Continuous Subcutaneous Insulin Infusion (CSII) Sets: Reduced Flow Interruptions with a Novel Catheter Set

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Abstract

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Effective CSII requires consistent insulin delivery via infusion set. An investigational, side-port 28G polymer infusion set has been designed to reduce flow interruptions including sub-alarm threshold (“silent”) occlusions (below pump pressure setpoint). With an in-line pressure measuring method that reliably reflects fluid flow, we compared the new set vs marketed set (Quickset). Preliminary studies indicate that this occlusion “silent” flow interruptions.

INTRODUCTION

Insulin infusion sets are critical components in continuous subcutaneous insulin infusion (CSII). Relative to its importance the amount of research on infusion sets has been inadequate. Available reports have shown irregularities in continuous subcutaneous insulin infusion (CSI) that patients find exasperating.

BD has developed a novel 28G polymer subcutaneous catheter infusion set (Figure 1) with proprietary side-port cannula technology to improve insulin delivery and reduce flow interruptions. Steady infusion set flow pressure rise is indicative of reduced flow and/or occlusion. Flow interruptions occur long before pump occlusion alerts (“silent occlusion”). Compared to other catheter infusion sets, preliminary studies indicated that this side-port infusion set reduces the frequency of flow interruptions.

This is a report on a hypothesis driven comparative study of the investigational BD FlowSmart™ infusion set and a commercially available infusion set, the BD Monarch™, assessing fluid flow pressure profiles with an in-line pressure measuring method that reliably reflects fluid flow.

OBJECTIVES

PRIMARY - With insulin diaphragm, compare subcutaneous fluid delivery following insertion of BD FlowSmart and Medtronic Quick-set (QS) infusion sets in human by studying differences in delivery pressure.

Secondary: Compare the occurrence of fluid pressure rise events during in-line basal and bolus delivery infusion by comparing the following sets: BD FlowSmart vs Medtronic Quick-set.

EXPLORATORY - Determine the occurrence of fluid leakage and leakage amount from insertion site after insulin diaphragm delivery between the BD FlowSmart and Medtronic Quick-set infusion sets.

RESULTS

60 subjects enrolled and completed the study (Table 1) providing 249 infusion sets for analysis. All infusion sets were included in the leakage analysis. 235 infusion sets were included in pressure analysis (11 removed due to leakage, 4 due to protocol deviation). 2.5% of sets were excluded (1 by pump, 2 by protocol deviation).

PRIMARY ENDPOINT

2.6% of the BD FlowSmart sets and 10.2% of the Medtronic Quick-set sets had almost 4 times fewer sets with flow interruptions.

Figure 2 - subject attached to 4 infusion sets connected to pump transducers & data logger

Figure 3 - basal/bolus sequence and timing

Figure 4 - Comparison of devices for percent time of interruption

Figure 5 - Comparison of devices for percent time of interruption

CONCLUSIONS

Compared to a frequently used commercial infusion set, the BD FlowSmart insulin infusion set provides more consistent insulin delivery with significantly fewer flow interruptions and no difference with insertion site leakage. Reducing the frequency of “silent occlusions” with CSII could potentially reduce unexplained high blood sugar excursions and some patients.