

Abstract Details

Session title: Female infertility

Session type: Poster viewing session

Presentation number: P-383

★ Abstract title:

Can "patient-friendly" salivary hormone measurements replace serum monitoring of IVF patients? An European multi-center assessment.

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Study question:

Can a saliva based Estradiol (E2) assay replace the use of blood monitoring during a controlled ovarian stimulation (COS) cycle for IVF/ICSI?

Summary answer:

Salivary E2 based hormone testing provides an equivalent alternative to serum based assessment and may become the preferred method of COS monitoring in the future.

What is known already:

Salivary diagnostic testing is emerging as a less invasive, inexpensive alternative to serum analyte measurements with proven diagnostic accuracy in clinical settings. This study aimed to determine the performance of a salivary hormone competitive immunoassay for monitoring patient E2 levels during monitored cycles for infertility treatment. Such treatments encompass: Undergoing monitored infertility treatment employing controlled ovarian stimulation (COS) with oral agents or gonadotropins for Ovulation induction/ IUI and COS for IVF/ICSI.

Study design, size, duration:

The prospective study was performed at 4 different European clinics (Italy, Spain, Belgium, France), between 9/2016-11/2017, whereby at each venipuncture appointment, subjects also collected a saliva sample via passive drool according to the assay specifications. In total 152, 214, 184 and 104 samples were collected from 59, 122, 40 and 40 patients respectively. Between 1 and 6 samples were collected from each individual patient. 122 patients collected ≥ 3 samples in an individual cycle.

Participants/materials, setting, methods:

Saliva samples were coded, de-identified and stored frozen. They were then run blinded in a separate facility. Saliva and serum correlation were calculated using the matched mean saliva and serum assay results for all E2 data points collected. Pearson product moment correlations of the serum and saliva were conducted using the natural log transformed data. Data was assessed per clinic and overall taking into account the different serum E2 testing platforms used per clinic.

Main results and the role of chance:

One to six salivary E2 samples were analyzed for each patient. In the four clinics the correlation coefficients of Saliva E2 to serum values were Italy: $r = 0.69$, $p < 0.001$; France: $r = 0.53$, $p < 0.001$; Belgium: $r = 0.75$, $p < 0.001$; Spain: $r = 0.79$, $p < 0.001$. Mean (\pm SD) serum E2 values (pg/ml) differed between clinics reflecting different demographics and approaches to patient stimulation [Italy: 803 ± 760 , France: 862 ± 892 ; Belgium: 1174 ± 933 ; Spain: 1276 ± 1026 . The respective mean (\pm SD) saliva values (pg/ml) were 17 ± 9 , 26 ± 15 ,

24±14 and 24±14. When examining individual patients who collected ≥3 samples in one cycle, more than 75% of patients showed an individual within cycle correlation of >0.7 and 62% a correlation of >0.9. Patients with discolored saliva samples generally showed poor correlations, indicating that they failed to collect according to protocol. Patient surveys have also shown that saliva based hormone testing is associated with improved patient satisfaction and decreased stress.

Limitations, reasons for caution:

The results could be limited as the study was conducted in an unselected population of all patients performing IVF. A further limitation was that although patients were informed on collection protocols it was evident that some patient saliva samples may have been sub optimally collected which influences the assay outcome.

Wider implications of the findings:

Rapid, salivary E2 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 hormone monitoring for fertility treatments in the future.

Trial registration number:

NCT03162809

Keywords:

diagnostic
saliva assay
Estradiol