control is an important part of postoperative patient care, which is associated with promoting patient recovery, shortening hospital stay, and reducing medical costs.[1] Patient-controlled analgesia (PCA) is one of the most popular modalities of acute postoperative pain management. PCA is a method of analgesic administration in which an automatic infusion device controls the flow limit, thereby allowing patients to self-administer analgesics as per their requirement. PCA has proven its superiority over conventional nurse-controlled analgesia in decreasing postoperative pain.[2] It has also been proven to improve patient satisfaction, preserve good pulmonary function, and shorten hospital stay.[3] However, there is a high likelihood of medication errors, such as those in transcribing, prescribing, programming, dispensing, and monitoring, occurring at each stage.[4–6] Occasionally, ≥2 combined errors can lead to complex errors in PCA.[7] Most PCA involves opioid-based regimens. Therefore, errors in PCA are associated with a risk of opioid overdose and may cause serious adverse clinical outcomes.[7–9]

Many attempts to define and reduce PCA-associated medication errors have been made over a long period. Resources on PCA-related medication errors have divided the errors into 2 main categories: human factor-related errors and device-related errors. PCA device-related errors account for 79% of the total errors in intravenous PCA, and human factor-related errors account for 6.5% of them.[10]

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So far, studies have mostly focused on protection against human factor-related errors in PCA. Several types of safety intervention programs, including those involving purchasing easier-to-use PCA pumps, using a standardized PCA protocol, educating nurses, and implementing an independent double-check system policy, have been established to prevent human factor-related errors in PCA. Paul et al[8] reported that these patient safety interventions considerably improve and stabilize the safety of PCA administration. Relatively less research has been directed toward PCA device-related errors. However, there have been anecdotal case reports regarding PCA device malfunction associated with fatal morbidities that demanded emergent resuscitation.[11]

In this study, we assessed the incidence of PCA device-related errors according to the type of continuous infusion pump and described the characteristics of these errors and their clinical outcomes.

METHODS

This retrospective study was approved by the Asan Medical Center Institutional Review Board. The requirement for written informed consent was waived by the institutional review board. Data were obtained from the electronic medical record database of the acute pain service (APS). The APS team comprises 3 nurses and staff anesthesiologists. Twice a day, APS nurses perform rounds of all postoperative patients using PCA devices and visit the patients during the daytime on weekdays. During routine rounds, the APS nurses interview each patient and review their medical records. Using a numeric rating scale, the APS nurses also check and record the scores for pain with and without movement and also note the amount of PCA medication delivered, symptoms and signs of opioid overdose, and any additional pain control medications administered. When an error or adverse event suddenly occurs during the use of PCA device, the APS team members receive direct calls from the clinician or ward nurses. The APS nurses notify the staff anesthesiologist about significant safety errors or problems that they cannot manage. All events were systemically recorded during nurse rounding sessions.

Two anesthesiologist reviewers (H.J.S., S.-H.K.) obtained and independently reviewed all events of PCA device-related errors from January 1, 2011 to December 31, 2014. Intravenous PCA, epidural PCA, and nerve block PCA were applied to patients. The number of prescriptions for PCA devices during the study period was considered as the total number of cases. In our institution, we have established a routine PCA safety protocol to reduce and rule out human error during PCA administration. First, at least 2 health care providers, typically a doctor and a nurse, mix and dispense the medication together. Second, after dispensing, the providers check the PCA device together and record information in a time-out sheet; this includes PCA setting, drug dosage, and priming status. When the total volume of the drug cannot be identified, the whole PCA device, including the box case and accessory, should be weighed before the next administration to a patient. Third, when a patient is admitted to, and discharged from, the postanesthetic recovery unit (PACU), a PACU nurse routinely checks the PCA program and remaining drug volume. Fourth, no person, except the anesthesiologist and APS team nurse, may manipulate or change the PCA.

Human error was defined as prescription error (use of wrong analgesic, incorrect dosing, duplicate medication orders) and operating error (accidental pump misprogramming, false triggering by proxy). After ruling out human error, remaining cases were regarded as device-associated error, and each case was confirmed to be mostly associated with the PCA device component. Selected cases were classified into 4 categories based on the error mechanism: overflow (from any cause wherein >5% of the intended amount of drug was given), underflow (from any cause wherein <5% of the intended amount of drug was given), display error (error displayed on the window, or activated alarm signal, without actual flow rate change; eg, error message or alarm without any cause, frozen program key button, abrupt shut down with full charging), and broken pump device (physical breakdown or crack of PCA infuser or accessories). When any discrepancy regarding case categorization was noticed between the reviewers, it was resolved through discussions with a third reviewer (J.-H.H.). In our hospital, 4 types of PCA devices are applied to patients: elastomeric balloon infuser (Accufuser Plus; Woo Young Medical, Seoul, Korea); carbon dioxide gas-driven infuser (ANAPA; EHWA Biomedics, Seoul, Korea); semielectronic disposable pump (AutoMed3400; Ace Medical, Seoul, Korea); and electronic programmable pump (Accumate 1100; Woo Young Medical, Seoul, Korea). All 4 PCA device types have acquired Conformité Européene certificate, International Organization for Standardization certificate, and Good Manufacturing Practice certificate. Staff anesthesiologists decided which type of PCA device to apply depending on the type of operation, patient demographics, and expected postoperative pain severity.

The clinical outcomes were determined based on clinical records up to postoperative day 3. When the PCA error was detected later than postoperative day 3, additional data of 3 days before and 1 day after error detection were collected. The cases were classified into 4 categories: minimal physiological change, minor side effect of opioid, major physiological change, and inadequate analgesia. The definitions of each category are as follows. Minimal physiological change was defined as "no side effect or detectable patient symptom caused by the error in PCA error." Minor side effects of opioids included nausea, vomiting, pruritus, and other opioid side effects not involving any major systemic organs. Major physiological changes included side effects involving cardiovascular, respiratory, neurological, or other major system functions. Inadequate analgesia was defined as an numeric rating scale pain score of >5 or the administration of additional pain control. Cases could belong to ≥2 categories. We compared the clinical progress using vital sign records and pain scores. Although confirming the correlation between the error in PCA and the clinical outcome of the patient in each case can be challenging in a retrospective setting, we tried to include all adverse clinical events.

The rate of PCA device error of each type was calculated using confirmed cases of device error of each device type as the numerator, and the number of prescriptions of PCA devices as the denominator. Poisson regression was used to compare incidences of device error among various PCA

device types during the entire interval. Based on the exact Poisson method, 95% confidence intervals (CIs) were calculated. A *P* value of <.05 was considered to indicate statistical significance.

The primary aim of this study is to estimate the incidences, so that we could justify the sample size in terms of the accuracy of estimating the incidence using CI width. According to the previous report,[8] error rate of electronic PCA was 0.25%. Based on our clinical experience, error rate of nonelectronic type PCA was expected to be approximately two thirds as large as the electronic type. Both types of devices attempted to achieve a CI width of 0.1%. Therefore, assuming that error rate with the electronic pumps is 0.25% and the error rate with nonelectronic pumps is expected relative 35% lower (0.16%), the required sample size is 40,414 and 26,692, respectively. Thus, we can see that the actual sample size in the study (N = 49,364, 33,334) is all appropriate.

RESULTS

During the 4-year study period, 82,698 surgical patients received PCA treatments. Among these, 610 cases (0.74%) were reported as human error, and 155 patients (0.19%) experienced PCA device-related errors. Surgery types were as follows: 48 gastrointestinal, 36 cardiothoracic, 27 hepatobiliary, 12 pelvic/gynecologic, and 10 orthopedic surgery. The number of PCA prescriptions, the number of device-related errors, and the rate of device-related errors among total errors in PCA are shown in Table 1. These data suggested that there was a significant difference in the error rate between each pump. The electronic programmable pump showed the highest error rate of 0.47% (95% CI, 0.36%–0.59%; Table 1) compared with each of other types of pumps (all *P* value for comparison against electronic programmable pump <.0001). The electronic pumps (ie, the semielectronic and electronic programmable types) had a higher error rate of 0.26% (95% CI, 0.21%–0.3%) than the nonelectronic pumps (ie, the elastomeric balloon infuser and carbon dioxide–driven infuser types; error rate, 0.09%; 95% CI, 0.06%–0.13%; *P* < .0001) (Table 1).

The PCA device-related error subtypes are shown in Table 2. There was a variation in the rank order of errors based on the PCA device type. The most common error category among all events, regardless of the device type, was underflow (n = 78; 50%). Among electronic programmable pumps, display errors (n = 27; 39%) were the most common. Among nonelectronic devices that did not demonstrate display errors, underflow errors were the most common (44%–70%).

Of the 155 patients, 3 lacked adequate medical records for categorizing their clinical course and were excluded from clinical outcome descriptions. Ninety-six of the remaining 152 patients (63%) experienced some type of adverse event possibly related to errors in PCA. Multiple adverse event types, such as inadequate analgesia with major physiological changes, could be selected according to the medical records. A total of 55.5% of the patients with PCA device-related errors experienced inadequate analgesia, which was the most common adverse clinical outcome. Opioid overdose symptoms, such as nausea, vomiting, and pruritus, occurred in 10 (6.5%) cases, 7 of which were related to analgesic overflow. Major physiological changes were noted in 9 (5.8%) cases (Table 3), 6 of which belonged to 2 categories, major physiological changes and inadequate analgesia. The main adverse outcomes of major physiological changes were transient desaturation or atelectasis (n = 3), hypotension requiring continuous inotropic infusion (n = 3), sleeping tendency (n = 1), and respiratory compromise (n = 2). Two patients exhibited severe respiratory depression, resulting in intensive care unit (ICU) admission. In the first case, a 63-year-old man, postgastrectomy patient was found drowsy within 2 hours after leaving the PACU. A semielectronic disposable pump had been applied to him, and 200 mL

Table 1. Device-Related PCA Errors by Continuous Infusion Pump Type

Device Type	Elastomeric Balloon Infuser	Carbon Dioxide-Driven Infuser	Semielectronic Disposable Pump	Electronic Programmable Pump
Device-associated error (n)	9	20	56	70
No. of infusion pump type (n)	14,625	18,709	34,312	15,052
Error rate (%)	0.062	0.107	0.163[a]	0.465[a,b]
95% CI	0.028–0.117	0.065–0.165	0.123–0.212	0.363–0.588

95% CI: exact Poisson method.

Abbreviations: CI, confidence interval; PCA, patient-controlled analgesia.

[a]The electronic pumps (the semielectronic and electronic programmable types) had a higher error rate than the nonelectronic pumps (the elastomeric balloon infuser and carbon dioxide-driven infuser types) (*P* < .0001).

[b]The electronic programmable pump showed the highest error rate compared with each of other types of pumps (*P* < .0001, each).

Table 2. Device-Related PCA Error Subtype by Infusion Pump Type

Device Type	Elastomeric Balloon Infuser (n = 9)	Carbon Dioxide-Driven Infuser (n = 20)	Semielectronic Disposable Pump (n = 56)	Electronic Programmable Pump (n = 70)	Total (n = 155)
Type of PCA error					
Overflow	4/9 (44.4%)	1/20 (5%)	7/56 (12.5%)	16/70 (22.9%)	28/155 (18.1%)
Underflow	4/9 (44.4%)	14/20 (70%)	37/56 (66.1%)	23/70 (32.9%)	78/155 (50.3%)
Defective display system	0/9	0/20	9/56 (16.1%)	27/70 (38.6%)	36/155 (23.2%)
Cracked infusion system	1/9 (11.1%)	5/20 (25%)	3/56 (5.4%)	4/70 (5.7%)	13/155 (8.4%)

Overflow: from any cause wherein >5% of intended amount of drug was given; underflow: from any cause wherein <5% of intended amount of drug was given; defective display system: inactivated alarm message or inadequately activated alarm with actual flow rate unchanged, frozen program key button; and cracked infusion system: physical breakdown or crack of PCA infuser or accessories.

Abbreviation: PCA, patient-controlled analgesia.

Table 3. Clinical Outcomes of the Device-Related PCA Error

	Underflow (n = 76)	Overflow (n = 28)	Display Error (n = 35)	Defective Pump (n = 13)	Total (n = 152)
No adverse event	20/76 (26.3%)	16/28 (57.1%)	14/35 (40.0%)	6/13 (46.2%)	56/152 (36.8%)
Any kind of adverse event					96/152 (63.2%)
Nausea/vomiting/pruritus	0/76	7/28 (25%)	3/35 (8.6%)	0/13	10/152 (6.6%)
Major harm[a]	4/76 (5.3%)	2/28 (7.1%)	2/35 (5.7%)	1/13 (7.7%)	9/152 (5.9%)
Inadequate analgesia	56/76 (73.7%)	3/28 (10.7%)	21/35 (60%)	6/13 (46.2%)	86/152 (56.6%)

Each case can be included to ≥2 overlapped categories.
Abbreviation: PCA, patient-controlled analgesia.
[a]Involving cardiovascular, respiratory, neurological, or other major system function.

of PCA fluid containing oxycodone (200 mg) had been administered over 110 minutes. After intravenous naloxone administration and immediate intubation, he was admitted to the ICU. In the second case, a 54-year-old male patient experienced analgesic overflow on the operation day. A balloon elastomeric infuser had been applied to him, and 150 mL of 200-mL PCA fluid containing fentanyl (2250 μg) had been administered over 7 hours. He did not respond to intravenous flumazenil and was admitted to the ICU after intubation. This case was reported late to the APS team and is considered inappropriate treatment. The APS team noted that the basal infusion rate, set at 0.5 mL/h, had been infused 150 mL for 7 hours (approximately 0.35 mL/min). Both patients recovered from severe respiratory depression without sequelae.

DISCUSSION

The present study comprised 82,698 patients using PCA devices over a 4-year period, and we investigated 4 different types of PCA devices that were applied to these patients. The overall number of PCA device-related errors was 155 (0.19%), while 610 (0.74%) were reported as human error. Electronic PCA devices, especially electronic programmable pumps, were associated with a higher rate of device-related errors. Although each pump type had a different prevalence of PCA-related error characteristics, the most common type of error was underflow. Approximately 63% patients with PCA device-related errors experienced some type of adverse outcome, but there was no case of mortality.

The possible causes of errors in PCA can be divided into 2 main categories; human factor-related errors and device-related errors. According to the data of the US Food and Drug Administration Manufacturer and User Facility Device Experience, approximately 6.5% of intravenous PCA-related errors were due to operator factors, among which almost half resulted in patient harm.[10,12] Most errors (80%) were associated with pump misprogramming, some of which were associated with morbidity and mortality.[10,13] By contrast, device-related errors accounted for 75%–80% of PCA errors, among which only 0.5% resulted in patient harm. Switches, motors, batteries, display boards, and software were the main components of device errors.[10,12] Numerous researches for reducing PCA-related errors have been published, which suggest a combination of methods to lower overall errors in PCA administration and PCA misprogramming. These methods include the use of a well-designed PCA pump, the use of a preprinted protocol, the education of nurses, and independent double-checks.[8,9] Until now, investigators have focused on the human factor-related errors in PCA. Relatively less research has been directed toward PCA device-related errors.

In our hospital, 4 different types of PCA devices are applied to patients. They can be roughly divided into electronic and nonelectronic devices. Nonelectronic devices have many advantages, such as portability, simplicity, and disposability, over electronic ones. These devices can also eliminate the errors in risk programming.[14] Using electronic PCA devices, anesthesiologists can more specifically adjust the basal infusion rate, bolus infusion rate, and lockout time, with a precise amount of delivery. Moreover, these devices can record the infusion history profile with complex settings, according to the time of postoperative progress. However, electronic devices have a higher frequency of errors, especially display errors, than nonelectronic PCA devices. Possible disadvantages of an electronic pump include inappropriate alarm (alarm fatigue), battery maintenance, and detachable sets, which carry the risk of inadvertent disconnection. In our hospital, PCA devices that displayed error alarms are immediately removed or stopped during APS nurse rounds. During that time, adequate pain control may not be provided to the patient or a large amount of opioid may be administered by order. Furthermore, alarm sounds may make the patient more anxious if an adequate response is not available. An alternate perspective is that only electronic devices have audible alarm systems, which enable the medical team to notice errors when unexpected pump malfunction occurs. Nonelectronic pumps have no audible alarm; hence, the detection of errors could be considerably delayed or missed. Some cases in which the errors in PCA were trivial and caused no harm to the patient may have been missed. This could be the reason why electronic devices appear more vulnerable to errors.

Overflow accounted for 18.1% (28 of 152) of PCA device-related errors. However, the most significant adverse events, 2 cases of respiratory arrest, were associated with analgesic overflow errors. Moreover, these cases displayed a clear relationship between PCA device-related errors and clinical outcomes. Although overflow errors accounted for only 18% of total device-related errors, they were of clinical importance and may have caused severe patient harm, including respiratory arrest and hypotension, as well as mortality. Device malfunction mechanisms, such as the breakdown of the free-flow protection device and unintentional electrical short circuit connection, have been reported to cause analgesic overflow errors.[11,15–17] Mechanical safety device and dose-limit alarm incorporation have been proposed for safety improvement.[18] Particularly, the limitation of a drug dose over a 1-hour period has been proposed

for anesthesiologists to react promptly to device alarms.[11] Most patients using PCA are admitted in the general ward rather than the ICU after surgery; therefore, some of them are exposed to relatively insufficient monitoring and care. Considering patient safety aspects, the use of a certain device type with infrequent overflow events is recommended.

Inadequate analgesia accounted for PCA device-related errors in 55.5% of the patients. Specifically, 70% of the patients with underflow errors experienced inadequate analgesia. Numerous factors influence the adequacy of analgesia, such as the patient demographics, type of surgical procedure, and individual susceptibility to pain. The definite correlation between underflow and inadequate pain control is not as certain as that between overflow and respiratory depression. However, several clinical practice guidelines recognize inadequate acute pain management as a problem,[19] and uncontrolled postoperative pain is associated with several acute and chronic detrimental effects. It is important for anesthesiologists to recognize and eliminate the possibility of postoperative pain under treatment. Underflow errors should be considered as seriously as overflow errors. Taken together, effective postoperative pain management requires a balance between safety issues, mainly from overflow, and satisfaction issues, mainly from underflow.

Our study has several limitations. First, when a defective pump device is discovered, the nurses disconnect the device and replace it with a new one before applying PCA to patients in the operating room or recovery unit. Hence, some defective pumps may have been excluded from our recording. We reviewed the total device prescriptions in our electronic system. However, the pump defect-notifying system was developed in the middle of our study period, and not every nurse uses the system. Therefore, we could not count the number of defective infuser cases detected before application. Second, adequacy of the catheter itself may be underestimated during analysis. In our records, there was no case reported as a catheter problem, including block alarm. However, relatively higher incidences of epidural PCA error (0.35%), relative to overall incidence of PCA error (0.19%), imply that epidural catheter blockade might be wrongly classified as a device error. Even though our APS team nurses are trained to first check the catheter patency during block alarm, catheter-related problems with epidural and nerve block PCA could be confused with a pump problem. Third, the correlation between PCA device-related errors and clinical outcomes varied according to the clinical situation. Although side effects were reported only when there was suspicion of involvement with the PCA, causality cannot be confirmed because of the retrospective study design. Furthermore, common adverse effects associated with opioids via PCA, which may occur with correct or erroneous administration, include nausea and vomiting, pruritus, and constipation. Adjustment for possible confounding of the association of interest could be considered as well because of the low event rate. In this respect, the conventional taxonomy system for adverse drug event categorization was not applied to these cases. Several types of sorting systems have been applied to categorize PCA-related errors.[9,10,20] In the near future, a new taxonomy for PCA medication errors must be established to facilitate the recording and reporting of errors and clinical consequences.

Thus, our study revealed that electronic PCA devices showed more frequent device-related errors than non-electronic PCA devices. A total of 63% of patients with PCA device-related errors suffered from adverse clinical outcomes. This result emphasizes the importance of PCA device selection. For most patients in the general ward who are not under continuous close monitoring conditions, PCA devices with less likelihood of overflow are recommended. Technological advances, such as improved PCA designs based on ergonomic and cognitive engineering principles, as well as other safety features, might significantly contribute to reductions in the incidence and severity of PCA errors. Nonetheless, the results from this study can help to improve patient safety and ensure quality care.

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