

Implantable real-time continuous glucose sensor: evaluation of the effectiveness of dexamethasone and of the impact of local vascularization on the operation of the sensor

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BACKGROUND and AIMS

Implantable fluorescence-based real-time continuous glucose monitoring (CGM) system (Eversense-Senseonics®) includes 1) a small sensor inserted subcutaneously by a doctor, 2) a removable smart transmitter worn over the sensor, and 3) a mobile app to display the glucose readings.

The Sensor, inserted subcutaneously, has a silicone ring component that contains a small amount of anti-inflammatory steroid drug (dexamethasone acetate or DXA) that is eluted locally to reduce tissue inflammation around the Sensor.

The silicone ring is designed to release dexamethasone acetate in a controlled manner, over the all insertion period, by allowing its slow elution from the sensor to the local tissue surrounding the implant. The total dexamethasone acetate content of the sensor is ≤ 2 mg.

The aim of the study is to demonstrate the true benefits of the dexamethasone acetate in eluding fibrosis and tissue inflammation around the subcutaneous Sensor and to investigate whether the different local vascularization of the patient may affects the operation of the Sensor.

METHODS

We ran the insertion in 4 patients with type 1 diabetes, 1 woman and 3 men aged from 24 to 59 years. We perform a doppler ultrasound evaluation at the first, the second and the third month after the insertion to evaluate the hypothetical presence of a foreign body reaction and to study the variability of the subcutaneous vascularization in the patients's arms.

RESULTS

Using the ultrasound probe, it was easy to locate the sensor and evaluate the absence of a foreign body reaction and the formation of a fibrotic capsule around the sensor in all the three different ultrasounds (at the first, second and third months after the implant). It was also easy to locate each sensor: they were at a depth of between 3 and 4.5 mm, perfectly placed longitudinally over the arm.

Thanks to doppler it was possible to study the different subcutaneous vascularization of the 4 patients. Despite the interindividual variability, the operation of the sensor and the reading of the data were not affected in any way.

CONCLUSIONS

In conclusion we can say that:

- The acetate dexamethasone ring is effective in avoiding the risk of foreign body reaction throughout the insertion period;
- Subcutaneous vascularization does not affect the operation of the sensor in any way;
- The sensor is easily recognizable in the ultrasound images.

The next step will be to keep patients monitored; we will perform a doppler ultrasound even at 4 months after insertion.

