PROBLEMS ASSOCIATED WITH INTRAVENOUS PATIENT-CONTROLLED ANALGESIA (IV PCA) INFUSION PUMPS: AN ANALYSIS OF THE MANUFACTURER AND USER FACILITY DEVICE EXPERIENCE (MAUDE) DATABASE

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ABSTRACT

Objective: To examine the number, type, and frequency of adverse events associated with IV PCA equipment reported to the MAUDE database during the years 2002 through 2003. We also evaluated the number and type of MAUDE event reports received from each of the 20 US Food and Drug Administration (FDA) region offices.

Methods: A retrospective database of MAUDE reports received from 1/1/2002 through 12/31/2003 was downloaded into an Access database. Data were then exported into statistical software (SPSS version 13.0) for further analysis.

Results: A total of 2,009 IV PCA-related event reports were received during the period 2002 through 2003. Among all IV PCA-related reports (N = 2,009), 79.1% (n = 1,590) were attributed to possible device-related events, 6.5% (n = 131) possible adverse drug reactions, 0.6% (n = 12) possible patient-related events, and 12.5% (n = 251) were indeterminate events. Among all IV PCA-related reports (N = 2,009), 79.1% (n = 1,590) were attributed to possible device-related events, 6.5% (n = 131) possible adverse drug reactions, 0.6% (n = 12) possible patient-related events, and 12.5% (n = 251) were indeterminate events. More than half (61%) of the reported possible device-related events were confirmed upon inspection by the device manufacturer.

Conclusions: Although reporting bias may contribute to the high frequency of possible device-related events, we note that over half of possible device-related events were confirmed upon inspection by the manufacturer. To our knowledge, this is the first study to use a large, retrospective database to examine IV PCA-related problems.

REFERENCES


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