Basal Rate Delivery Accuracy of Durable Insulin Pumps

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Background and Aims: Continuous infusion of a basal rate is one of the key elements of insulin pump therapy. Test settings to assess basal rate delivery are described in EN 60601-2-24. However, there are no normative requirements regarding acceptable minimum accuracy. In this study, the basal rate accuracy of different durable insulin pumps was tested.

Method: In an experimental setting following procedures of EN 60601-2-24, five insulin pumps with different insulin infusion sets (IIS) were evaluated (Table 1). Insulin pumps were filled with insulin aspart (NovoRapido®, Novo Nordisk) and installed with the tip of the cannula in a water-filled beaker placed on an electronic balance (Figure 1). To avoid evaporation, an oil film was applied. Insulin pumps were set to a basal rate of 1.0 U/h and weight increase was recorded for 72 h. Each combination of insulin pump and IIS was tested 9 times.

Results: Over the whole 72 h, the systems showed a slightly higher mean weight increase than expected with the programmed basal rate (Table 2). Deviations were larger during the first 24 h (Table 2). Regarding the mean delivery over 1-h windows, large variations between the individual windows were observed (Figure 2 and 3).

Conclusion: In this study, cumulative basal rate delivery deviations were within a range of ±5% for all tested insulin pump systems, as specified by the manufacturers.

Table 1: System characteristics of evaluated insulin pumps. T=Teflon, S=Steel.

Table 2: Total deviation for each system (1-9) during different time ranges.

Figure 1: Test setting based on IEC 60601-2-24.

Figure 2: Percentage deviation of 1-hour windows for each system (1-9) over 72 h.

Figure 3: Mean delivery over 1-h windows in course of time; for each insulin pump system (1-9). Set rate: 1.0 U/h. Black dashed line represents target delivery, red dotted lines represent target delivery ±15%, colored dashes represent the individual measurements.

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