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Adverse events involving intravenous patient-controlled analgesia

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Abstract: PURPOSE: This article systematically characterizes aspects of all Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) reports associated with i.v. patient-controlled analgesia (PCA) postoperative use during a two-year index period. METHODS: Intravenous PCA represents a well-accepted and satisfactory means of acute pain treatment; case reports and large case series have described the occurrence of i.v. PCA-related adverse drug events (ADEs). MAUDE data files were downloaded, and all records pertaining to i.v. PCA devices were extracted for the two-year period from January 1, 2002, through December 31, 2003. Medical device events were categorized by their reported cause, including patient-related event, device safety event, operator error, and adverse reactions to opioids. Because there was not sufficient information to grade the certainty of each reported cause, all reported causes were graded "possible," except for device safety events that were confirmed on inspection by the manufacturer. RESULTS: There were 2009 individual i.v. PCA-related MAUDE medical device events reported during the two-year period. Of these events, 1590 (79.1%) were classified as possible device safety events, 131 (6.5%) as possible operator error, 25 (1.2%) as possible adverse reactions to opioids, 12 (0.6%) as possible patient-related events, and 235 (11.7%) as indeterminate. CONCLUSION: Manufacturer-confirmed device malfunction was a major cause of reported ADE with i.v. PCA infusion pumps while operator errors were more likely to be associated with more serious adverse outcomes than device safety problems. To reduce the incidence of these problems, potential vulnerabilities in the design and manufacture of i.v. PCA pumps must be identified and addressed.

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Strengths: This is the only systematic analgesic of modern PCA adverse events published to date.

Weakness: There were mandatory reports and as such this would interfere under-reporting of adverse events. Other voluntarily reported data base reflects less serious adverse events. Also, it is impossible to assess incidence versus overall use as PCA pumps are in widespread use.

Relevance to Palliative Care: Although our Tertiary Unit does not use PCA devices, many other programs do. The adverse event associated with their use do not make them a perfect alternative to the Edmonton Injector.