A prospective comparison of transvaginal ultrasound, saline infusion sonohysterography, and diagnostic hysteroscopy in the evaluation of endometrial pathology

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Objective: To compare the diagnostic performance of saline infusion sonohysterography (SIS), transvaginal ultrasound (TVS), and diagnostic hysteroscopy (DH) in the detection of endometrial lesions in symptomatic women.
Design: Prospective, comparative study.
Setting: Obstetrics and Gynecology Department of a tertiary academic hospital.
Patient(s): A total of 105 consecutive women presenting in an outpatient clinic with symptoms of menorrhagia, postmenopausal bleeding, and infertility.
Intervention(s): Each patient had TVS, SIS, and DH.
Main Outcome Measure(s): The sensitivity, specificity, and positive and negative likelihood ratios (LR+ and LR-) for TVS, SIS, and DH were determined for the diagnosis of endometrial pathology. More specifically, the diagnostic performance of each of these three methods was compared after receiver operating characteristic analysis.
Result(s): By comparative analysis of the area under the curve, DH was found to have a significantly better diagnostic performance compared to SIS and TVS. In addition, after comparing the receiver operating characteristic curves, DH was found to be significantly more precise in the diagnosis of intracavitary masses than TVS and SIS. However, SIS was more accurate compared to TVS.
Conclusion(s): Saline infusion sonohysterography appears to be more valuable than TVS in the diagnosis of intracavitary masses (both polyps and myomas). (Fertil Steril® 2010;94:2720–5. ©2010 by American Society for Reproductive Medicine.)

Key Words: Diagnostic hysteroscopy, endometrial cancer, endometrial hyperplasia, endometrial pathology, endometrial polyp, myoma, saline infusion sonohysterography, structural uterine anomalies, transvaginal ultrasound

Transvaginal ultrasound (TVS) is universally preferred as the initial, noninvasive diagnostic procedure for evaluating uterine diseases (1–3). Saline infusion sonohysterography (SIS) has the multiple merits of TVS, and it was introduced as an improved method for the diagnosis of endometrial diseases. The sensitivity of SIS has been described as >87% and its specificity as >66% in the diagnosis of any endometrial pathology (2). Furthermore, in terms of cost effectiveness, decision analysis studies indicate that first-line SIS is superior to first-line diagnostic hysteroscopy (DH) in the evaluation of menorrhagia (4). However, although its diagnostic performance in terms of specificity and sensitivity has been appraised in various studies, its comparative diagnostic value against TVS and DH has not been explored. Our prospective study compared the diagnostic performance of TVS, SIS, and DH in the detection of endometrial lesions in symptomatic women.

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MATERIALS AND METHODS

Study Population

This prospective, blind, controlled study was performed from 2004 to 2006. Ethics committee approval was obtained from the Aristotle University of Thessaloniki, as appropriate. We performed a power analysis on the findings of relevant published research, in which the sensitivity of TVS, SIS, and DH for the diagnosis of any endometrial pathology was 54%, 86%, and 86%, respectively (5); we determined that we needed to recruit a study population of 38 patients to detect a statistically significant difference (each one undergoing the three different diagnostic techniques for pair-wise analysis, for type I error <0.05 and type II error <0.10). Considering that there was not enough data in the literature to perform a power analysis for pair-wise comparison of receiver operating characteristic (ROC) curves, we hypothesized that [1] the area under the curve (AUC) for DH was near 0.950 given that final diagnosis was based on DH and biopsy and [2] the difference in the AUC between the diagnostic performance of the different pairs was at least 0.100, with rho coefficient 0.500. The study population needed to detect a statistically significant difference was calculated to be 81 patients (each one undergoing the three different diagnostic techniques for

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pair-wise analysis, for type 1 error <0.05 and type 2 error <0.10). For safety reasons, we decided to enroll a sample population of approximately 100 patients in the study.

Thus, our study population consisted of 105 consecutive patients who were examined in the outpatient clinic. Exclusion criteria were [1] the clinical presence of pelvic inflammatory disease, [2] evidence of pregnancy, and [3] recent uterine surgery. Inclusion criteria were [1] premenopausal women presenting with abnormal uterine bleeding, [2] infertility patients, and [3] postmenopausal women with vaginal bleeding.

Description of the Three Techniques

After detailed explanation of the three procedures (TVS, SIS, hysteroscopy plus dilation and curettage), consent was obtained from all patients. After admission, TVS was performed always by the same examiner (D.T.), and SIS was performed in sequence always by another examiner (E.An.); each was blinded to the other's results. Conventional TVS and SIS were performed in two perpendicular planes, both sagittal and transverse, scanning from cornua to cornua using a device equipped with an endovaginal probe (Sonoline G40, probe: EV9-4; Siemens AG, Erlangen, Germany). Diagnostic hysteroscopy was performed the next day by a third examiner (G.G.) with a rigid 30-degree hysteroscope and a diagnostic sheath with a diameter of 5 mm, or a 8.6-mm outer diameter resectoscope was used (Storz Endoscopy, Tuttlingen, Germany). Tissue was collected for histologic examination and establishment of the definite diagnosis. The clinician who performed the diagnostic hysteroscopy was unaware of the histology results.

Final diagnosis was based on the combined hysteroscopic and histologic diagnoses; the histologic diagnosis was preferred to the hysteroscopic diagnosis. Diagnoses for diseases with endometrium and intracavitary masses (polyps, myomas) were determined after the histology results. The diagnosis for structural abnormalities was determined during diagnostic hysteroscopy. Standard sonographic and hysteroscopic criteria already described were used for the diagnosis of endometrial diseases during TVS, SIS, and DH (6–8).

"Diseases of endometrium" included endometrial hyperplasia and carcinoma. "Intracavitary masses" included endometrial polyps and myomas. "Structural abnormalities" was used to describe any congenital uterine abnormality or the presence of uterine synechiae.

Statistics

All data were collected and recorded in an electronic database (Excel; Microsoft, Redmond, WA). The statistical package SPSS 14.0. (Chicago, IL) was used to obtain basic descriptive statistics for each demographic parameter. Fisher's chi exact test and Student's *t*-test were used to compare means between nonparametric and parametric values, respectively. The sensitivity, specificity, and positive and negative likelihood ratios were calculated for TVS, SIS, and DH. The ROC curves were obtained via SPSS 14.0 and MedCalc (MedCalc Software, Mariakerke, Belgium). The comparisons between the produced ROC curves were calculated with MedCalc.

RESULTS

The initial cohort comprised 105 women with gynecologic symptoms; there were 55 premenopausal patients presenting with abnormal uterine bleeding, 28 infertility patients, and 22 postmenopausal women with vaginal bleeding. Seven patients were excluded from analysis as they did not undergo all three procedures. Saline infusion sonohysterography was not performed in two cases due to cervical stenosis (2 out of 105, 1.9%). Diagnostic hysteroscopy was not performed in five cases: three women with type II submucous myomas (3 out of 105, 2.8%) who underwent hysterectomy, and two women who underwent dilation and curettage (2 out of 105, 1.9%) instead of DH.

The investigations were completed according to the study design in 98 patients (98 out of 105, 93.33%). The mean age of the patients was 43.3 years (range: 26 to 71 years); 77 women (77 out of 98, 78.6%) were premenopausal and 21 women (21 out of 98, 21.4%) were postmenopausal; 36.8% of the patients were nulliparous. Mean weight of the population was 70.3 kg (± 13.8 kg).

The TVS, SIS, and DH results for the diagnosis of these conditions are summarized in Table 1. The sensitivity, specificity, positive likelihood ratios (LR+), and negative likelihood ratios (LR–) of TVS, SIS, and DH are shown in Table 2.

As the calculation of sensitivity and specificity does not give the opportunity to immediately compare each method with the others, the evaluation of the diagnostic efficacy of each method was studied using ROC analysis. The ROC curves for TVS, SIS, and DH for the diagnosis of any endometrial pathology, diseases of the endometrium (hyperplasia and cancer), intracavitary masses (polyps and myomas), and structural uterine anomalies are shown in Figure 1.

In the diagnosis of any endometrial pathology, DH was the most accurate diagnostic technique (AUC = 0.953), followed by SIS (AUC = 0.759) and TVS (AUC = 0.725). Furthermore, the pair-wise comparison of the AUCs revealed that DH had statistically significantly superior diagnostic performance compared with SIS ($P<.001$) and TVS ($P<.001$). When compared with each other, TVS and SIS appeared to have similar value in the diagnosis of any abnormality.

In the diagnosis of endometrial diseases such as hyperplasia or endometrial cancer, DH was the most accurate diagnostic technique (AUC = 0.857), followed by SIS (AUC = 0.632) and TVS (AUC = 0.615). Nevertheless, the pair-wise comparison of the AUCs revealed that DH had higher diagnostic accuracy compared with TVS and SIS ($P=.097$ and $P=.095$, respectively), although it was not statistically significant. There was no difference between TVS and SIS in the diagnosis of endometrial lesions.

In the diagnosis of any intracavitary mass (either endometrial polyp or submucous myoma), DH was the most accurate diagnostic technique (AUC = 0.941), followed by SIS (AUC = 0.782) and TVS (AUC = 0.612). The pair-wise comparison of the AUCs revealed DH had statistically significantly superior diagnostic performance compared with SIS ($P=.001$) and TVS ($P<.001$). Saline infusion sonohysterography was found to be statistically significantly more accurate than TVS for the diagnosis of intracavitary masses ($P=.010$). Diagnostic hysteroscopy was again found to be statistically significantly more accurate (AUCmyomas = 0.994; AUCpolyps = 0.961) compared with TVS (AUC myomas = 0.609; AUC polyps = 0.627) and SIS (AUC myomas = 0.858; AUC polyps = 0.810) for the diagnosis of intracavitary myomas and endometrial polyps (myomas: $P<.001$ and $P=.031$, respectively; polyps: $P<.005$ and $P=.001$, respectively). Saline infusion sonohysterography was statistically significantly more accurate for the diagnosis of intracavitary myomas and endometrial polyps compared with TVS ($P=.003$ and $P=.005$, respectively). In the investigation of structural abnormalities, when ROC curves were compared, no method was statistically significantly better than the others.

DISCUSSION

Although the success of TVS and SIS bears a degree of subjectivity and is related to the experience of clinician performing the procedure, our study evaluated the diagnostic performance of TVS, SIS,

TABLE 1

Diagnostic hypotheses from transvaginal ultrasound (TVS), saline infusion sonohysterography (SIS), and diagnostic hysteroscopy (DH) and the final diagnosis (by hysteroscopy ± biopsy) in the study population.

	TVS		SIS		DH		Final diagnosis	
Diagnosis	n	%	n	%	n	%	n	%
Normal	22	22.4	21	21.4	24	24.5	25	25.5
Abnormal	76	77.6	77	78.6	74	75.5	73	74.5
Diseases of endometrium	35	35.7	4	4.1	5	5.1	7	7.1
Hyperplasia	—		—		2	40.0	3	42.8
Cancer	—		—		3	60.0	4	57.1
Intracavitary masses	35	35.7	67	68.4	60	61.2	57	58.2
Myoma	8	22.8	19	28.4	16	26.7	15	26.3
Polyp	27	78.2	48	71.6	44	73.3	42	73.7
Structural abnormalities	6	6.1	6	6.1	8	8.2	8	8.2
Asherman	—		—		1	12.5	1	12.5
Congenital	6	100	6	100	7	87.5	7	87.5
Other								
Endometritis	0	0	0	0	1	1.0	1	1.0
Total	98		98		98		98	

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and DH in assessing endometrial pathology in the hands of clinicians in everyday practice. The sensitivity and the specificity of each method were measured, and the diagnostic values were compared using ROC analysis. The results from each of the methods were compared with results obtained from hysteroscopy combined with biopsy, the current gold standard for the investigation of endometrial lesions.

A ROC curve analysis appears to be the more precise statistical method for the comparison of two different diagnostic techniques. Our study was designed to compare the diagnostic performance of TVS, SIS, and DH in a statistically rigorous fashion, and it appears that the study was adequately powered to achieve this objective. Previous relevant studies were performed without the formation of ROC curves; therefore, the direct comparison of our results with other published research may be inappropriate. Nevertheless, our results are strongly indicative of the statistical trends that have been found when comparing TVS, SIS, and DH.

Any Endometrial Pathology

In the diagnosis of any endometrial pathology, DH was found to be the most accurate diagnostic technique compared with TVS and SIS, whereas there was no statistically significant difference in the diagnostic performances of SIS and TVS. These results are similar to those of other published studies. Kelecsi et al. (9) found TVS, SIS, and DH had sensitivities of 56%, 81%, and 85%, respectively, and specificities of 72%, 100%, and 100% respectively, for the detection of any endometrial pathology. A recent meta-analysis showed that pooled sensitivity and specificity of SIS in uterine cavity evaluation were respectively 95% and 88% in the investigation of abnormal uterine bleeding (10). Overall, it appears SIS does not offer additional information when compared with TVS in the initial diagnostic approach of symptomatic women. The best diagnostic tool is DH, but it remains an expensive, interventional method.

Endometrial Hyperplasia and Endometrial Cancer

For the diagnosis of endometrial diseases such as hyperplasia or endometrial cancer, DH seems to have higher, but not statistically significant, diagnostic accuracy compared with the other methods. The diagnostic value of TVS was comparable to that of SIS, and there was no statistically significant difference between these two techniques for the diagnosis of endometrial hyperplasia or cancer. This is possibly due to the relatively small study sample, but our results agree with other similar studies. In the investigation of diseases of the endometrium (hyperplasia and cancer), Krampl et al. (11) showed TVS, SIS, and DH had sensitivities of 33%, 33%, and 22%, and specificities of 88%, 92%, and 87%, respectively.

Diseases of the endometrium such as endometrial hyperplasia and cancer cannot be distinguished by TVS or SIS. During TVS, the endometrium is measured, and endometrial pathology is suspected when there is increased endometrial thickness. In our study, TVS was not able to discriminate endometrial hyperplasia or endometrial cancer from intracavitary lesions; therefore, an increased number of endometrial polyps and myomas were not adequately recognized with this method. The specificity of TVS for the diagnosis of diseases of endometrium was consequently lower compared with the specificity of SIS and DH. Diagnostic hysteroscopy, on the other hand, can misdiagnose normal endometrium for small endometrial polyps. The polypoid functional endometrium can mimic minor abnormal polyps, and the examiner can misread this condition as an intracavitary lesion. A case of endometrial cancer was also misdiagnosed by DH as an endometrial polyp. This was an expected finding as hysteroscopy mandates endometrial biopsy (hysteroscopic or dilation and curettage) to exclude malignancies. Apparently, TVS, SIS, or DH cannot replace biopsy in cases where endometrial cancer is suspected.

Intracavitary Masses (Submucous Myomas and Endometrial Polyps)

Diagnostic hysteroscopy also appears to be the best technique, compared with TVS and SIS, for the diagnosis of any intracavitary mass (either endometrial polyp or submucous myoma), whereas SIS showed statistically significantly more accuracy as a diagnostic method compared with TVS. There are similar results reported in the literature. For the diagnosis of intracavitary masses, Krampl et al. (11) found

TABLE 2

The sensitivity, specificity, positive likelihood ratio (LR+) and negative likelihood ratio (LR–) for the different pathologic conditions diagnosed in the study.

	TVS	CI	SIS	CI	DH	CI
Any abnormality						
Sensitivity (%)	89.04	75.94–95.13	91.78	82.96–96.90	97.26	90.43–99.59
Specificity (%)	56.00	34.94–75.57	60.00	38.68–78.84	92.00	73.93–98.78
LR+	2.02	1.29–3.17	2.29	1.41–3.73	12.16	3.22–45.96
LR–	0.20	0.09–0.41	0.14	0.06–0.31	0.03	0.01–0.12
Diseases of endometrium						
Sensitivity (%)	57.14	18.75–89.58	28.57	4.52–70.73	71.43	29.27–95.48
Specificity (%)	65.93	55.25–75.55	97.80	92.27–99.67	100.00	95.99–100.00
LR+	1.68	0.83–3.39	13.00	2.14–78.88	—	—
LR–	0.65	0.27–1.55	0.73	0.46–1.17	0.71	0.45–1.14
Intracavitary masses						
Sensitivity (%)	44.83	31.75–58.46	91.38	81.01–97.11	98.25	90.57–99.71
Specificity (%)	77.50	61.54–89.14	65.00	48.32–79.36	85.37	70.82–94.40
LR+	1.99	1.05–3.79	2.61	1.70–4.01	6.71	3.20–14.07
LR–	0.71	0.53–0.95	0.13	0.06–0.32	0.02	0.00–0.14
Myoma						
Sensitivity (%)	26.67	7.95–55.09	80.00	51.91–95.43	100.00	78.03–100.00
Specificity (%)	95.18	88.11–98.64	91.57	83.39–96.53	98.80	93.44–98.80
LR+	5.53	1.55–19.75	9.49	4.47–20.14	83.00	11.83–582.31
LR–	0.77	0.57–1.05	0.22	0.08–0.60	—	—
Polyp						
Sensitivity (%)	41.86	27.02–57.87	85.71	71.45–94.54	97.67	87.67–99.61
Specificity (%)	83.64	71.19–92.22	78.57	65.56–88.40	90.91	80.03–96.95
LR+	2.56	1.28–5.12	4.00	2.39–6.70	10.74	4.65–24.81
LR–	0.70	0.53–0.92	0.18	0.09–0.39	0.03	0.00–0.18
Structural						
Sensitivity (%)	75.00	35.05–96.07	75.00	35.05–96.07	100.00	62.91–100.00
Specificity (%)	100.00	95.94–100.00	100.00	95.94–100.00	98.85	95.94–100.00
LR+	—	—	—	—	—	—
LR–	0.25	0.08–0.83	0.25	0.08–0.83	0.00	—

Notes: CI = confidence interval; DH = diagnostic hysteroscopy; SIS = saline infusion sonohysterography; TVS = transvaginal ultrasound.

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that TVS, SIS, and DH had sensitivities of 23%, 94%, and 100%, and specificities of 93%, 84%, and 87%, respectively; and Bonnamy et al. (5) found sensitivities of 57%, 95%, and 88%, and specificities of 69%, 77%, and 85% for TVS, SIS, and DH, respectively.

Similar results were found for the diagnosis of intracavitary myomas; DH was the most accurate diagnostic technique followed by SIS. The results of our study support that the same applies in the diagnosis of endometrial polyps; DH performs better than SIS, and SIS performs better than TVS. Other published studies agree with these results. For the diagnosis of intracavitary myomas, Cepni et al. (12) found that TVS, SIS, and DH had sensitivities of 58%, 81%, and 90% and specificities of 94%, 98%, and 95%, respectively. Similarly, for endometrial polyps, Cepni et al. (12) found TVS, SIS, and DH had sensitivities of 72%, 91%, and 94% and specificities of 50%, 61%, and 58%, respectively. Soares et al. (13) showed TVS, SIS, and DH had sensitivities of 75%, 50%, and 100% and specificities of 82%, 96%, and 100%, respectively, for the diagnosis of polypoid lesions.

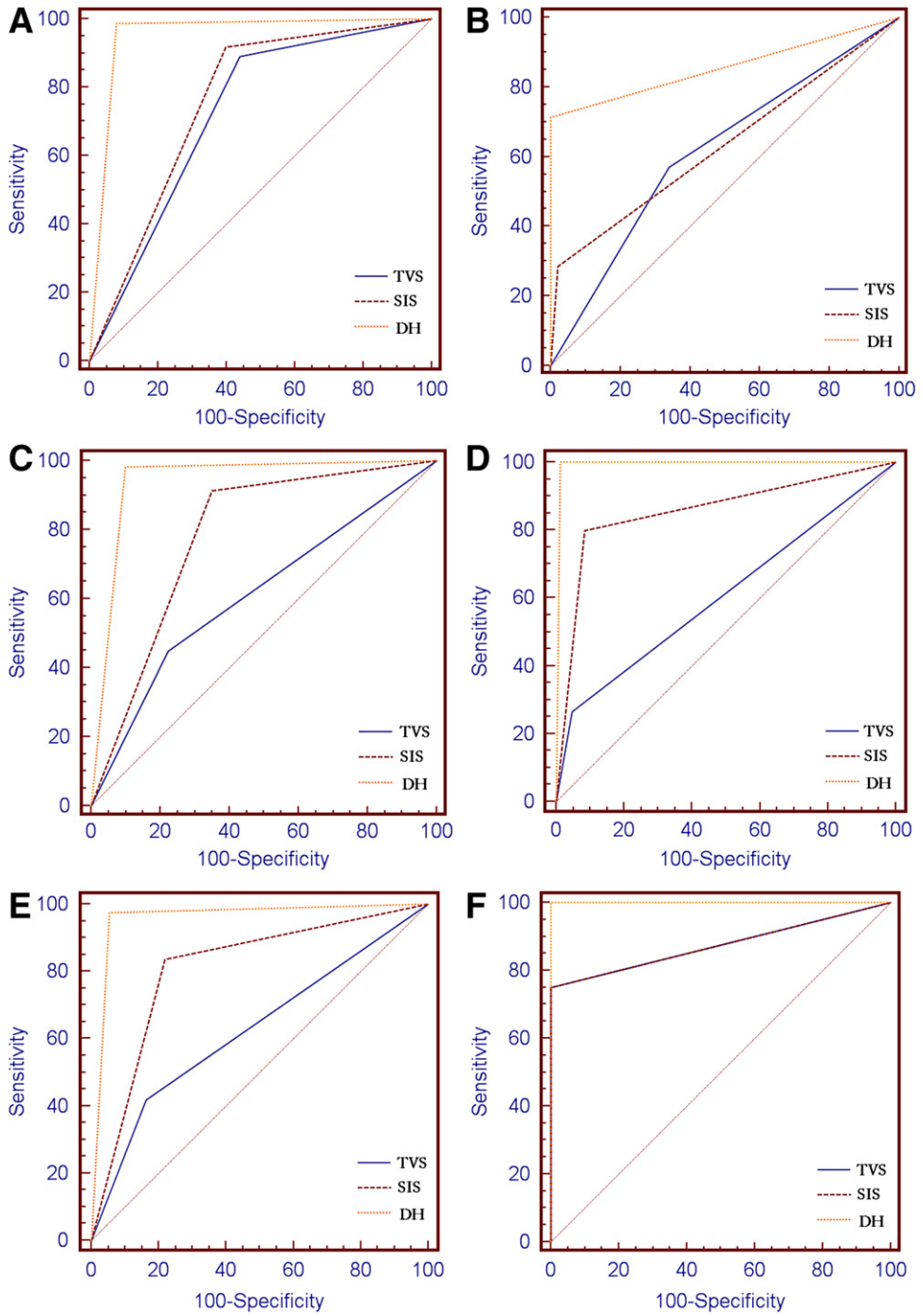
These results highlight the potential role of SIS in the everyday clinical practice. Endometrial polyps and submucous myomas are benign endometrial lesions that warrant treatment. Their management is mainly surgical and predominantly hysteroscopic. Thus, the comparative diagnostic accuracy of TVS, SIS, and DH in the detection of intracavitary masses (polyps and myomas included) is important for the clinician. As expected, DH is more accurate both in the detection of any endometrial pathology and more specifically in the detection of intracavitary masses. On the other hand, although SIS appears to have similar diagnostic accuracy to TVS for the detection of any endometrial pathology, SIS was statistically significantly more accurate compared with TVS for the diagnosis of intracavitary masses. Thus, the routine use of SIS after TVS could increase the moderate sensitivity of TVS (44.8%) in the diagnosis of intracavitary masses. Therefore, whenever an intracavitary mass is suspected in TVS, the clinician should complete the diagnostic work up with SIS. With this approach, the clinician is assisted in the decision whether to avoid an unnecessary DH or to be optimally prepared for an advance hysteroscopic procedure. Apparently SIS can be used when TVS cannot ensure the presence of uterine cavity abnormalities or is incapable of defining the exact nature of the abnormality (12).

Structural Uterine Abnormalities

For investigation of structural abnormalities, the diagnostic performances of TVS, SIS, and DH did not statistically significantly differ. Due to the small sample size, no reliable conclusions could be

FIGURE 1

Comparison of receiver operating characteristic (ROC) curves of the diagnostic performance of transvaginal ultrasound (TVS), saline infusion sonohysterography (SIS), and diagnostic hysteroscopy (DH). (**A**) Any endometrial pathology. (**B**) Diseases of the endometrium (endometrial hyperplasia and cervical cancer). (**C**) Intracavitary masses (myomas and polyps). (**D**) Myomas. (**E**) Endometrial polyps. (**F**) Structural abnormalities.



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reached, but our results are in agreement with other published studies. Soares et al. (13) found TVS, SIS, and DH had sensitivities of 44%, 44%, and 77% and specificities of 96%, 100%, and 100%, respectively, in the diagnosis of uterine malformations. Operative hysteroscopy is mandatory for the final diagnosis and treatment of these not-infrequent abnormalities (14).

The results of our study provide good quality, valuable information about which diagnostic procedures should be used in the basic

work-up evaluation of women presenting with a suspected endometrial pathology. Diagnostic hysteroscopy was found to be a better technique in the diagnosis of any endometrial abnormality compared with SIS and TVS. However, SIS appears to be more valuable than TVS in the diagnosis of intracavitary masses (both polyps and myomas), which recommends its routine use before hysteroscopy when endometrial polyps or myomas are suspected to assist clinicians in the optimal preoperative preparation of patients.

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