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Self-operated endovaginal telemonitoring: a prospective, clinical validation study

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Objective: To study the comparability of self-operated endovaginal telemonitoring (SOET) with conventional two-dimensional transvaginal sonography (2D-TVS) monitoring during assisted reproductive technology (ART) cycles.
Design: Single center, observational, single-blinded cohort study.
Setting: University-affiliated in vitro fertilization center.
Patient(s): A total of 60 women undergoing ART cycles.
Intervention(s): Explanation, training, and use of SOET system, and measurements of follicular and endometrial diameter with SOET and 2D-TVS.
Main Outcome Measure(s): Correlation of the total number of follicles >10 mm measured by SOET versus conventional 2D-TVS.
Result(s): In 16 cases (26.7%) the images were judged unsuitable for analysis. In these excluded cases the body mass index (BMI) was statistically significantly higher (29.3 vs. 24.4 kg/m^2). The total number of follicles >10 mm was highly similar comparing SOET with conventional 2D-TVS ($r = 0.91$). For the concordance of whether more than 19 follicles or more than 25 follicles >10 mm were present, we found agreement between the methods in 43 of 44 cases ($\kappa = 0.88$) and 43 of 44 cases ($\kappa = 0.85$), respectively. For concordance on predefined human chorionic gonadotropin administration criteria, agreement was found in 39 of 44 cases ($\kappa = 0.734$).
Conclusion(s): The incidence of SOET videos not suitable for analysis seems to be associated with higher BMI. Otherwise, SOET showed good agreement with conventional 2D-TVS both for follicles and endometrium measurements. More importantly we also found good concordance regarding the cutoffs relevant for clinical decisions. (Fertil Steril® 2016;■:■–■. ©2016 by American Society for Reproductive Medicine.)
Key Words: ART cycles, self-operated endovaginal telemonitoring, telemonitoring, transvaginal sonography

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The endovaginal ultrasonographic monitoring of follicular growth during assisted reproductive technology (ART) cycles is essential for timing of sexual intercourse or intrauterine insemination (IUI) as well as for monitoring ovarian response to follicle-stimulating hormone stimulation in patients undergoing controlled ovarian stimulation (COS) for in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI). For the latter, finding the optimal time-point for human chorionic gonadotropin (hCG) administration and detecting hyperresponding patients who are at risk for developing ovarian hyperstimulation syndrome (OHSS) are of great clinical importance. For monitoring the ovarian activity, patients typically need to undergo several scheduled examinations during the course of one treatment cycle, which is burdensome for the patient and uses precious resources of the treatment center.

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Performing transvaginal sonography (TVS) at home by the patient or partner in ovulation induction (OI) or COS cycles could eliminate some—if not all, in selected cases—monitoring visits at the treatment center. The self-operated endovaginal telemonitoring (SOET; SONAURA) system consists of a vaginal probe connected by universal serial bus (USB) to a small tablet that is suitable for home use by the patient (Fig. 1). A specific website application to which the recorded data are immediately uploaded allows the operator to perform follicular and endometrial two-dimensional (2D) measurements using the video recorded by the patient.

As yet, only one clinical study on SOET in COS on IVF patients has been performed (1), in which SOET was not inferior in terms of number of metaphase 2 oocytes obtained as compared with conventional 2D TVS. However, the study was prematurely terminated and did not allow the assessment of infrequent events such as OHSS occurrence in the cases erroneously not canceled because of ovarian hyperresponse. Our study tested the comparability of SOET with 2D-TVS when performed in the same patient, on the same day, and we extended the tested population to patients undergoing ovulation induction (OI) or intrauterine insemination (IUI). We examined the correlation between SOET and 2D-TVS findings as well as the concordance between the systems in detecting predefined criteria usually employed for clinical decisions during monitoring, such as the follicular size to trigger final oocyte maturation and the total number of follicles to estimate the risk of OHSS.

FIGURE 1

The self-operated endovaginal telemonitoring (SOET) system used in this study (SONAURA).

Pereira. Self-operated endovaginal telemonitoring. Fertil Steril 2016.

MATERIAL AND METHODS

Between May and June 2015, we performed a prospective, single center, observational, single-blinded cohort study comparing SOET with conventional 2D-TVS monitoring during ART cycles, including monitoring of natural cycles, OI cycles with clomiphene citrate or follicle-stimulating hormone, and COS cycles for IVF or ICSI. The study took place at a university-affiliated IVF center. Institutional review board approval was not necessary because no pharmaceutic drugs were tested, the ultrasound device is marked for conformity in the European Economic Area (CE labeled), and the SOET findings did not alter the clinical treatment. However, all relevant data protection regulations were followed.

Study Protocol

Patients first underwent conventional 2D-TVS monitoring to measure endometrial thickness and the diameter of all follicles by calculating a mean value from two perpendicular axes. An experienced physician used a Voluson S6 2D (GE Healthcare). Patients then were asked to participate in the study when the following criteria has been met: willingness to use SOET, presence of two ovaries, and a body mass index (BMI) ≤ 40 kg/m^2. Patients with ovaries that could not be visualized by conventional 2D-TVS were excluded.

After the routine 2D-TVS examination, an explanation of the SOET system and patient training in SOET use were provided in a separate room. The patient was placed on a gynaecologic chair and learned the basic use of the tablet, including how to recognize the uterus and both ovaries. The training continued until the patient felt confident with the SOET procedure. The patient was then transferred to an outpatient room with a bed, where she self-recorded first her right ovary, then the uterus with the endometrium, and finally the left ovary while lying or sitting on a bed. After recording the images, which lasted by the default setting 30 seconds for each ovary and 15 seconds for the uterus, the patient was able to check the recorded images before transmitting the file by wireless LAN. If the patient did not consider the images to be useable, another recording could be made. The videos were then transmitted to imaging software where a different operator, who was not aware of the measurements yielded by the 2D-TVS, performed the 2D measurements of the follicles and endometrium. The video images could be stopped or played forward or backward, and two calipers were used to measure the endometrial diameter and each follicle at its two largest diameters. Video images were considered unsuitable for analysis if the endometrium or if at least one of the ovaries could not be visualized.

Outcome Measures

The primary outcome was defined as the correlation of the total number of follicles >10 mm measured by SOET versus conventional 2D-TVS. Furthermore, the number of follicles was assessed in four size categories: 11–14 mm, 15–17 mm, 18–20 mm, and $\geq$ 20 mm. Follicles ≤ 10 mm were not included in the analysis. The secondary outcomes were incidence of videos not suitable for analysis as judged by the