

Study Demonstrates Accuracy of GlySure CIGMS in Critically III Patients



GlySure Limited has announced publication of a manuscript in the <u>Journal of Diabetes Science and Technology</u>, which validates the safety and performance of the GlySureTM Continuous Intravascular Glucose Monitoring System (CIGMS) in measuring plasma glucose concentrations in critically ill patients without disrupting current clinical practice.

The study, titled "The Development of a Continuous Intravascular Glucose Monitoring Sensor," outlines the development strategy for an intravascular continuous glucose sensor and provides clinical data from use of the GlySure CIGMS in 47 patients in the Cardiac Intensive Care Unit (ICU) and Medical ICU (MICU). In each patient, a GlySure sensor was placed through a GlySure central venous catheter (CVC) and measured their blood glucose concentration every 15 seconds. Comparison blood samples were taken at 2 hourly, then 4 hourly intervals.

Study results showed that the GlySure CIGMS is capable of safely and accurately measuring intravenous glucose concentrations continuously for up to five days in patients with a range of clinical conditions.

Proper control of glycemic levels in hospital ICUs has been the subject of several research publications and debate over the past twenty years. Multiple studies have demonstrated the need for a tool that enables safe and effective glucose control in the ICU for the reduction of both morbidity and mortality in critically ill patients.

"This study demonstrates the benefits of continuous over intermittent glucose monitoring, and that the GlySure CIGMS effectively addresses this clinical need," said Barry Crane, Chief Technology Officer of GlySure and lead manuscript author. "A prime requirement in the design of this sensor was that the configuration should facilitate ease of use and would not disrupt normal ICU procedures. Feedback we have received from physicians and nurses regarding use of this product demonstrates that this requirement has been met."

Current methods of blood glucose measurement in the ICU, such as use of a finger stick and a glucometer, as well as subcutaneous glucose sensors, which were both originally designed for home diabetic use, have been shown to be less accurate, particularly in severely ill patients. This is due to the fact that they do not monitor the patient's glycemic state continuously, as well as the potential for interference from complex drug regimens used in the ICU.

The GlySure CIGMS is a glucose monitor based on a fluorescent diboronic acid receptor that is highly selective to glucose, which enables it to continuously measure and accurately report plasma glucose concentrations directly in a patient's vascular system. This real-time information enables more effective glycemic control over intermittent devices, subsequently reducing patient risk. The GlySure CIGMS comprises of three main parts: a monitor, a disposable fibre optic sensor and a disposable 5 lumen central venous catheter (CVC), similar to that typically used in the ICU.

GlySure has launched its CIGMS in Europe for glucose management in adult cardiac surgery patients following receipt of CE Mark certification earlier this month. In addition, the Company has initiated a multicentre trial to support an expanded indication for all intensive care adult patients.

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Published on : Mon, 13 Jul 2015