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Adolescent Use of Insulin and Patient-Controlled Analgesia Pump Technology: A 10-Year Food and Drug Administration Retrospective Study of Adverse Events

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What's Known on This Subject

Infusion pumps are a growing technology that is becoming more widely used in the adolescent age group. Insulin pumps may offer a tighter control of blood glucose. Patient-controlled analgesia pumps deliver pain medications with continuous infusion and programmable features.

What This Study Adds

This study examines 10 years of FDA adverse event reports with the use of insulin and PCA pumps in the adolescent age group. Concerns about the use of this technology in the 12- to 21-year age group are discussed.

ABSTRACT

OBJECTIVES. From January 1, 2005, through December 31, 2005, the Food and Drug Administration received 5 adolescent death reports associated with the use of insulin pumps, raising concerns about use of this device in this age group. To understand better the types of infusion pump–related problems in adolescents, we performed a comprehensive evaluation of insulin and patient-controlled analgesic pump–related adverse events reported for adolescents that were received by the Food and Drug Administration from 1996 to 2005.

METHODS. A search for medical device adverse event reports from January 1, 1996 through December 31, 2005, involving insulin pumps or patient-controlled analgesic pumps used by patients who were aged 12 to 21 years was conducted in the Food and Drug Administration's Manufacturer and User Facility Device Experience Database. Reports were reviewed for demographic characteristics, type of adverse event, and patient morbidity, and potential contributory factors were classified from narratives in the reports.

RESULTS. A total of 1674 reports were identified: 1594 for insulin pumps and 53 for patient-controlled analgesic pumps. In reports of insulin pump events, there were 13 reported deaths, 2 reports that indicated possible suicide attempts, and several additional reports indicating severe hypoglycemic or hyperglycemic events that seemed to be device-related. A total of 102 (6.4%) insulin-pump reports highlighted factors that may have contributed to the adverse event, including problems associated with compliance, education, sports-related activities, and dropping or damaging the pump. Eighty-two percent of cases involving the insulin pump resulted in hospitalization. Half of the reports involving patient-controlled analgesic pumps indicated that the patient received an excess of medication; tampering and noncompliance were evident in some cases.

CONCLUSIONS. Adolescents are a special population who deserve careful consideration of risk and benefit for use of device technology. Studies need to further identify safety problems in this age group.

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Key Words

medical devices, adolescent, infusion pump, diabetes, analgesia, adverse events, postmarket surveillance

Abbreviations

PCA—patient-controlled analgesia
 FDA—Food and Drug Administration
 PMA—premarket approval
 DKA—diabetic ketoacidosis
 MAUDE—Manufacturer and User Facility Device Experience

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INFUSION PUMPS are a growing technology that has been used predominately in the adult population but that has in recent years become more prevalent among adolescents. Large population-based studies have shown high rates of preventable adverse events among hospitalized children,¹ notably adolescents.² Miller et al¹ studied pediatric adverse events by using patient safety indicators and found that both young adolescents, aged 10 to 14, and older adolescents, aged 15 to 19, experienced the highest rates of in-hospital adverse events, with older adolescents experiencing nearly twice the adverse event rate of younger group (odds ratio: 1.9; 95% confidence interval: 1.7–2.0). Adolescents who have diabetes may experience device-related problems for a variety of reasons that vary

with patient and disease characteristics.³ Few studies have examined device-related problems for patient-controlled analgesia (PCA) pumps.

From January 1, 2005, through December 31, 2005, the Food and Drug Administration (FDA) received 5 death reports in which teenage insulin pump users may have been negligent or noncompliant with the use of the device. This prompted a review of infusion pump-related adverse events in this age group to understand better the scope, severity, and type of circumstances described in reports.

It is important to understand the regulatory background and context for which pump devices are used. The majority of insulin pumps that are used for treatment of diabetes are cleared by the FDA through the 510(k) or premarket notification process. The 510(k) process is one type of regulatory pathway for medical devices to enter the market. It allows a manufacturer to show substantial equivalence to a previously approved and marketed device.⁴ Alternatively, marketing approval may be obtained by demonstrating with reasonable assurance that the device is safe and effective for its intended use through premarket approval (PMA).⁵ Many pumps are cleared for use in the general population through the 510(k) process; however, some pumps, such as implantable pumps, are approved through the PMA process. The PMA is the most stringent type of device marketing application required by FDA.

An insulin pump may offer tighter control of blood glucose levels while aiming to avoid diabetic ketoacidosis (DKA) and hypoglycemia. Pumps can be programmed to provide insulin at a basal rate and also to deliver meal-time or supplementary bolus doses of insulin. The attainment of normoglycemic levels helps to reduce the risk of complications of diabetes; however, insulin pumps have the potential to overmedicate and undermedicate. For example, insulin delivery may be impeded by a weak or depleted battery, occlusion of the infusion set, or even leakage. In some cases, insulin may precipitate and occlude the needle or tubing, thereby impeding delivery of the drug. Other hazards may result in free-flow or excessive insulin administration, putting patients at risk for hypoglycemia.⁶

There are many device components, such as hardware and software, that can contribute to the delivery system and proper device function. If the device should malfunction, then this may result in overinfusion, underinfusion, or delivery of a lethal dose of insulin. Errors associated with filling, refilling, or changing dosage or concentration of the product delivered by the device may also lead to problems of overdelivery or underdelivery of drugs. Other critical issues that should be considered are the accuracy of the software (eg, telemetry), accuracy of dosage calculation, and accuracy of programming the device. Catheter-related problems, such as kinking, leakage, and blockage, may compromise patient outcome. In some implantable pumps, migration may occur, and blockage may also result from marked fibrosis and tissue growth at the implantation site, necessitating removal of the device.

The genesis for PCA pumps was a result of the quest

for more effective pain treatment. PCA technology has evolved and is not restricted to a single class of analgesics or single mode of administration. The pumps deliver intravenous, subcutaneous, and epidural infusions. Patients do not have to wait for administration of their medications by a nurse and may self-administer narcotic analgesia as prescribed by their physician. The two most prevalent modes of administration found in PCA pumps are demand dosing, which delivers a fixed, self-administered dose intermittently, and a fixed-rate background continuous infusion with supplemental patient demand dosing. Most pumps offer both modes with programmable features that allow the pumps to be adjusted by clinicians, who can adjust the bolus size, lockout intervals, and continuous rate infusion. The greatest hazard to patients is increased risk for overmedication, particularly narcotic overinfusion that may lead to respiratory depression. PCA pumps differ in the methods used to store and deliver medication and hardware and software designs. Pumps can be worn, attached to an intravenous pole, or placed at the bedside.

METHODS

The FDA's medical device adverse event reports database was searched for all reports of insulin pumps and PCA pumps, for patients aged 12 to 21, that were received from January 1, 1996, through December 31, 2005. The database, also known as the Manufacturer and User Facility Device Experience (MAUDE) system, includes all mandatory and voluntary adverse event reports involving medical devices that are submitted to the FDA.⁷ The FDA requires manufacturers and user facilities to report adverse events whenever a death or serious injury was or may have been attributed to a medical device or when a medical device was possibly related to a death or serious injury, including events occurring as a result of device failure, malfunction, improper or inadequate device design, manufacturing, labeling, or user error (21 CFR §803.3). Information from these reports is entered into the FDA's MAUDE database.

All reports were identified by using codes specific for insulin or PCA pumps, and duplicate reports were merged. Data were reviewed and evaluated for all reports by using the narrative text and the summary patient or device problem codes indicating the overall nature of the device or patient problem as described by the reporter. For example, with insulin pumps, a patient problem code indicating "hypoglycemia" or "low blood glucose" would be assigned to a report indicating that the patient received too much insulin and experienced a low blood sugar. When summarizing the total number of reports with hypoglycemic complications, we included reports that had more or less of the following patient problem codes: hypoglycemia, low blood glucose, overmedication, insulin shock, and overdose. Reports that were classified as hyperglycemia were identified by using codes for hyperglycemia, undermedication, and underdose. Severe complications as indicated by patient problem code or text indicating DKA, coma, and seizures were also assessed. Reports were further reviewed for the types of injury or malfunction. Details of patient

TABLE 1 FDA Adverse Event Reports for Insulin Pumps in Adolescents, Aged 12 to 21 Years, January 1, 1996, through December 31, 2005

| Parameter | n (%) |
|------------------------------------|-------------|
| Total (n = 1594 reports) | |
| Males | 637 (40.0) |
| Females | 934 (58.6) |
| Unknown | 23 (1.4) |
| Types of events (n = 1594 reports) | |
| Injuries | 1038 (65.1) |
| Malfunctions | 528 (33.1) |
| Other events | 15 (0.9) |
| Deaths | 13 (0.8) |

Source of reports: 1562 manufacturer, 31 voluntary, 1 distributor, 0 user facility.

problems in the narrative text allowed us to group further the types of adolescent issues into the following categories: education, noncompliance, sports and other activities, device misuse, risk-taking behaviors, responsibility and care of the device, pubertal growth, problems occurring while away from home, and lack of parental supervision. Reports were classified as “noncompliance” when the text described that the adolescent failed to keep parent(s) informed, failed to follow diabetic protocol and report problems to caregiver, failed to provide adequate feedback, and was negligent in caring for the device. Reports that were classified in the education category revealed that the adolescent was unfamiliar with the device and its operation and how to troubleshoot. Reports that were classified in the risk-taking category had narrative text describing instances of alcohol abuse, stress, and possible suicidal attempts.

Adverse event reports for PCA pumps were similarly reviewed. Complications that were associated with narcotic use and narcotic drug-related adverse effects were also evaluated.

RESULTS

Insulin Pumps

From January 1, 1996, through December 31, 2005, there were 1594 FDA adverse event reports for patients aged 12 to 21 (Table 1). Almost all (n = 1562; 98.0%) were manufacturer reports. During this 10-year period, the annual number of insulin pump reports to the FDA for adolescents increased; since 2003, there was a greater

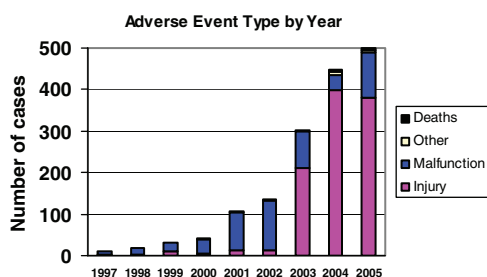


FIGURE 1

FDA adverse event reports for insulin pumps, aged 12 to 21, 1996–2005. Death reports: n = 5 in 2005; n = 4 in 2004; n = 1 in 2003; n = 2 in 2001; n = 1 in 2000.

TABLE 2 102 Insulin Pump Reports (6.4%) Indicating Special Adolescent Issues That May Have Contributed to the Adverse Event

| Parameter | n |
|---|------|
| Total no. of cases | 102 |
| Males | 42 |
| Females | 59 |
| Gender not reported | 1 |
| Age, mean y | 15.8 |
| No. hospitalized | 82 |
| Adolescent issues | |
| Education | 47 |
| Noncompliance | 19 |
| Both education and noncompliance | 2 |
| Sports and other activities ^a | 12 |
| Device misuse | 8 |
| Risk-taking behaviors ^b | 4 |
| Responsibility and care of the device (irresponsible/negligent in care of device) | 5 |
| Pubertal growth ^c | 3 |
| Occurred when away from home | 1 |
| Lack of parental supervision | 1 |

^a Activities: 3 swimming; 1 each for sailing, bowling, snowboarding, jogging, basketball, football, baseball, biking, and horsing around).

^b Two possible suicide attempts.

^c Size, growth spurt, and musculature.

proportion of patient injuries than device malfunctions (Fig 1). A total of 499 (31.3%) adverse event reports were received in 2005. Of these, 381 (76.4%) were patient injuries and 109 (21.8%) were device malfunctions. There were a total of 13 insulin pump-related deaths (8 females, 5 males; mean age: 16.0 years). Reported deaths were related to either hyperglycemic or hypoglycemic complications (n = 5), DKA (n = 3), seizure (n = 1), or coma (n = 1), and 3 death reports did not indicate a cause. Five deaths occurred at home. Three deaths occurred at times when parental supervision was lacking (1 away at college; 1 while the usual family caregiver was away; 1 patient, aged 19 years, was cared for by the adolescent’s spouse).

There were 987 (61.9%) reports with patient problems of hyperglycemia, and 46.6% of these indicated that the patient had DKA. Seventy-three (7.4%) of the 987 reports revealed problems of underinfusion. In these reports, the device problems included error messages (n = 55), incorrect use (n = 24), alarm problems (n = 29), loosening and/or occlusion of the catheters (n = 22), bent cannula (n = 22), and screen display problems (n = 14). There were also 31 reports of the device’s need for repair, replacement, or removal and 19 reports of device failure and/or failure to deliver.

A total of 167 (10.5%) reports included patient and device problems with hypoglycemia or overdelivery of insulin. Several reports were coded as overmedication (n = 15; 17.5%), overdose (n = 7; 4.2%), and insulin shock (n = 1; 0.6%). Device codes also indicated incorrect use of the device (n = 18), problem with self-activating key and overbolusing (n = 9), error message (n = 8), and alarm problems (n = 8). In 60 (35.9%) of the 167 reports, the device problem was coded as unknown.

TABLE 3 FDA Adverse Event Reports for PCA Pumps in Adolescents, Aged 12 to 21 Years, January 1, 1996, through December 31, 2005

| Parameter | n (%) |
|---|------------|
| Total reports aged 12–20 y | 53 (100.0) |
| Males | 28 (52.8) |
| Females | 25 (47.2) |
| Outcome or adverse event type | |
| Death (2 postoperative, 2 sickle cell disease, 1 severe Demerol reaction) | 5 (9.4) |
| Injury | 19 (35.8) |
| Malfunction | 21 (39.6) |
| Other event | 8 (32.0) |
| Indication for use | |
| Orthopedic | 8 (15.1) |
| Sickle cell disease | 8 (15.1) |
| Cancer | 7 (13.2) |
| Pregnancy-related | 7 (13.2) |
| Abdominal surgery | 3 (5.7) |
| Other (2 other postoperative, 1 renal, 1 cholecystitis, 1 gunshot) | 5 (9.4) |
| Unknown or not enough information | 15 (28.3) |

Source of reports: 41 manufacturer, 8 user facility, and 4 voluntary.

In 102 (6.4%) reports, special adolescent issues were identified (Table 2). Eighty-two (80.4%) of the 102 reports resulted in hospitalization. The top 3 issues that were associated with these reports were education, noncompliance, and problems during sports or other activities. Four reports indicated risk-taking behaviors (including 2 reports of insulin overbolusing that were thought to be suicide attempts).

Adverse Events for PCA Pumps

A total of 53 reports of adverse events were associated with PCA pumps, including 5 deaths, 19 injuries, 21 malfunctions, and 8 other events (Table 3). In most cases, the device was used to treat pain associated with orthopedic conditions, cancer, sickle cell disease, and pregnancy-related events.

Five death reports included a 19-year-old woman who died of overdosage and overmedication of morphine after cesarean section, a 12-year-old boy who died of an adverse drug reaction to Demerol, a 14-year-old girl who died of overdosage of Dilaudid after surgery, and 2 other adolescents who died during hospitalization for pain control of sickle cell crisis. Twenty-seven (50.9%) reports indicated that the patient received an excess dose of medication (overinfusion, overdosing, overmedication, or overdosage). Twelve of the 27 reports described respiratory depression and unresponsiveness that required ventilation and/or Narcan administration. There were 2 reports of adolescents who had tampered with their PCA pump and successfully removed morphine from the device and 1 report of an adolescent who smoked marijuana while using the pump.

DISCUSSION

Insulin Pumps

Within the 10-year study period, we found >1500 unique reports of insulin pump-related adverse events among adolescent users. Although this large number of reports may reflect the expanding use in the pediatric age group,⁸ the unique challenges posed by adolescent users should be considered. It is widely recognized that tight control of glucose levels can be used to achieve lower hemoglobin A_{1c} levels. Any insulin treatment modality, including delivery of insulin via pump, may be used to achieve this goal. Good glycemic control of diabetes during childhood and adolescence minimizes the risk for microvascular complications in adulthood,⁹ and intensive insulin pump therapy may provide an effective alternative to repeated insulin injection therapy by lowering hemoglobin A_{1c}⁹ and allowing for continuous adjustment with added bolus features¹⁰; however, few studies have closely examined the safety issues for teenage patients. It is known that control of blood glucose often deteriorates during puberty^{11,12} and that chronically ill adolescents may be more difficult to treat medically than younger children with the same illnesses.^{13,14} Whereas some investigators^{15,16} support the use of insulin pumps for adolescents with frequent episodes of DKA, others caution about the risks of both hypoglycemic and hyperglycemic events with pump therapy.^{17,18} Although we recognize that the method of insulin delivery, as well as other confounders, plays a role, we think that understanding device-related problems in the adolescent age group is important. Our data indicated that nearly two thirds of FDA reports revealed problems with hyperglycemia. Boland et al⁸ conducted a nonrandomized trial comparing insulin pump therapy and repeated injections in a cohort of 75 adolescents who were followed for 12 months with assessments of glycemic control, psychological variables, coping, and adverse events (severe hypoglycemia or DKA). They found that both groups were similar in quality of life, psychological profiles, and depression but noted that those who used infusion pumps experienced fewer severe hypoglycemic events.⁸ Bode et al¹⁹ also supported that infusion therapy brings about a decrease in hypoglycemic problems, whereas other studies found that continuous subcutaneous insulin infusion showed high variability in blood glucose control.^{20–23} Ahern et al²⁴ studied 161 children (including 59 adolescents) and found improved diabetes control but not statistically significantly fewer episodes of hypoglycemic events for the adolescent age group.

Although insulin pumps may mimic physiologic insulin replacement, they may be problematic because of adolescent lifestyle and psychosocial factors.³ Adolescent-aged issues were implicated in many of the FDA reports. We noted several adverse events related to extracurricular activities and accidental dropping and breaking of the pump. This was also reported by Burdick et al²⁵ in a study of 48 adolescents who received insulin pump therapy: 52% reported disconnecting their pump for exercise. A Finnish study of adolescents with diabetes revealed that 75% believe that they had satisfactorily

complied with the protocol, whereas, on review, only one fifth had actually complied.²⁶ This study pointed out that teens tend to give health care providers answers that were compliant with expectations and identified conflicts between the adolescent and parents or other caregivers about diabetic care. Better diabetic control among adolescents has been associated with greater parental involvement.²⁷ The FDA reports revealed 3 deaths that occurred at times when there was no parental supervision.

Difficulties may also arise when teens are careless or tamper with their medical devices, injuring themselves. An increased risk for hypoglycemic complications may occur with binge drinking of alcohol. In our study, a patient who was away at college was found dead in his dorm room after being out with friends the night before. Teenagers with chronic medical disorders have an increased risk for stress and behavioral and psychiatric disorders.^{28,29} Two hospitalized patients with diabetes in our series overbolused with insulin, and the reports indicated that these may have been suicide attempts. A review of the literature revealed a case report of a 14-year-old girl who administered hair conditioner through her intravenous infusion pump and died.³⁰ It is unclear whether her death was attributable to risk-taking behavior or an intentional suicide. Healthcare providers should be aware of possible suicidal ideation among teens with diabetes and potential risks with misuse of medical devices.

Only a few studies have evaluated insulin pump malfunctions that occurred in adolescent patients. A retrospective study of 6 adolescents found 1 teen hospitalized on 2 different occasions for DKA associated with device malfunction.¹⁶ Weintrob et al³¹ conducted a small study of 20 adolescent patients and found a higher number of ketotic events for pump users ($P = .003$), all related to infusion set problems. In another study, Saha et al³² reported that 3 adolescent pump users experienced ketoacidosis related to disconnection and occlusion of the infusion catheters. Our study found that one third of all pump-related problems were malfunctions, and detailed information reported various device problems with error messages and problems with the alarm, catheter, and screen display.

PCA Pumps

PCA pumps have become an important strategy in pain management for pediatric medical conditions. Although the delivery of opioids has been shown to be effective for pain relief,³³ their administration carries the risk for respiratory depression. In our study, we found 12 cases of respiratory depression that required medical intervention. Two studies in the literature also reported older children and adolescents who experienced problems with oxygen desaturation.^{34,35} In our series, more than half of the adverse events indicated that the adolescent received an excess bolus of opioid. In most of the reports, it was unclear whether incorrect dosage boluses, programming errors, drug errors, or accidental bolus administration had occurred. Although studies do indicate that age affects opioid dosing³⁶ few have discussed the human

factor issues surrounding the use in the adolescent age group. In a pediatric case series of PCA use among patients with sickle cell disease, Shapiro et al³⁷ noted that 1 adolescent tampered with the device as a possible suicidal gesture. We found 2 cases in our series. Three deaths reported to the FDA indicated that the adolescents were found unconscious too late after overdosage of narcotics, and other reports seemed to be near-miss occurrences that would have been lethal if they had gone unnoticed with time delay. Patients with PCA pumps may allow others to push the button on their pump, and this can result in serious consequences and death.³⁸ This has led to advisories from manufacturers, ECRI Institute, and the Joint Commission on Accreditation of Healthcare Organizations that allowing anyone other than the patient to press the PCA delivery request button is contraindicated.³⁹ Life-threatening complications of respiratory depression, oversedation and confusion highlight the need for careful selection and monitoring of adolescent patients who receive this device.

Limitations

There are many limitations to this study. The majority of adverse event reports were submitted by manufacturers. The accuracy and completeness of the reports were not verified by the FDA. By limiting our search to the specific age group (12–21 years), we were unable to capture reports with missing age information. Medical device adverse event reports cannot clearly establish a cause-and-effect relationship of an injury or illness with the device. The recognition of a device-related event is often subjective and imprecise. The reports had insufficient details about patient factors, such as patient compliance, socioeconomic status, medical history, disease severity, duration of disease, history of substance abuse, years of pump use, and developmental stage of puberty. There were no data on use of pump devices and sales in this age group to provide the denominator to calculate incidence rates of adverse events. Adverse event reports for PCA pumps also had missing information regarding the type of analgesia, dosage, diagnosis, and severity of illness.

CONCLUSIONS

The use of infusion pump technology for the treatment of diabetes and pain management may pose special risks for the adolescent. This article provides a summary of adolescent-related adverse event reports for insulin pump and PCA therapies. Device-related adverse events that occur in this age group are likely to be underreported in the MAUDE database and in the published literature. The precise rates of device-related complications should be further studied and misuse of these devices be further studied in the adolescent population. Health care practitioners, medical care facilities, and consumers are encouraged to report device-related problems through the FDA Medwatch program: www.fda.gov/medwatch.

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