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UROGENITAL

Magnetic resonance hysterosalpingography in diagnostic work-up of female infertility – comparison with conventional hysterosalpingography: a randomised study

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Abstract

Objective To compare diagnostic accuracy of MR-hysterosalpingography (MR-HSG) and conventional hysterosalpingography (X-HSG) in the evaluation of female infertility.

Methods Forty women received prospectively both X-HSG, the gold standard technique, and MR-HSG on the same day but the order in which they were conducted was randomised. A 1.5 Tesla MRI was performed with classical sequences for pelvic analysis and an additional 3D T1-weighted sequence with intra-uterine injection of gadolinium. Two radiologists independently interpreted X-HSG and MR-HSG according to randomisation, blinded to the other results. They both then performed a second interpretation of MR-HSG blinded to the first reading with a minimum time delay of 1 week. Diagnostic performance of MR-HSG for analysis of tubal and intracavity abnormalities was evaluated by calculating sensitivity (Se), specificity (Sp), positive predictive value (PPV) and negative predictive value (NPV).

Results Twenty-six patients were included. Diagnostic performance of MR-HSG was: Se: 91.7% (95% CI 61.5–99.8); Sp: 92.9% (95% CI 66.1–99.8) ; PPV: 91.7% (95% CI 61.5–99.8); NPV: 92.9% (95% CI 66.1–99.8). Pain analysis showed a significant statistical difference between the two procedures: average VAS for X-HSG was 4.43 (95% CI 3.50–5.36) versus 3.46 (95% CI 2.62–4.31) for MR-HSG, p=0,01. Intra- and inter-rater agreements for detection of tubal or intracavity abnormalities were 0.92 (95% CI 0.78–1.00) and 0.76 (95% CI 0.52–1.00).

Conclusion MR-HSG is a well-tolerated technique demonstrating high accuracy in investigating tubal patency and intra-uterine abnormalities for diagnostic work-up of female infertility.

Key Points

- *MR-hysterosalpingography is an innovative technique.*
- *Hysterosalpingography can be used to investigate tubal patency and intracavity abnormalities.*
- *Hysterosalpingography is a potential 'one-stop-shop' imaging technique for a single comprehensive examination of female infertility.*

Keywords Female infertility · Magnetic resonance imaging · Hysterosalpingography · Fallopian tubes · Uterus

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Abbreviations

CI	Confidence interval
FOV	Field of view
hCG	Human chorionic gonadotropin
ICC	Intraclass correlation coefficient
K	Kappa coefficient
MRI	Magnetic resonance imaging
MR-HSG	Magnetic resonance hysterosalpingography
NPV	Negative predictive value
PACS	Picture archiving system

PPV	Positive predictive value
Se	Sensitivity
Sp	Specificity
SPIR	Spectral Presaturation with Inversion Recovery
T1W	T1-weighted
T2W	T2-weighted
TE	Echo time
TR	Repetition time
TSE	Turbo spin echo
VAS	Visual analogue scale
WHO	World Health Organization
X-HSG	Conventional hysterosalpingography

Introduction

Infertility is defined by the WHO (World Health Organization) as the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse. Assisted-reproduction techniques progress continuously. As a result, the evaluation of infertile women has to be as accurate as possible. Diagnostic work-up of female infertility is a multi-modality approach that is required to identify organic causes of infertility and to guide clinical management. MRI is the most accurate imaging technique for diagnosing the main organic causes of infertility as endometriosis, adenomyosis, leiomyomas or congenital anomalies of the genital tract [1–4]. However, it is unable to assess tubal patency or fallopian tube abnormalities, which account for 25–40% of female infertility causes [1]. Conventional hysterosalpingography (X-HSG) remains the most commonly used procedure to diagnose fallopian tube patency, with a high specificity of 83% but a relatively poor sensitivity of 65% [2]. The main disadvantage of the technique is the ionising radiation exposure of reproductive organs in young women. Multiples alternative techniques have been studied for evaluating tubal abnormalities in infertile women in a single non-ionising comprehensive examination. First, hysterosalpingosonography was developed [3]. This is an ultrasound-based technique that involves the direct injection of fluid into fallopian tubes via the uterine cavity. It is recognised to be a rapid, easily performed and well tolerated procedure that is capable of examining the uterus and ovaries at the same time. Sensitivity and specificity are, respectively, 92% and 95% when it is performed by an expert operator [4]. Its main limitation is the important inter-observer variability.

MRI has the advantage of being non-ionising and non-operator dependent. Over recent decades, some authors have studied this modality for the evaluation of the uterine cavity and tubal patency as a single and complete comprehensive examination, which is termed MR-hysterosalpingography (MR-HSG) [5–9]. Most of them studied the feasibility of dynamic intracavity injection of gadolinium with T1-weighted sequences but without comparison with a gold standard examination. Sadowski et al have compared this technique to conventional hysterosalpingography but only on 17 patients with a median delay of 76 days between modalities [10]. Recently, Ma et al compared MR-HSG and X-HSG or laparoscopy performed in the previous 6 months [11]. Unterweger et al performed both examinations on the same day but without randomisation and only on ten patients [8].

To our knowledge, no study has reported in a prospective randomised study the comparison of MR-HSG with X-HSG, the gold standard technique in the diagnosis of tubal patency, performed on the same day to allow for contemporaneous comparison.

The purpose of our study was to compare MR-HSG results with conventional hysterosalpingography, both performed on the same day for the evaluation of tubal and intracavity abnormalities in infertile women.

Materials and methods

Study design

This monocentric, prospective, randomised (sequence of the procedures, MR-HSG and X-HSG) study evaluated consecutive patients referred for investigation of infertility to the Radiology Department at the Nice University Hospital from January 2013 to November 2016. Written informed consent for the procedures was obtained from all patients. The study was carried out in accordance with the Declaration of Helsinki and was approved by the ethics committee Sud Mediterranée V, France (number 12.007) and the French National Security Drug Agency (ANSM 2011-A01635–36). It is registered in the ClinicalTrial.gov database (NCT02108665).

Inclusion criteria were:

- Women 18 years old and over.
- Needing X-HSG for investigation of infertility.
- As well as MRI because of pelvic pain, dysmenorrhoea or other complaints.

Exclusion criteria were:

- Contraindications for MRI: pacemaker, metallic implants, adverse reactions to MR contrast media-gadolinium.
- Contraindications for X-HSG: adverse reactions to iodinated contrast media, cervico-vaginal or pelvic infection, pregnancy.

A serum hCG test was carried out systematically before the examinations.

X-HSG and MR HSG were performed on the same day.

Patients were randomised in a 1:1 ratio to two arms:

- Arm 1: X-HSG then MR-HSG
- Arm 2: MR-HSG then X-HSG

MRI and HSG techniques

The examination was performed using a flexible 5-French cervical balloon catheter, placed by a gynaecologist in the MRI preparation room. Then, the patient was moved to the appropriate room according to the randomisation schedule (MR-HSG and then X-HSG, arm 1 or X-HSG and then MR-HSG, arm 2).

Antibiotic therapy was systematically administered on the day of the examinations before both procedures with 1 g of azithromycin orally.

MRI technique

MRI was performed on a 1.5 Tesla unit (Achieva, Philips, Best, The Netherlands) equipped with a 32 phased-array surface coil, with the patient in the supine position.

The following sequences were acquired:

- T2-weighted (T2W) turbo spin-echo (TSE) sequences in axial and sagittal planes with: echo time (TE), 90 ms; repetition time (TR), 4,500 ms; field of view (FOV), 250 x 230; slice thickness, 3.0 mm/1.0 mm.
- T1-weighted (T1W) TSE sequence in sagittal plane with: TE, 7 ms; TR, 627 ms; FOV, 250x207; slice thickness, 3.0 mm/1.0 mm.
- T1W TSE sequence in axial plane with fat suppression (SPIR sequence).

Then, specific sequences to study uterine cavity and tubal patency were performed: T1-weighted sequences with fat suppression in coronal plane: TE, 50 ms; TR, 500 ms; FOV : 378x297x150) without and with gadolinium contrast media agent. The injection was soft and automatic through the catheter with an injection speed of 0.3 cc/s, during a multiphase acquisition dynamic time-resolved T1-weighted sequence. The MRI contrast agent, Dotarem (gadoteric acid, Guerbet) was injected. One millilitre of Dotarem was diluted in 14 ml of saline solution; the total amoung of injection depended on the uterus size (up to 8 ml). The acquisition volume was repeated nine times, every 8 s. A post-contrast acquisition was performed in T1 TSE fat-suppressed sequence. Injection was interrupted by pain or significant discomfort.

HSG technique

The contrast media agent for X-HSG was Telebrix Hystero 250 mgI/ml (meglumine ioxithalamate, Guerbet). An initial radiograph of the pelvis was obtained with the catheter in place before contrast material was instilled. The balloon catheter was inflated by the radiologist with 2 or 3 ml of water in case of loss of permeability. Then, the contrast media agent was slowly instilled by the radiologist with fluoroscopic images obtained to evaluate the uterine cavity, fallopian tubes and free peritoneal spill. Injection was interrupted by pain or significant discomfort.

At the end of each examination patients were asked to evaluate the pain associated with the procedure using a visual analogue scale (VAS)

Image post processing and data analysis

All images were anonymised and recorded on the hospital picture archiving system (PACS). Two independent radiologists studied the images, both with 5 years' experience. On the day of procedures, each radiologist independently interpreted X-HSG or MR-HSG according to the randomisation, blinded to the results of the other examination. In a minimum time-delay of 1 week from the first analysis, both radiologists independently interpreted all the MR-HSG, blinded to the first reading. Thus, all MR-HSGs were interpreted by both radiologists for inter-rater agreement and each MR-HSG was interpreted twice by a radiologist for intra-rater agreement.

On each reading notes were recorded and the following items were checked:

- Uterine cavity visualisation
- Uterine cavity abnormalities such as: synechiae, endometrial polyp, intracavity leiomyoma, adenomyosis or congenital anomaly of the genital tract
- Fallopian tubes visualisation and their diameter
- Right and left tubal patency, with attestation of free peritoneal spill
- Other abnormalities.

On MR-HSG reading note, added morphological anomalies were reported:

- Ovarian endometriosis
- Deeply infiltrating endometriosis
- Leiomyomas
- Adenomyosis
- Congenital anomaly of the genital tract
- Other abnormalities.

Figure 1 shows a normal MR-HSG.

Statistical analysis

Allocation of the sequence of the procedures (MR-HSG or X-HSG first) was performed through central randomisation organised by the methodological centre of the study

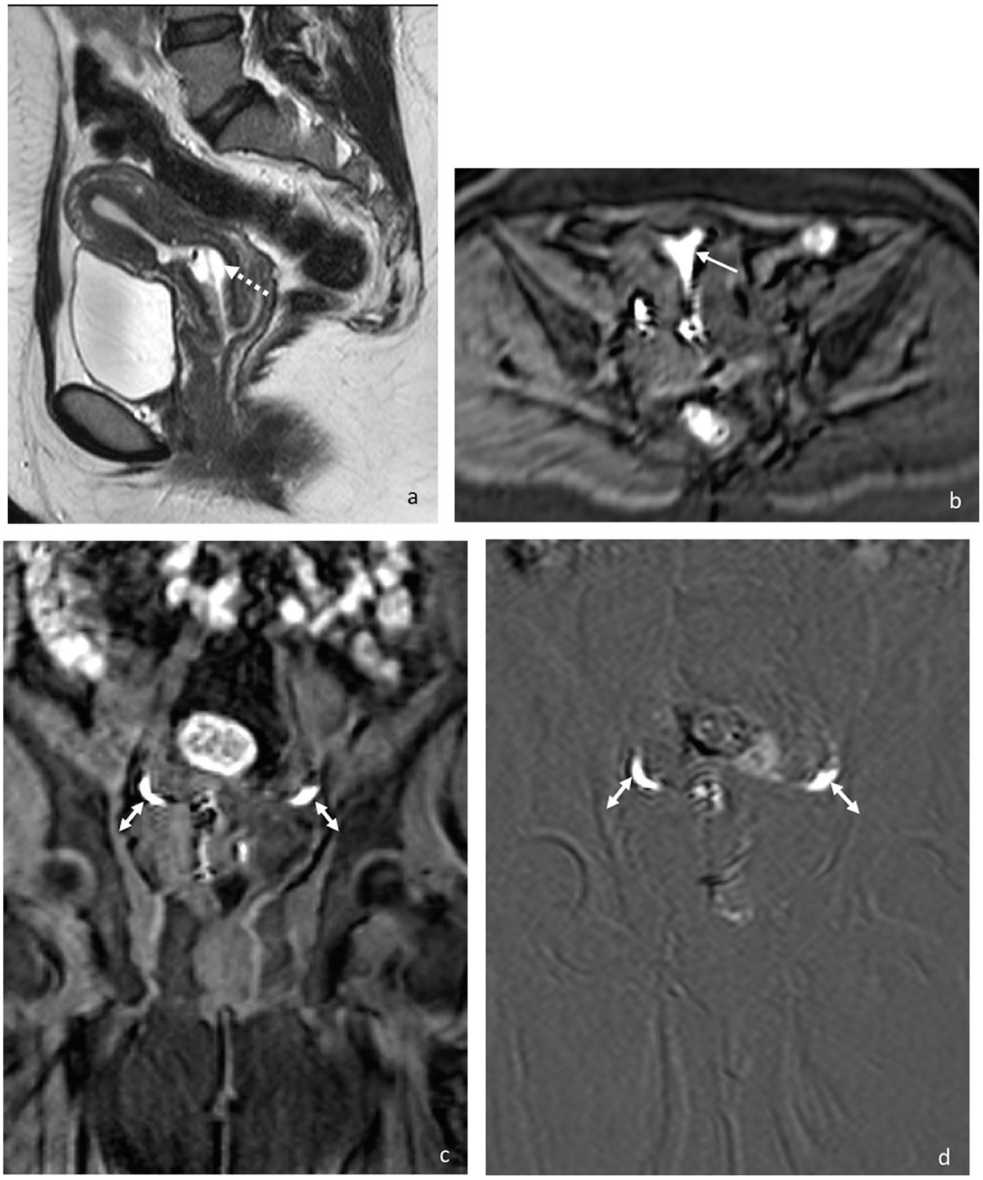

Fig. 1 Normal MR-HSG. (a): Sagittal T2 TSE image: the dotted line arrow shows the balloon catheter. (b): Oblique axial T1 TSE fat-suppressed image with intra-uterine injection: the arrow shows the uterine cavity, well sealed, without abnormality. (c) Coronal T1 TSE fat-suppressed image with intra-uterine injection and (d) with subtracted reconstruction: double arrows show free peritoneal spill

(Department of Clinical Research of the Nice University Hospital) using a fax exchange with the investigator.

A description of the study population and medical history are represented as means and standard deviations for continuous normal variables and number and percentage per class for categorical variables. Failure rate was calculated as the ratio between failed procedures and total women randomised.

The diagnostic performance of MR-HSG was defined by its sensitivity (Se), specificity (Sp), and negative and positive predictive values (NPV and PPV) with 95% confidence intervals (CIs). We considered a composite endpoint, presence of tubal and/or cavity abnormality, as our principal outcome. Cavity abnormality was defined as the presence of synechiae, endometrial polyp, intracavity leiomyoma, adenomyosis or congenital anomaly of the genital tract. Absence of free peritoneal spill assessed a tubal abnormality. Accuracy was then assessed for tubal abnormalities endpoint globally and taking into account laterality and characteristics of the abnormalities.

The rate of added uterine and extra-uterine diagnosis with MRI was calculated as the ratio between the number of women diagnosed only with MRI divided by the total number of women who underwent MRI. If abnormalities were detected on both examinations, localisation and matching and mismatching examinations were noted.

Pain during the procedure was evaluated by the patient with a VAS and compared between the two procedures using Wilcoxon's rank sum test with adjustment for period effect. *P*-values < 0.05 were considered indicative of a statistically significant difference.

The inter- and intra-observer agreement were calculated using a Kappa coefficient (κ). κ >0.6 and >0.8 were

considered, respectively, as good or very good interobserver agreement.

All the tests were two-sided and the significance level was set to 5%. Statistical analyses were performed using SAS Enterprise Guide 5.1 (2012, SAS Institute Inc., Cary, NC, USA).

Results

Population studied

We randomised 40 patients, 19 in arm 1 and 21 in arm 2. We successfully evaluated 11 patients in arm 1 and 15 patients in arm 2. In 14 patients the examination was not completed in one procedure at least: nine patients because of catheterisation failure, two because of dysfunction in inflating the balloon, two because of claustrophobia and one because of a dilution contrast agent problem.

The mean age of the analysed population was 32.5 years (range, 28–38) without a statistically significant difference between the two arms.

The indication was primary infertility in 12 patients and secondary infertility in 14 patients. We have reported six patients with a history of pelvic surgery, four with pelvic infection, three with leiomyomas, one with deeply infiltrating endometriosis and one with adenomyosis.

Population characteristics are summarised in Table 1.

Diagnostic performance and accuracy of MR-hysterosalpingography in tubal and cavity abnomalities

– Diagnostic performance of MR-HSG for analysis of tubal and cavity abnormalities was:

- Sensitivity : 91.7% (95% CI 61.5–99.8).
- Specificity: 92.9% (95% CI 66.1–99.8).
- Positive predictive value: 91.7% (95% CI 61.5–99.8).
- Negative predictive value: 92.9% (95% CI 66.1–99.8).

– Diagnostic accuracy of MR-HSG for ‘global’ analysis of tubal abnormalities (without distinguishing laterality or characteristic of abnormality) was 88.5% (95% CI 69.9–97.6), correctly classifying 23 patients in relation to X-HSG.
– Diagnostic accuracy of MR-HSG for analysis of tubal abnormalities with laterality matching was 76.9% (95% CI 56.4–91.3), correctly classifying 20 patients in relation to X-HSG.
– Diagnostic accuracy of MR-HSG for ‘perfect’ analysis of tubal abnormalities with laterality and characteristic of abnormality matching was 73.1% (95%

Table 1 Population characteristics

	Successful population (n=26)		Group 1 (n= 11)		Group 2 (n= 15)	
	n	(%)	n	(%)	n	(%)
Age (mean ± SD)	26	32,7 ± 5.8	11	34,4 ± 6.3	15	31,4 ± 5.36
Antecedents						
Primary infertility	12	-46.1	6	-54.6	6	-40
Secondary infertility	14	-53.9	5	-45.4	9	-60
Pelvic infection	4	-15.4	0	0	4	-26.7
Pelvic surgery	6	-23.1	3	-27.3	3	-20
Endometrioma	2	-7.7	0	0	2	-13.3
Deep endometriosis.	1	-3.9	0	0	1	-6.7
Myomas	3	-11.5	3	-27.5	0	0
Adenomyosis	1	-3.9	1	-9.1	0	0
Assisted reproductive techniques	0	0	0	0	0	0
Pregnancy interruption	5	-19.2	1	-9.1	4	-26.7
Spontaneous aborption	5	-19.2	2	-18.2	3	-20
Others:	6	-23.1	2	-18.2	4	-26.7
Conisation	*2*	*-33.3*	*1*	*-50*	*1*	*-25*
Functional ovarian cyst	*1*	*-16.7*	*1*	*-50*	*0*	*0*
Morbid obesity	*1*	*-16.7*	*0*	*0*	*1*	*-25*
Salpingectomy	*1*	*-16.7*	*0*	*0*	*1*	*-25*
Tubes ligature	*1*	*-16.7*	*0*	*0*	*1*	*-25*

CI 52.2–88.4), correctly classifying 19 patients in relation to X-HSG.

Figure 2 shows a bilateral salpinx with distal occlusion.

Additional diagnoses

MR data were analysed in 39 patients; one patient refused the procedure because of claustrophobia. MRI permitted diagnosis in eight cases of deeply infiltrating endometriosis , six of which were unknown, so 16% added diagnosis. It also allowed diagnosis of seven cases of ovarian endometriosis, three of which were unknown, so 8% added diagnosis. Finally, it detected ten cases of leiomyomas, five of which were unknown, so 12.5% added diagnosis.

Abnormality mismatching

On 26 patients, 13 had no tubal or cavity abnormalities. Thirteen patients had at least one tubal abnormality and three patients had intracavity abnormalities. On these 13 patients, six had total matching between the two procedures: three had bilateral tubal abnormalities and three had unilateral tubal abnormalities.

Table 2 compares the results of MR-HSG examinations with those of X-HSG.

Pain evaluation

Pain analysis showed a significant statistical difference between the two procedures: mean VAS for X-HSG and MR-HSG was 4.43 (95% CI 3.50–5.36) and 3.46 (95% CI 2.62–4.31) respectively, p=0.01.

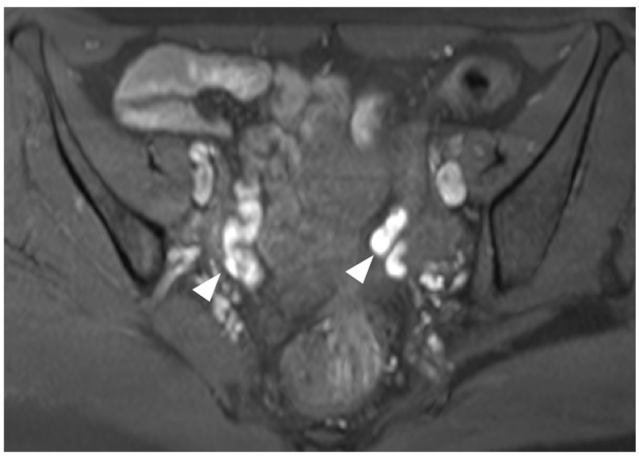

Fig. 2 Bilateral salpinx with distal obstruction. Arrowheads show distal occlusion of right and left fallopian tubes that are gadolinium-contrast filled. Salpinges were not recognised on morphological sequences because of their non-fluid signal on T2-weighted images. They were revealed on intra-cavity injection. The MR-HSG attests to the absence of peritoneal spill

Reproducibility

Intra- and inter-rater agreement (kappa) for detection of tubal or intracavity abnormalities were 0.92 (95% CI 0.78–1.00) and 0.76 (95% CI 0.52–1.00), respectively.

Unwanted events

We identified five unwanted events: four because of pain during examinations including two that presented with vagal symptoms. There was one case of salpingitis after the procedures.

Discussion

To our knowledge, this is the first time MR-HSG has been compared to X-HSG prospectively and in a randomised study. This study demonstrates the ability of MR-HSG to assess tubal abnormalities with a sensitivity of 91.7% and a specificity of 92.9%. Our diagnostic accuracy decreased from 88.5% to 73.1% when we improved the tubal characteristics requirement. This decrease could be explained by our magnetic imaging protocol parameters with a low temporal and spatial resolution on 1.5T MRI, which prevented assessing the contrast-media flow passage through the fallopian tube and the level of obstruction. Our acquisition volume was repeated nine times every 8 s. These parameters are suboptimal for correctly analysing tubal patency and only satisfactory for a contrast-media peritoneal accumulation study. On the contrary, Cipolla et al have proposed MR-HSG performed on 3T MRI with better parameters for spatial and temporal acquisition and visualised ‘real-time’ contrast-media flow through tubes [12]. Furthermore, our spatial parameters did not allow examination of normal thin fallopian tubes and their mucous folds, which are important prognostic factors for tubal viability. Carrascosa et al also recommended using 3T MRI for assessing fallopian tube morphology, with excellent spatial and temporal resolutions [13].

X-HSG is the imaging gold standard to evaluate tubal patency. However, it exposes the reproductive organs of a potentially fertile woman to ionising radiation and provides a limited evaluation of other causes of infertility. Furthermore, its advantage for fertility prognosis is still controversial. Perquin et al showed the same fertility prognosis between X-HSG and coelioscopy versus coelioscopy only [14]. Mo et al have demonstrated that chlamydia serum evaluation has comparable results to X-HSG for evaluation of tubal abnormalities, with a sensitivity of 68% and specificity of 82% [15]. In our study, seven discordant cases were noted, which could be explained by the imperfect MRI parameters and by the relatively low sensitivity of X-HSG for tubal abnormalities that

Table 2 Comparison of results of MR-HSG and X-HSG examinations

	Abnormalities detected on MR-HSG	Abnormalities detected on X-HSG	Commentaries	Cause of mismatching
N=1-13	No	No	No abnormality	-
N=14-19	Yes	Yes	Total matching	-
N=20	Yes	No	Pain during X-HSG, interrupted before completion	Technical problems on X-HSG
N=21	No	Yes	Tubal spasm on X-HSG	
N=22	No	Yes	Ostial air bubble on X-HSG	
N=23	Yes	No	Uterine cavity abnormality seen only on MR-HSG	Better performance on MR-HSG
N=24	Yes	No	Patency not seen on MR-HSG	Better performance on X-HSG
N=25	Yes	Yes	Mismatching on laterality of the abnormality	
N=26	Yes	No	Mismatching between the two observers	

could only be revealed with MR-HSG. However, four abnormalities were only detected by MR-HSG.

We have studied alternative procedures in an attempt to find a single 'one stop shop' comprehensive examination in the work-up of female infertility, such as sonohysterography as proposed by Groszmann et al [16]. MR-HSG should be an interesting alternative for a 'one stop shop' work-up of infertility with a high accuracy for uterine and extra-uterine abnormalities and the possibility to assess tubal patency.

MRI diagnosed 23% cases of endometriosis, unknown before the procedures, and four cases of polycystic ovary syndrome. Because of their impact on infertility, the discovery of these abnormalities could have a direct therapeutic impact.

HSG is an invasive, uncomfortable and painful procedure. In our study, we found a significantly lower VAS score with MR-HSG than with X-HSG (4.43 vs. 3.46). This could be explained by the gadolinium contrast agent in MR imaging being less viscous than iodinated contrast media.

Reproducibility for tubal analysis in MR-HSG was good with an ICC of 76.4. This is a favourable point, differentiating it from the sonohysterography studies, which carry a poor reproducibility.

The main limitation of our study is the high failure rate of 35% observed, resulting in a smaller study population than expected and consequently a less powered statistical analysis with large CIs. This is basically explained by under-optimised conditions of cervical catheter placement in the MRI preparation room without a gynaecological examination table. Furthermore, the room was not optimised for patient relaxation because of noise and aggressive light. In addition, there was high operator variability, from residents to experienced hospital practitioner, which probably explains our main limitation. Moving between different rooms is another possible reason for catheter displacement, but it was unavoidable because of our protocol.

Our study was different from those of other authors, using an automatic injection of gadolinium contrast agent, when Cipolla et al and Sadowski et al performed manual injections [10, 12]. We preferred automatic contrast injection to evaluate this new technique in real conditions and to appreciate its daily feasibility without interrupting MRI acquisition by manual injection or balloon catheter inflation. The automatic injection allowed us to reduce examination time and decrease patient discomfort. However, it probably increased our failure rate.

Conclusion

In summary, MR-HSG is an innovative and well tolerated technique, permitting a single comprehensive examination of the uterus, ovaries and the fallopian tubes for diagnostic work-up of female infertility. It is a promising technique for tubal patency analysis but still limited for tubal morphological study. It should be an interesting 'one stop shop' examination as an alternative to X-HSG but requires further research to improve the acquisition protocol.

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Compliance with ethical standards

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Informed consent Written informed consent was obtained from all subjects (patients) in this study.

Ethical approval Institutional Review Board approval was obtained.

Methodology
• prospective
• randomised controlled trial
• performed at one institution

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