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CASE REPORT

OVERDOSE OF OPIOID FROM PATIENT-CONTROLLED ANALGESIA PUMPS

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SUMMARY

Two incidents have occurred in our hospital when a patient-controlled analgesia pump has accidentally delivered the whole contents of the syringe of diamorphine (60 mg) over a period of approximately 1 h. Electrical corruption of the pumps' program has been identified as the probable cause. All pumps of this type have been modified to prevent such occurrences.

KEY WORDS

Analgesia, postoperative: patient controlled. Complications: opioid overdose, respiratory depression.

Patient controlled analgesia (PCA) has become established as an important technique for the administration of opioids for control of postoperative and other acute pain. PCA has a high safety record [1], and there is only one reported death resulting from equipment failure [2]. Two potentially lethal malfunctions of PCA pumps are presented.

CASE REPORTS

Patient No. 1

A 67-yr-old woman underwent laparotomy for intestinal obstruction. A malignant ovarian tumour was discovered, with deposits obstructing the terminal ileum, and an ovarian cystectomy and ileal resection were performed.

Anaesthesia and recovery were uncomplicated. PCA was used after operation with a Graseby PCAS pump which was connected to the i.v. infusion cannula by a one-way Y-connector (Abbott PCA Mini Bore with anti-syphon valve). According to the standard practice in this hospital [3], the pump was loaded with diamorphine 60 mg and set to give a 1-mg bolus dose with a 3-min lock-out time and no background infusion. No difficulties were encountered initially and monitoring was carried out satisfactorily. The patient achieved good pain relief, although she required diamorphine 59 mg in the first 24 h. Forty-three hours after operation, she had received diamorphine 115 mg, the pump was noted to be nearly empty, and a third syringe was prepared. Our standard practice to change the syringe was followed: the pump key was turned to "REPROG"; the gate was opened; the syringe was exchanged; the gate was closed; the key was turned to "ON". The pump was checked to confirm that the green light was illuminated, indicating that it was running. No alteration was made to the program.

After 1 h, the nurses were alerted by an alarm from the pump indicating that the syringe was empty. The patient was unrouseable and cyanosed, with a very slow ventilatory frequency. Immediate resuscitative measures were taken and the duty anaesthetist (P.K.) was summoned. Naloxone 400 μg was given, with rapid improvement in consciousness and ventilation. An infusion of doxapram 2 mg min^{-1} and naloxone 6 μg min^{-1} was commenced and supplementary oxygen was given via a face mask. A pulse oximeter was connected and close observation was maintained. After 6 h, the infusion was discontinued and further analgesia provided by papaveretum i.m. Further progress was uneventful and the patient experienced no residual effects.

The PCA pump was taken out of service immediately. Inspection of the pump was carried out by the hospital Electronic and Biomedical Engineering department, together with the technical director of Graseby Medical and a consultant anaesthetist (W.G.N.). It was confirmed from the PCAS totalizer and the ward monitoring chart that diamorphine 59 mg had been delivered over a period of about 1 h. No fault was found with the pump, the program settings or any other aspect of management. The incident was reported to the Department of Health and a Hazard Notice was issued.

Patient No. 2

Approximately 1 yr later, a 47-year-old man underwent laparotomy for an acute abdomen; he was healthy, but had a long history of chronic back pain. An appendicectomy was performed and the patient was returned to the ward. PCA was instituted after operation using a Graseby PCAS pump, again according to our standard practice. The pump was loaded with diamorphine 60 mg and set to give a 1-mg bolus dose with a 3-min lock-out time and no background infusion. No initial difficulties were encountered and monitoring was carried out satisfactorily.

A second syringe of diamorphine was supplied 18 h after operation and 14 h later the alarm of the PCA pump alerted the nurses that the syringe was empty. It was noticed that the pump registered that

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only 97 boluses had been given to the patient who, at that time was awake, co-operative and breathing spontaneously.

A third syringe was reloaded and a few moments later the pump's "OCCLUSION" alarm was heard. The nurse discovered immediately that she had clamped the tubing from the syringe during the reloading, unclamped it and pressed the "RUN" button.

After 40 min, a nurse was alerted by the pump's "SYRINGE EMPTY" alarm, and the patient was found to be deeply cyanosed and apnoeic. He was resuscitated successfully, PCA was discontinued and he made an otherwise uneventful recovery.

The PCA pump was taken out of service immediately and a superficial inspection of the pump was carried out. The pump's record of the number of boluses given was still 97. Therefore, according to the prescription and programming, only 97 mg should have been given. However, the PCA totalizer showed that the patient had received a total of diamorphine 177.8 mg and it was concluded that something had interfered with the pump's mechanism at the time of the 97th bolus. There was no evidence from the patient or nurses of any human interference. The patient remembered the gradual onset of somnolence, of being aware that something was wrong and of being unable to respond. It seems that the initial 23 mg given (after the 97th bolus) up to the time of the nurse changing the syringe had only a limited effect on the patient.

It was agreed that further inspection of the pump should be carried out by Graseby Medical in conjunction with a representative of the Medical Devices Directorate of the Department of Health. A Hazard Notice was issued.

DISCUSSION

PCA has been used world-wide for several years, particularly in the U.S.A., and there are more than 1000 PCA devices in use in the U.K. In spite of this extensive use, there are only two episodes recorded of equipment malfunction leading to opioid overdose [2, 4], and we are aware also of a third incident occurring in Australia in 1990. Our hospital has 32 pumps and has used the technique in some 5000 patients over the last 5 yr. To have two incidents occur within the space of 1 yr is extraordinary when set against the world usage of PCA. Three areas which may have caused this were examined: mismanagement, equipment fault and external electrical interference.

The PCA monitoring charts provided invaluable information for analysis; both patients had been monitored correctly according to our hospital standing orders on PCA management. Incorrect setting of the pumps was eliminated: both pumps were programmed in the standard way and had functioned normally for more than 24 h. No reprogramming had been undertaken as nurses are not allowed to interfere with the programming [3]. Syphoning of opioid from the syringe [4] was eliminated, as anti-syphon valves were fitted. Each pump was inspected by engineers from Graseby Medical. No electrical or mechanical fault was found with the first pump. A capacitor on the mains power input of the second pump was found to be inadequately soldered, and this may have allowed a power surge to develop.

It was concluded that electrical interference was the most likely cause of both incidents. Three possible sources were identified. First, power surges from the mains electrical supply could have occurred. Second, movement of the electrical plug within the mains input socket could lead to power fluctuations. Third, a static electricity discharge from the patient or the bed could have affected the pump. Both of the last two alternatives had been observed to corrupt the programming of PCA pumps, causing them to "fail-safe" [3]. Normally, the Graseby PCAS carries out its own internal self checks and if any abnormality is discovered, it disables itself.

The first incident could not be reproduced. It was speculated that the program had been corrupted by electrical interference during a bolus, causing the pump to fail to switch off the syringe driving motor. At the time of the incident, Graseby Medical were issuing modification kits to provide hardware protection against mains current fluctuations and improved software "self-checking". Unfortunately, the kits had arrived only a few days before, but had not been installed before this incident. Subsequently, all our pumps were adapted according to the Manufacturer's instructions.

In spite of these improvements, episodes of pumps failing-safe because of program corruption have continued to occur occasionally in this Hospital. These were observed usually to be associated with static electricity discharges.

The second incident reported here was reproduced by Graseby's engineers who demonstrated a rare sequence of events involving static electricity which could corrupt the programming and lead to the type of problem that occurred. Further software modifications to enhance safety have been undertaken, and all our pumps are now fitted with this second modification.

PCA pump manufacturers will continue to improve the safety of their products. Unfortunately, as versatility and complexity of design increase, the number of potential faults that can occur does increase [5]. A mechanical safety device, impervious to electrical disturbances, may need to be incorporated to prevent continuous overinfusion.

The survival of both our patients is attributable in part to the high requirement for opioid of each, and that they were relatively tolerant to the rapid diamorphine overdose. No system of opioid administration is 100% safe. Spinal opioid analgesia and PCA probably have acceptable levels of safety [6]. However, this must be set against the unknown morbidity and mortality arising from i.m. administration and inadequate analgesia. The case reports presented must be seen against this background.

The rapid response of the nurses to the alarms of the pumps also contributed to survival. Both events occurred during daytime; patient No. 2 was nursed in a six-bedded bay opposite to the nursing station and patient No. 1 in the 3rd bay of an adjacent ward. However, it has been noticed commonly that such alarms can be left unattended for some time, often

because of staff shortages. We have continued to observe the failure of nurses to carry out simple monitoring according to our schedules, in spite of time saved by the reduced number of i.m. injections [3]. Recently, we have been observing failure of nurses to recognize abnormalities in the variables they monitor (as with patient No. 2), reflecting failure in education of nurses in pain management.

The current nursing practice ("team nursing") of distributing patients throughout a ward also must be examined critically from the point of view of safety. Seriously ill postoperative patients requiring acute pain management sometimes are placed in the most remote corner of the ward.

PCA continues as our major technique for the relief of acute pain in this hospital. We are addressing the problems of improving our monitoring and our teaching, in addition to the broader issues of nursing care on the wards.

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