

The international agreement study on the diagnosis of the septate uterus at office hysteroscopy in infertile patients

Janine G. Smit, M.D.,^a Jenneke C. Kasius, M.D., Ph.D.,^a Marinus J. C. Eijkemans, Ph.D.,^b Sebastiaan Veersema, M.D.,^c Human M. Fatemi, M.D., Ph.D.,^d Evert J. P. Santbrink van, M.D., Ph.D.,^e Rudi Campo, M.D., Ph.D.,^f and Frank J. M. Broekmans, M.D., Ph.D.^a

^a Department of Reproductive Medicine and Gynecology, University Medical Center Utrecht, Utrecht, the Netherlands;

^b Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, Utrecht, the Netherlands;

^c Department of Reproductive Medicine and Gynecology, St. Antonius Hospital, Nieuwegein, the Netherlands;

^d Department of Reproductive Medicine, Academic Hospital at the Dutch-speaking Brussels Free University, Brussels, Belgium; ^e Department of Reproductive Medicine and Gynecology, Reinier de Graaf Group, Voorburg, the Netherlands;

and ^f Leuven Institute for Fertility and Embryology, Tiensevest, Leuven, Belgium

Objective: To assess the international agreement on the hysteroscopic diagnosis of septate uterus.

Design: Interobserver study.

Setting: Eight hysteroscopy recordings were put online on the website of the European Society of Gynaecological Endoscopy.

Patient(s): Asymptomatic, infertile women indicated for a first in vitro fertilization (IVF)/intracytoplasmic sperm injection (ICSI) treatment cycle.

Intervention(s): Office hysteroscopy.

Main Outcome Measure(s): The interobserver agreement on the uterine shape and necessity to correct the abnormality found.

Result(s): Seventy-eight observers from 24 different countries assessed 8 hysteroscopy recordings. The interobserver agreement on uterine shape variations septate and arcuate was fair (intraclass correlation coefficient = 0.27). Observers from the same country reached a significantly higher level of agreement. The agreement on the necessity of correction was poor (intraclass correlation coefficient = 0.17). The most distinct features for diagnosing a septate uterus judged to be the extent of endocavitary bulging and the angle of the bulging structure from the fundal area.

Conclusion(s): The agreement among international experts on the hysteroscopic diagnosis of the septate uterus was found to be poor.

This may have implications for the accuracy of screening hysteroscopy for diagnosing uterine

cavity abnormalities in infertile patients. Development of consented definitions for the hystero-

scopic diagnosis of septate and arcuate uterus is recommended. (Fertil Steril® 2013;99:2108–13.

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Key Words: Hysteroscopy, septate uterus, uterine anomalies, interobserver agreement

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The septate uterus is the most frequent congenital uterine anomaly in infertile women with a prevalence that varies from 3.0%–15.4% (1). A causal role of septate uterus in infertility has been

suggested (1–4). Also associations were found between septate uterus and a high miscarriages rate (44.3%), preterm delivery (22.4%), and obstetrics complications (1, 4–6). Studies suggest an improvement in pregnancy and preterm delivery rates after hysteroscopic septum resection (3, 5, 7–9), although final proof from randomized studies is still being awaited (TRUST-trial, B.W.J. Mol et al., trust@studies-obsgyn.nl, NTR 1676). The arcuate uterus comprises a mild indentation of the fundus into

Received November 7, 2012; revised January 30, 2013; accepted February 14, 2013; published online March 13, 2013.

J.G.S. has nothing to disclose. J.C.K. has nothing to disclose. M.J.C.E. has nothing to disclose. S.V. reports being on the Advisory Board of Hologic; consultancy with Essure; payment for lectures from J&J; trainer in laparoscopic course Elancourt for Covidien; and travel expenses paid by Nordic for participation in ESGE meeting in London 2012. H.M.F. reports payment for lectures from MSD, Ferring, Serono, Ibsa, and Besins. E.J.P.S.v. has nothing to disclose. R.C. reports consultancy with and royalties from Karl Storz endoscope; and patent on Trophy hysteroscope. F.J.M.B. has nothing to disclose.

Reprint requests: Janine G. Smit, M.D., Department of Reproductive Medicine and Gynaecology, UMC Utrecht, Room F05.126, 3584 CX Utrecht, the Netherlands (E-mail: j.smit-6@umcutrecht.nl).

Fertility and Sterility® Vol. 99, No. 7, June 2013 0015-0282/\$36.00

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the uterine cavity. It is considered to be a variation of a normal uterine anatomy and has not been associated with adverse reproductive outcome (1, 4, 6, 10, 11). As a consequence no further treatment is indicated for this uterine anomaly (11).

In view of the presumed different clinical consequences for the septate and arcuate uterine anatomic variation, a correct discrimination is critical. However, the differentiation between both conditions has appeared to be difficult. Combined hysteroscopic and laparoscopic examination of the uterine cavity and external contour are mostly used to evaluate the differential diagnosis of uterine anomalies (12, 13). Less invasive tests, such as saline infusion sonography and three-dimensional (3D) sonography, have also proven to be accurate for diagnosing uterine malformations (14–17). Nevertheless, in daily practice the septate uterus is often detected and instantly treated by hysteroscopy.

Hysteroscopy is regarded as the gold standard for diagnosing intrauterine abnormalities (18–23). However, the reported prevalence of congenital uterine malformations detected by hysteroscopy differs considerably between studies (4, 24–26). In addition, The American Fertility Society (AFS) classification system seems not conclusive for the hysteroscopic evaluation of septate and arcuate uterus as clear definitions are absent. The question can therefore be posed whether the variation in the observed prevalence of these uterine anomalies is caused by observer bias. To our knowledge only two studies reported on the reproducibility of diagnosing intrauterine abnormalities through hysteroscopy (27, 28). In both studies the interobserver agreement appeared to be disappointing. These studies, however, were not conclusive for uterine anomalies such as the septate and arcuate uterus.

The aim of this study was to evaluate the international interobserver agreement on the hysteroscopic differential diagnosis of a septate uterus making use of recordings of hysteroscopies of asymptomatic infertile patients before IVF treatment with no abnormalities at transvaginal sonography. In addition, an effort was made to detect diagnostic criteria that are of potential use for a standardized definition.

MATERIALS AND METHODS

Eight video recordings of hysteroscopies of asymptomatic, infertile women indicated for IVF/ICSI treatment were put online on the website of the European Society for Gynaecological Endoscopy (ESGE). The selection consisted of seven recordings diagnosed as either arcuate or septate uterus by four experienced gynecologists, and one recording judged as a normal uterine cavity (Supplemental Fig. 1, available online). Hysteroscopy recordings were obtained in the context of a trial on the Treatment Efficacy of unsuspected uterine Abnormalities on subsequent IVF treatment (TEA trial, register number: NCT00830401) (29). For this purpose, 678 hysteroscopies were performed in a group of asymptomatic infertile patients, indicated for an IVF/ICSI treatment cycle at the University Medical Center Utrecht and the Academic Hospital at the Dutch-speaking Brussels Free University. The study was approved by the Institutional Review Board of the two participating centers. Informed consent was obtained.

Hysteroscopy Recordings

Hysteroscopy procedures were scheduled in the early-to-midfollicular phase of a menstrual cycle (days 3–10), 1–3 months before starting the IVF/ICSI treatment. From February to October 2008, all hysteroscopy examinations, performed under the supervision of one gynecologist (F.B.) at the University Medical Center Utrecht, were recorded on a DVD. These office hysteroscopies were carried out in a standardized manner, using a 5-mm outer diameter, continuous flow hysteroscope with 30 degree direction of view (Karl Storz Endoscopy, Stöpler medical instruments). Normal sterile, isotonic saline solution was used for distension of the uterine cavity, under a standard pressure of 40 mmHg. The recordings were edited in such a way that every recording started at the entrance into the uterine cavity and ended just before leaving the outer ostium of the cervix.

Observers

The selected hysteroscopy recordings were put online on the ESGE website. Gynecologists visiting the website were asked to assess the recordings with specific focus on the shape of the uterine cavity. Characteristics of the observers, such as the level of medical specialization, years of experience with performing hysteroscopy, number of hysteroscopies performed, and institutional affiliation, were recorded.

Evaluation

Evaluation of the hysteroscopy recordings was conducted using standardized assessment forms (Supplemental Table 1, available online). To mimic normal practice as much as possible no definitions of septate and arcuate were offered to the observers. The assessment forms contained nine questions about the quality of the recording, internal shape of the uterine cavity (normal, arcuate, septate), and the suggested therapeutic management. The observers were asked to judge the video recordings and fill out each form, under the baseline information that there had been diagnosed a normal outer contour of the uterine fundus by laparoscopy. Finally, their opinion on which hysteroscopy characteristic(s) should be applied to diagnose a septate uterus was listed. Two investigators (J.S. and J.K.) screened all assessment forms. Duplicates were removed and observers were not taken into analysis if the reliability of the assessments was questioned (e.g., when major contradictions in observations were presents). All observers were blinded for the medical history of the patients.

Outcomes

The primary study outcome was the international interobserver agreement on the hysteroscopic diagnosis of a septate uterus. Secondary study outcomes were the interobserver agreement on the necessity of correction, interobserver agreement on the uterine shape per country, interobserver agreement on the uterine shape per various levels of experience, and the agreement on certain hysteroscopic characteristics of a septate uterus.

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