H47 Fatalities Due to the Failure of Continuous Subcutaneous Insulin Infusion Devices: A Report of Six Cases

Timothy L. Williams, MD, King County MEO, 325 9th Avenue, Box 359792, Seattle, WA 98104-2499; Andrew Ziegler, BS, Ohio Northern University, Ada, OH 45810; Nicole A. Yarid, King County MEO, 325 9th Avenue, Seattle, WA 98104; Daniel L. Schultz, MD, Lifelink Tissue Bank, 9661 Delaney Creek Boulevard, Tampa, FL 33619; and Elizabeth A. Bundock, MD, PhD, Office of the Chief Medical Examiner, 111 Colchester Avenue, Burlington, VT 05401*

The goals of this presentation are to provide: (1) an understanding of how insulin pumps work; and, (2) recognition of potentially fatal malfunctions of insulin pumps.

This presentation will impact the forensic science community by providing the results of a series of cases that have not previously been presented in the literature.

Treatment of diabetes mellitus often requires injection of exogenous insulin to manage the disease. Some patients elect to use Continuous Subcutaneous Insulin Infusion (CSII) devices rather than repeated needle sticks for the administration of insulin. Malfunctions of any component of the CSII device can result in insufficient insulin delivery and, if not recognized in a timely manner, can lead to fatal ketoacidosis.[1] While there are studies describing complications of CSII devices in living patients, the literature is extremely limited in describing CSII failure-associated mortality.

This study presents a series of six cases of fatal diabetic ketoacidosis resulting from insulin infusion set malfunctions in patients undergoing continuous subcutaneous insulin infusion. The six cases were compiled from four different medical examiner offices in the United States. The patients varied in age, ranging from 37 to 79 years old. Both genders are represented as are both types of diabetes mellitus. Autopsy examination, including toxicologic analysis, was performed on all cases. In four of the six autopsies, no anatomical abnormalities were observed. The findings in the other two autopsies were either not significant to cause the patient's death or could be considered secondary to the patient's history of diabetes.

Infusion set malfunctions are among the most common and significant complications of CSII devices.[2,3] In all six cases, the malfunction was identified to be failure of the cannula to puncture or remain in the skin (in five of the six cases, the insulin infusion set failed to puncture the skin, and in one case it appeared that the Insulin Infusion Set (IIS) had initially punctured the skin to some extent, but it was unclear if the cannula had failed to fully insert or had inserted and subsequently dislodged). Also, in five of the six cases, the cannulas were bent or kinked; in one case, the cannula appeared straight but was not inserted through the skin. Four of the six cases involved perpendicularly inserted cannulas, all of which were bent or kinked. Of the two angled cannulas, one was bent and another had failed to insert. In all cases, infusion set malfunction resulted in the failure of insulin infusion, which then resulted in fatal ketoacidosis.

The cause of death in all cases was certified as either diabetic ketoacidosis or complications of diabetes mellitus; however, since it is possible to consider the unexpected natural death of diabetic ketoacidosis which occurred as a result of improper application of their therapeutic device as either natural or accident, there is variation in classification of the manner of death. In the six cases presented in this study, manner of death was classified as accident in three cases and natural in three cases.

Recognition of these potentially fatal CSII-device malfunctions is important in order to prevent future deaths. Though only six cases are presented, given the widespread use of this treatment modality, it is likely there are unrecognized instances in which failure to properly place the IIS cannula during CSII therapy allowed the patient's diabetic condition to progress to a fatal state of ketoacidosis. Examining and understanding these six deaths can lead to future prevention through advancing technological applications and educational practices as well as contribute to proper classification of deaths related to CSII failure.

Reference(s):

1. Centers for Disease Control and Prevention. *National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014.* Atlanta, GA: U.S. Department of Health and Human Services; 2014.
2. Pickup, J.C., Yemane, N., Brackenridge, A., and Pender, S. (2014). Nonmetabolic Complications of Continuous Subcutaneous Insulin Infusion: A Patient Survey. *Diabetes Technology & Therapeutics.* 16(3), 145-149.
3. Heinemann, L. and Krinelke, L. (2012). Insulin Infusion Set: The Achilles Heel of Continuous Subcutaneous Insulin Infusion. *Journal of Diabetes Science and Technology.* 6(4), 954-964.

Insulin Pump, Insulin Infusion, Mortality

*Presenting Author