Journal of Diabetes Science and Technology
Volume 6, Issue 5, September 2012

ORIGINAL ARTICLE

Pediatric Use of Insulin Pump Technology: A Retrospective Study of Adverse Events in Children Ages 1–12 Years

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Abstract

Background:

Growing technological improvements in insulin pump design have increased the use of these devices in young children. To better understand the types of infusion pump-related problems and associated adverse events in this age group, we performed a comprehensive evaluation of pump-related adverse event reports received by the U.S. Food and Drug Administration (FDA) for children ages 1–12 years.

Methods:

A query was conducted of FDA's Manufacturer and User Facility Device Experience database from January 1, 1996, through December 31, 2009, in children ages 1–12 years involving insulin pumps. Report narratives were individually reviewed for age, gender, and seriousness of outcomes. Device or patient problems and potential contributory factors were assessed.

Results:

Over the past 14 years, 1774 (7%) of all insulin pump adverse event reports were identified in children ages 1–12. Of these reports, 777 (43%) resulted in hospitalization. In hospitalized cases (n = 614), diabetic ketoacidosis and/or hyperglycemia were the predominant patient problems, and in other cases (n = 98), hypoglycemia was evident. There were 106 emergency room visits, 19 cases requiring paramedic attention, and five deaths. The majority of reports indicated that the devices were not returned to the manufacturer, and root causes were not always confirmed.

Conclusions:

Younger children with diabetes deserve careful consideration of the risk and benefit of insulin pump technology. Studies are needed to better understand pediatric safety issues and to identify the root cause of adverse events. Problems related to patient education, device misuse, and malfunctions were found, highlighting the need to strengthen user training for children and their caregivers.

J Diabetes Sci Technol 2012;6(5):1053-1059

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Abbreviations: (DKA) diabetic ketoacidosis, (FDA) U.S. Food and Drug Administration, (MAUDE) Manufacturer and User Facility Device Experience

Keywords: adverse event reports, children, device-related problems, diabetes, diabetic ketoacidosis, hospitalization, hyperglycemia, hypoglycemia, insulin pump, malfunction, manufacturer evaluation, pediatric, postmarket, use error

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