

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

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**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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**T**he 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](mailto:trust@studies-obsgyn.nl), NTR 1676). The arcuate uterus comprises a mild indentation of the fundus into

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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.

## Statistical Analysis

Statistical analysis was performed using SPSS version 17.0 (SPSS Inc.) and R version 2.13.0 (<http://www.r-project.org/>). The interobserver agreement was expressed as the intraclass correlation coefficient (ICC). The ICC is an approximation of the overall weighted kappa and was applied to calculate the mean kappa values (30). A kappa value (and therefore ICC) of <0.20 represents poor agreement, 0.21–0.40 fair agreement, 0.41–0.60 moderate agreement, 0.61–0.80 substantial agreement, and a value of 0.81–1.00 indicates almost perfect agreement (31). A linear mixed model was used to calculate ICC using the video recording as a random effect. The ICC was calculated from the mixed model as  $ICC = \frac{\text{variance}\{\text{recording}\}}{\text{variance}\{\text{recording}\} + \text{residual}\{\text{variance}\}}$ , as the residual variance is due to the differences between observers. A likelihood ratio test comparing a model where the random effect depends on the factor of interest with a model with one single random effects term was used to calculate *P* values between different groups. Because the likelihood ratio test that was used gave a negative  $\chi^2$  for some factors that could be attributed to individual observers, we decided to check the reliability of the assessments of all observers. After scrutinizing the data, four observers were excluded.

## RESULTS

From November 2009 until June 2010, 78 gynecologists from 24 different countries assessed the hysteroscopy recordings on the ESGE website (Table 1). The group of participants consisted of 71 gynecologists and 7 residents with a mean age of 46.8 years (SD ± 11.7 years). Among

**TABLE 1**

### Characteristics of participants.

No. of participants	78
Specialist OBGYN	71
Resident OBGYN	7
Age (y)	46.8 (11.7)
Years of experience	13.8 (7.8)
No. of hysteroscopies performed	3,886 (6,166)
No. of participating countries	24
Residence (no. of observers per country)	
Europe	
United Kingdom	15
The Netherlands, Italy	8
Greece	7
Portugal	6
Spain	5
Belgium	3
Switzerland, Romania, Germany, France, Czech Republic	2
Serbia, Finland, Croatia, Cyprus, Hungary	1
United States of America	1
Australia	1
Middle East	
Israel	4
Egypt	2
South America	
Paraguay, Mexico, Brazil	1

Note: Data are given as mean ± SD.

Smit. Hysteroscopic agreement on septate uterus. *Fertil Steril* 2013.

**TABLE 2**

### Interobserver agreement.

Overall interobserver agreement	ICC	<i>P</i> value
Uterine shape	0.27	
Quality of recording	0.41	
Necessity of correction	0.17	
Agreement on uterine shape per subgroup		
Country (n = 66) <sup>a</sup>		< .001
Switzerland	0.53	
Germany	0.48	
Portugal	0.44	
Romania	0.39	
United Kingdom	0.34	
Spain	0.29	
The Netherlands	0.28	
Six countries <sup>b</sup>	<0.27	
No. of hysteroscopies (n = 78)		< .001
30–500	0.30	
500–2,000	0.26	
2,000–5,000	0.27	
>5,000	0.17	
Quality (n = 78)		.006
Good	0.31	
Intermediate	0.25	
Poor	0.02	

Note: ICC = intraclass correlation coefficient.

<sup>a</sup> Countries with at least two participants.

<sup>b</sup> Greece, Italy, Israel, Belgium, Egypt, France.

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the observers the mean number of hysteroscopies performed was 3,886 (SD ± 6,166) and the average years of experience with performing hysteroscopy was 13.8 years (SD ± 7.8 years).

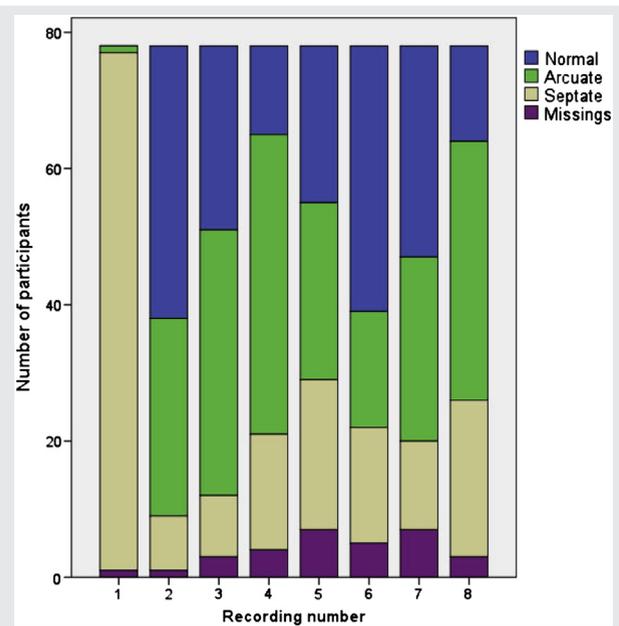
## Interobserver Agreement

The interobserver agreement was calculated for evaluation of the internal uterine shape, the necessity to correct the abnormality, and the quality of the hysteroscopy recording. Fair agreement between observers was found for the evaluation of the uterine shape, with an ICC of 0.27 (Table 2, Fig. 1). For the opinion on the necessity to correct the uterine malformation, the agreement among participants appeared to be poor (ICC 0.17). The interobserver agreement on the quality of the hysteroscopy recordings was slightly better (ICC 0.41). In total, 81.4% of the assessments of the hysteroscopy recordings on quality were judged as good or intermediate.

Additional analyses were performed to assess the agreement on the evaluation of the uterine shape in different groups of observers. For countries with at least two participants, the agreement among the observers was calculated. The Czech Republic could not be included into analysis due to a large number of missing values.

In most of the countries, the level of agreement between observers was higher compared with the overall interobserver agreement (ICC 0–0.53, *P* = .017; Table 2). Among observers from Switzerland the highest level of agreement was reached (ICC 0.53). A comparison based on the number of hysteroscopies performed showed that the level of interobserver agreement is lowest in the group of observers who performed

**FIGURE 1**



Opinion on uterine shape.

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the highest numbers of hysteroscopies (ICC 0.17,  $P < .001$ ; Table 2). Interobserver agreement appeared to be higher between observers who scored the quality of a hysteroscopy recording as good (ICC 0.31) compared with observers who scored the quality of the video recording as poor (ICC 0.02,  $P = .006$ ).

### Opinion on Hysteroscopic Characteristics of the Septate Uterus

The opinion of 66 observers was listed on the hysteroscopic characteristic(s) that should be applied for diagnosing a septate uterus (Table 3). The most distinct features for diagnosing a septate uterus seemed to be the extent of endocavitary bulging and the angle of the bulging structure from the fundal area (septate uterus, sharp angle vs. arcuate uterus, obtuse angle). In total, 66.7% of the participants

**TABLE 3**

#### Opinion on hysteroscopic characteristics of the septate uterus.

Features	Participants (n)
Extent of intracavitary development (A)	14
Angle of the bulging structure from the fundal area (B)	13
Visualization of both tubal ostia from one intracavitary viewpoint (C)	2
A and B	17
A and C	9
A, B, and C	8
B and C	3

Smit. Hysteroscopic agreement on septate uterus. Fertil Steril 2013.

choose one of these characteristics or a combination of both features as most distinctive for diagnosing a septate uterus.

### DISCUSSION

To our knowledge this study is the first to investigate the reproducibility of office hysteroscopy for diagnosing septate uterus in asymptomatic infertile patients. The international interobserver agreement in discriminating septate and arcuate uterus appeared to be rather disappointing (ICC 0.27). The agreement on the diagnosis of a septate uterus appeared to be better when evident fundal bulging was present (Supplemental Fig. 1B, recording 1). Consequently, the consensus on the uterine shape seemed to be poor especially for the less profound variations. In addition, observers from the same country reached a much higher level of agreement in most cases. It was not possible to assess whether this could be explained by training from a single center as information on the training hospital was lacking. However, these findings together endorse the need for the development of well-defined international diagnostic criteria for discriminating septate and arcuate uterus. In present study, the extent of endocavitary bulging and the angle of the bulging structure from the fundal area seem to be the most distinct features, as judged by the participants, for diagnosing a septate uterus.

Whereas some studies exist on the accuracy of hysteroscopy, at present, only two studies have reported on the reproducibility of hysteroscopy in diagnosing intrauterine abnormalities such as polyps, leiomyomas, and adhesions. These studies showed that the interobserver agreement is substantial in symptomatic patients (mean  $\kappa$ , 0.63) but only moderate in asymptomatic women (mean  $\kappa$ , 0.49) (27, 28). Both studies, however, were not conclusive for uterine malformations such as the septate and arcuate uterus. Although hysteroscopy is generally accepted as the gold standard to diagnose intrauterine pathology, the international interobserver agreement for diagnosing septate and arcuate uterus appeared to be low in the current study (ICC 0.27). Hence, the accuracy of hysteroscopy for diagnosing uterine malformations in asymptomatic patients may be lower than expected and alternative diagnostic techniques might be needed. Other imaging techniques, such as 3D sonography and saline infusion sonography/gel installation sonography are promising alternatives for diagnosing uterine malformations. The 3D sonography appears to be extremely accurate in diagnosing congenital malformations of the uterus (32, 33). The reproducibility of the 3D sonography, in women with an abnormal transvaginal sonography, was found to be almost perfect, with a kappa coefficient of 0.97 (34). Also, saline infusion sonography has appeared to be highly accurate in identifying uterine anomalies (accuracy, 90.9%;  $\kappa$ , 0.81) (35).

Some limitations of this study need to be addressed. Recordings of hysteroscopy procedures were used to assess the uterine cavity. This may have influenced the reproducibility of the hysteroscopy as assessment of the video recordings was subject to the skills of the hysteroscopy performer. However, the majority of the hysteroscopy recordings were

judged to be of good or intermediate quality (82.6%). In addition, it can be asked whether the observers in this study are representative for a group of experienced gynecologists. A lack of experience with performing hysteroscopy among the observers could possibly have influenced the interobserver agreement. However, ESGE members are to be expected to have a particular interest for gynecological endoscopy. Therefore, it is unlikely that the degree of experience has negatively influenced the level of agreement. Also, the blinding of the observers for the patient's medical history could be interpreted as a study limitation. Specific aspects of the history, for example, presence of recurrent miscarriages, could change the a priori chance of different forms of uterine malformations and could therefore influence the recognition of one specific uterine anomaly. The final study limitation is that a very specific patient group was investigated, consisting of asymptomatic, infertile patients with no abnormalities at transvaginal sonography. Consequently, only small abnormalities and considerable observer variability were to be expected. The investigated subfertile population, however, is highly relevant in daily practice. Hysteroscopy is increasingly performed as standard procedure before fertility treatment. As it concerns mostly asymptomatic patients, with a normal transvaginal sonography, abnormalities detected by hysteroscopy are often small. As was shown in the TEA trial the difference between a large arcuate uterus and a small septum was often being debated. The present study confirms that the interobserver agreement on the diagnosis of a septate uterus is poor. A higher level of agreement might be present for large uterine malformations. Future studies may be relevant to investigate the interobserver agreement in a patient population with more profound abnormalities (e.g., subfertile women with ultrasound findings suggesting an uterine malformation).

The AFS classification is used worldwide for categorization of uterine malformations (36). This system, however, lacks a precise description of characteristics of the uterine anomalies that makes it difficult to distinguish between different categories (37). In addition, diagnostic methods to assess uterine malformations are not specified. Especially, differentiation between septate uterus (class V) and arcuate uterus (class VI) appears to be difficult. Although these anomalies have common features, no precise definition of both conditions has been described in the AFS classification. Consequently, the observed interobserver variability on hysteroscopic evaluation of the septate and arcuate uterus could be the result of shortcomings in the AFS classification system. Improvement of the interobserver agreement might probably be accomplished by the development of well-defined standards. In 2009, a subclassification system for AFS classes V and VI uterine malformations has been developed (10). This system categorizes uterine anomalies on the basis of a geometric schema comprising uterine septum length and fundus depth. Although this subclassification is only applicable to 3D sonography evaluation of uterine malformations, it might be of value to develop a similar system for hysteroscopic examination. Hysteroscopy features of a septate uterus might be compared with a hysterosalpingography (HSG) or 3D sonography image to

make its hysteroscopic diagnosis clear. Characteristics, such as endocavitary development, the angle of the bulging structure from the fundal area, and the possibility to visualize both tubal ostia from one intracavitary viewpoint, could be possible criteria for the hysteroscopic diagnosis of septate uterus. In the present study, the extent of endocavitary development and the angle of the bulging structure from the fundal area appeared to be the most distinct features for diagnosing a septate uterus. However, further research should be focused on the development of exact definitions of the arcuate and septate uterus.

In current practice, hysteroscopy combined with laparoscopy is still the standard procedure to evaluate uterine anomalies in most clinics. However, discriminating (sub) septate uterus, which usually requires treatment, and arcuate uterus, which is considered as a variation of the normal uterine anatomy, appeared to be difficult in the present study. Also, the level of agreement on the necessity to correct the abnormality was found to be poor. This indicates that even if a septate uterus is correctly diagnosed, the true value of a septum resection needs to be established. Misclassifying an arcuate uterus as septate may in such cases lead to substantial overtreatment with the risk of inflicting more damage than benefit of "normalizing" the arcuate shape. Therefore, the development of more precise definitions of septate and arcuate uterus will enable a more accurate diagnostic workup of uterine abnormalities in infertility patients, and allow adequate studies on the efficacy of surgical correction.

In conclusion, the reproducibility among international endoscopy experts in discriminating between the uterine septa and the arcuate uterus on video recorded hysteroscopies was found to be quite poor. Development of well-defined diagnostic standards for the septate and arcuate uterus is recommended to improve the reliability of hysteroscopy as a screening tool in infertile patients.

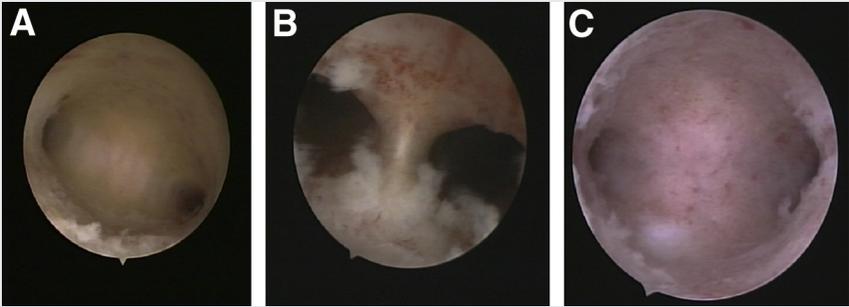
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**SUPPLEMENTAL FIGURE 1**



Images of hysteroscopy recordings used in this study. (A) recording 2; (B) recording 1; (C) recording 4.

*Smit. Hysteroscopic agreement on septate uterus. Fertil Steril 2013.*

## SUPPLEMENTAL TABLE 1

## Assessment form: International Observer Study.

**Participant**

Name:

Date of birth (*dd-mm-yyyy*):

Current level of medical specialization:

Trainee/Resident Gynecologist 

Years of experience with performing hysteroscopy:

Estimated total no. of hysteroscopies performed:

Willing to participate in related studies in the future?

Yes No 

If so, please note your e-mail address:

**Institutional affiliation**

Name:

City:

Country:

**Hysteroscopy recording assessment** (video 1–8)

Quality of the recording:

Good Intermediate Poor 

Symmetrical uterus:

Yes No 

Left tubal os visualized:

Yes No 

Right tubal os visualized:

Yes No 

Shape uterine cavity:

Normal Arcuate Septate 

Extent into uterine cavity:

None 1/4 1/2 3/4 Other abnormalities present (*more than one option possible*):No Yes, polyp Yes, myoma Yes, adhesions Yes, other 

Correction of the compartmentalization of the cavity (i.e., metroplasty) necessary to optimize this woman's fertility?

Yes No 

Treatment of the other abnormality (if present) necessary to optimize this woman's fertility?

Yes No 

Comments:

**Final question**Which statement sounds appropriate for the hysteroscopic differential diagnosis between the septate and the arcuate uterus? (*more than one option possible*)**NB:** Please note that after answering this final question, you should not make any changes to the given answers in the previous 8 assessments.A: The extent of the bulging structure into the uterine cavity *Septate: far into the uterine cavity, arcuate: less far into the uterine cavity*B: The angle of the bulging structure that points into the uterine cavity from the fundal area *Septate: acute angle (<90°), arcuate: obtuse angle (>90°)*C: Whether or not both tubal ostia can be visualized at the same time in one video shot (the shot that 

would be obtained if the view would be set still at the level where the tip of the scope has just passed the internal os)

*Septate: both ostia cannot be visualized in this one view; arcuate: both ostia can be visualized in this one view*D: None of the above mentioned When completed, send form to [J.C.Kasius@umcutrecht.nl](mailto:J.C.Kasius@umcutrecht.nl).*Smit. Hysteroscopic agreement on septate uterus. Fertil Steril 2013.*