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Title:

Blind Validation of Estrogen Monitoring in Controlled Ovarian Stimulation IVF Cycles Using a "Patient-Friendly" Saliva-Based Estradiol Assay

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Objective:
Controlled ovarian stimulation (COH) during in vitro fertilization (IVF) cycles involves close monitoring of estradiol (E2) levels and measurements of follicle growth. E2 monitoring can occur multiple times during an IVF cycle and can add to anxiety levels of patients because of repeated blood draws and extra visits to the clinic. In contrast to blood draws, sampling saliva is non-invasive and can be performed remotely. Here, we present a blind validation of a novel saliva-based E2 assay performed in samples collected in 2 independent IVF clinics. The objective was to investigate whether a saliva based E2 assay could replace the use of blood monitoring during a COH cycle.

Design:
Blinded sample collection study.

Materials and Methods:
Concurrent serum and saliva E2 samples were collected from patients who provided between 1 and 7 samples on different days of their COH IVF cycle. Samples were collected in 2 large independent IVF laboratories. Saliva samples were frozen and run blinded in a separate laboratory while Serum E2 values were assessed routinely in the participating IVF clinics. Saliva samples were measured and validated using an immunoassay developed in collaboration with Salimetrics LLC.

Results:

One to seven salivary E2 samples were analyzed for each patient (n=63). In clinics A and B, 30 and 33 patients had multiple saliva and serum samples collected. In Clinic A, 129 pairs of saliva and serum E2 were evaluated with a correlation coefficient of 0.91. In clinic B, 85 pairs were evaluated with a correlation coefficient of 0.88. More than 87% of patients showed an individual within cycle correlation of >0.7 and 66% a correlation of >0.9 (range 0.42-1.0). Patients with discolored saliva samples generally showed poor correlation. This most likely indicated that they failed to follow the instructions for collection.

Conclusions:

Salivary estradiol based hormone testing provides an equivalent alternative to serum based assessment. The ease of saliva sampling allows a reduction in treatment burden, improved patient satisfaction and decreased stress. Saliva based hormone tests may become the preferred method of COH monitoring in the future.

Support:

None.

References:

None.