

Examination of the Accuracy and Stability of an Arterial Sensor for Glucose Monitoring in a Porcine Model Using Glucose Clamp Technique

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Objective:

Intravascular glucose sensors have the potential to improve and facilitate glycemic control in critically ill patients and in contrast to subcutaneous devices might overcome measurement delay and accuracy issues.

Method:

This study investigated the accuracy and stability of a novel in-vivo biosensor for arterial glucose monitoring tested in a hypo- and hyperglycemic clamp experiment in pigs. In total, 12 sensors were tested over 5 consecutive days in 6 different pigs. Samples of sensor and reference measurement pairs were obtained every 15 minutes. The intended use of the sensor allows 96 hours of sensing.

Result:

1337 pairs of glucose values (range 37-458 mg/dl) were available for analysis. The systems met ISO 15197:2013 criteria in 99.2%. Fulfilment of ISO 15197:2013 was 100% for glucose <100 mg/dl (n=414) and 98.8% for glucose >100 mg/dl (n=923). The mean absolute relative difference (MARD) during the entire glycemic range of all sensors was $4.5 \pm 4.1\%$. The MARDs within the hypoglycemic (<70 mg/dl), euglycemic (70-180 mg/dl) and hyperglycemic glucose ranges (>180 mg/dl) were $5.8 \pm 5.2\%$, $3.8 \pm 3.1\%$ and $5.0 \pm 4.3\%$, respectively. Sensors indicated comparable performance assessed by MARD on all days investigated (day 1, 3 and 5). None of the systems showed premature failures.

Conclusion:

In a porcine model, the performance of the biosensor revealed a promising performance. The transfer of these results into a human setting is the logical next step.