Human Reproduction vol.12 no.7 pp.1436–1439, 1997

Is routine diagnostic laparoscopy for infertility still justified? A pilot study assessing the use of hysterosalpingo-contrast sonography and magnetic resonance imaging

Gubby Ayida[1,4], Paul Chamberlain[1], David Barlow[1], Philippe Koninckx[3], Stephen Golding[2] and Stephen Kennedy[1]

[1]Nuffield Department of Obstetrics and Gynaecology, and [2]Department of Radiology, University of Oxford, Oxford Radcliffe Hospital, Oxford, UK, [3]Department of Obstetrics and Gynaecology, UZ Gasthuisberg, Leuven 3000, Belgium

[4]To whom correspondence should be addressed: Senior Registrar, Dept. of Obstetrics and Gynaecology, Chelsea and Westminster Hospital, 369 Fulham Road, London SW10 9NH, UK

We assessed the value of hysterosalpingo-contrast sonography (HyCoSy) and magnetic resonance imaging (MRI) as alternatives to laparoscopy and dye insufflation with or without hysteroscopy in the investigation of infertility. A total of 19 women had all three procedures, in addition, one became pregnant after HyCoSy alone. The findings were: uterine fibroids (n = 5), minimal–mild endometriosis (n = 4) and moderate–severe endometriosis (n = 3) including one case of bilateral endometriomas, endometrial polyp (n = 1), polycystic ovaries (n = 2), bilateral dermoid cysts (n = 1), haemorrhagic corpus luteal cyst (n = 1) and minimal adhesions (n = 3). At laparoscopy, 31/37 tubes were patent and there was 84% concordance with the tubal patency findings at HyCoSy. The uterine fibroids and ovarian cysts were detected using transvaginal scanning; the endometrial polyp and a congenital uterine anomaly were identified using HyCoSy. These findings were detected using MRI, but in addition the technique distinguished the dermoid cysts from the endometriomas, identified the two other cases of moderate–severe endometriosis, fibroids <2 cm (n = 2) and adenomyosis (n = 5), and interpreted the haemorrhagic corpus luteum as an endometrioma. Our data suggest that women with normal HyCoSy and MRI findings have a normal pelvis and may not need routine surgical investigation.

Key words: HyCoSy/infertility/laparoscopy/MRI/transvaginal scanning

Introduction

The current practice of performing laparoscopy and dye insufflation with or without hysteroscopy (L&D ± H) to investigate all infertile women may not be necessary or cost effective. In theory, women with a normal pelvis could avoid surgery if they were initially screened using less invasive tests such as hysterosalpingo-contrast sonography (HyCoSy) and magnetic resonance imaging (MRI).

HyCoSy uses transvaginal scanning (TVS) with an ultrasound contrast medium to demonstrate tubal patency (Deichart *et al.*, 1989; Schlief and Deichert, 1991; Degendarht *et al.*, 1993) and delineate the uterine cavity (Balen *et al.*, 1993), thereby avoiding the irradiation risks associated with X-ray hysterosalpingography (van der Weiden and van Zijl, 1989). TVS also detects uterine and ovarian pathology. MRI is increasingly being advocated to evaluate adnexal masses (Mitchell *et al.*, 1987) and diagnose uterine anomalies (Pellerito *et al.*, 1992), fibroids (Dudiak *et al.*, 1988) and endometriosis (Togashi *et al.*, 1991). Takahashi *et al.* (1994) have reported that endometriotic deposits as small as 5 mm can be detected using a fat suppression technique.

In Oxford, 38% (40/104) of infertile women have an entirely normal pelvis at laparoscopy and 33% (34/104) have minimal–mild endometriosis (Forman *et al.*, 1993). If endometriosis of this severity is only a variant of normal without clinical significance, as is increasingly being advocated (Koninckx, 1994), then the percentage of women with a 'normal pelvis' in Oxford is actually 71%. Consequently, the development of non-surgical strategies to investigate infertility must be in the best interests of women in our population.

Materials and methods

A total of 20 infertile women (confirmed ovulation; normal hormonal profile and semen analysis) undergoing L&D ± H agreed to have MRI and HyCoSy as well. Exclusion criteria included galactosaemia and active pelvic inflammatory disease. The use of HyCoSy was approved by the Oxford ethics committee.

All HyCoSy examinations were performed between days 10–13 of the menstrual cycle using the new ultrasound contrast medium Echovist (Schering AG, Berlin, Germany), a galactose microparticle/air microbubble suspension. An Acuson 128-XP scanner (Acuson, Mountain View, CA, USA) with a 5 MHz vaginal probe (n = 18) or a Toshiba SSA 250A (Toshiba, Tokyo, Japan) with a 6 MHz probe (n = 2) was used. After initial TVS to determine uterine position and identify any uterine or adnexal abnormalities, the cervix was cleansed with aqueous chlorhexidene solution. A size 5 or 7 French double lumen (Ackrad, Cranford, NJ, USA) intrauterine catheter was inserted through the cervical os, the balloon inflated with 1–2 ml air and the Echovist suspension injected in 1–2 ml boluses whilst scanning continuously. The uterine cavity was examined as it distended with Echovist. Tubal patency was ascertained by demonstrating flow along the entire length of the tube or by streaming at the cornual end for at least 10 s with spillage into the pouch of Douglas. All procedures were video recorded.

MRI was performed using a 1.5 Tesla Signa system (GE Medical Systems, Milwaukee, WI, USA). Standard criteria for safety screening, including the 10 day rule, were applied. Spin echo imaging was used exclusively. T2 weighted images were obtained in the coronal, sagittal and axial planes, and T1 weighted images in the axial plane with and

Table I. Abnormal findings, by site, noted at laparoscopy and dye insufflation with or without hysteroscopy (L&D ± H), magnetic resonance imaging (MRI) and hysterosalpingo-contrast sonography (HyCoSy)

Site	L&D ± H (n = 19)	HyCoSy (n = 19)	MRI (n = 19)
Fallopian tubes			
Non-patent	6/37*	11/37*	–
Non-assessable	–	5/37*	–
Uterus			
Structural abnormality	1 (suspected)	Unicornuate uterus	Unicornuate uterus with non-communicating horn (removed prior to MRI)
Endometrial polyp	1	1	
Fibroids (submucosal)	5 (1)	3 (1)	7 (1)
Adenomyosis	–	–	5
Ovaries			
Dermoid	2	2	2
Endometrioma	2	2	3 (false positive 1)
Haemorrhagic corpus lutuem	1	–	–
Polycystic ovaries	2	2	2
Peritoneum			
Endometrial implants			
Minimal–mild	4	–	–
Moderate–severe	2	–	2
Adhesions			
Mild peritubular	2	–	–
Mild periovarian	1	–	–

*Previous salpingectomy.

without presaturation of fat, the latter to identify areas containing methaemoglobin. Images were read by one radiologist (SG) using a systematic reporting scheme to document uterine and ovarian morphology, signal characteristics and the presence of any abnormal structures or areas of abnormal signal intensity.

The surgical procedures were recorded on video for later review. Any endometriosis detected was graded according to the revised American Fertility Society (rAFS) classification system (1985). The MR and HyCoSy images, and the surgical findings were each interpreted by one clinician (S.G., P.C. and S.K. respectively) without knowledge of the results of the other two tests.

Results

The mean age of the study group was 33.6 ± 4.2 (range 30–42) years and 15/20 (75%) women were nulliparous. A total of 19 women had all three investigations performed; one woman conceived shortly after HyCoSy and did not therefore have MRI or L&D.

Findings at laparoscopy and dye insufflation with or without hysteroscopy

A total of 37/38 Fallopian tubes were assessed as one woman had previously had a salpingectomy. Six of the 37 (16%) tubes were blocked (Table I lists abnormal findings by site, since some patients had more than one pathology). In one case, there was a suggestion at laparoscopy of a congenital uterine anomaly with both tubes present, but the diagnosis could not be confirmed at hysteroscopy because of poor visualization of the uterine cavity. There were uterine fibroids present in five cases (one of which was submucosal) and one woman had an endometrial polyp. Seven women had endometriosis (rAFS stages I, n = 1; II, n = 3; III, n = 2 and IV, n = 1); bilateral endometriomas were found in one woman with stage III disease. Three other ovarian cysts were found at laparoscopy (dermoid, n = 2; haemorrhagic corpus luteum, n = 1) and two cases of polycystic ovaries. Minimal adhesions not associated with endometriosis were found in three cases: peritubal with patent tube (n = 1), peritubal with blocked tube (n = 1) and periovarian with the haemorrhagic corpus luteum (n = 1).

Transvaginal scanning

Three of the five cases of uterine fibroids and both cases of polycystic ovaries were identified using TVS. The four pathological ovarian cysts diagnosed at laparoscopy were detected but TVS could not differentiate the dermoid cysts from the endometriomas; the haemorrhagic corpus luteal cyst was not detected by TVS (performed 3 months prior to laparoscopy).

Hysterosalpingo-contrast sonography

The six non-patent Fallopian tubes at laparoscopy (in six women) were correctly diagnosed using HyCoSy. Five tubes (in three women) could not be assessed because of ovarian cysts distorting the pelvis (n = 2), fixed uterine retroversion (n = 1) and leakage of contrast medium (n = 2). Five tubes (in five women) appeared non-patent during HyCoSy but were patent at laparoscopy. Therefore, the concordance when the tubes were assessed by both HyCoSy and L&D was 84% (27/32).

Using HyCoSy the suspected congenital uterine anomaly at laparoscopy was diagnosed as a unicornuate uterus with a non-communicating horn. The endometrial polyp and submucosal fibroid noted at hysteroscopy were detected using HyCoSy (Table I).

Table II. Comparison of clinically signifcant findings at laparoscopy and dye insufflation and combined hysterosalpingo-contrast sonography (HyCoSy) and magnetic resonance imaging (MRI)

Procedure	Tubes	Adhesions	Endometriosis (stage III–IV)	Fibroids (submucosal)	Endometrial polyp	Ovarian cysts	Unicornuate uterus
Laparoscopy	6 NP	2[a]	3	1	1	4	1 (suspected)
HyCoSy + MRI	11 NP[b]	0	4[a]	1	1	4	1

[a]Includes patient with haemorrhagic corpus luteum.
[b]Includes the six non-patent (NP) tubes at laparoscopy.

Magnetic resonance imaging

MRI detected the five cases of uterine fibroids (plus another two with fibroids <2 cm in diameter) and the two cases of polycystic ovaries (Table I). Five cases of adenomyosis were also identified by this imaging technique alone. MRI correctly distinguished between the dermoid cysts and the endometriomas; the cyst that was interpreted at laparoscopy as a haemorrhagic corpus luteum had the appearance of an endometrioma on MRI. The endometrial polyp was not detected as it had been removed at hysteroscopy.

There were five pregnancies in the study group, including one which occurred a month after HyCoSy in the woman who had no other investigations.

Discussion

It could almost be claimed that only three tests are obligatory in the investigation of infertile couples. These are: (i) laboratory assessment of ovulation; (ii) semen analysis; and (iii) a test of tubal patency. The ESHRE Capri workshop group argue that these three tests have an established correlation with impaired fecundability and when unequivocally abnormal (azoospermia, bilateral tubal blockage or anovulation), fertility is unarguably impaired without therapy (Crosignani *et al.*, 1996).

L&D ± H is recommended by the Royal College of Obstetricians and Gynaecologists as the tubal patency investigation of choice for infertility (RCOG, 1992). The cost and associated surgical morbidity have traditionally been justified because laparoscopy, unlike X-ray hysterosalpingography, allows pelvic disease such as endometriosis and adhesions to be detected as well as the assessment of Fallopian tube patency. However, in the last few years there have been advances in MRI and high-resolution ultrasound, including the development of the ultrasound contrast medium, Echovist, which theoretically mean that Fallopian tube patency can be tested and endometriosis detected without surgical risk or exposure to ionizing radiation.

An approach to the investigation of infertility that is evidence based also leads us to question the importance of detecting 'lesions' that have no clinical significance. Thus, there is no evidence from a systematic review of randomized controlled trials that the medical treatment of minimal–mild endometriosis results in improved pregnancy rates (Hughes *et al.*, 1996). It is logical, therefore, to ask whether laparoscopy is still necessary if the majority of women have an anatomically normal pelvis with patent tubes which can be identified using imaging techniques that are safer and possibly more cost effective than surgery (Sugimura *et al.*, 1996).

In this pilot study, there was 84% (27/32) concordance between HyCoSy and L&D for tubal patency, a similar result to the reported figures of 60–80% between L&D and X-ray HSG (Swolin and Rosencrantz, 1972; Moghissi and Sim, 1975; Gabos, 1976). We have advocated that HyCoSy using Echovist should be used as a screening test for tubal patency (Ayida *et al.*, 1996) as it has high sensitivity and positive predictive value for the detection of patent tubes (Campbell *et al.*, 1994). HyCoSy using Echovist is cost effective (£73) and may therefore allow the majority of women with clearly patent tubes to avoid a diagnostic laparoscopy. Absent flow may be caused by tubal blockage or poor visualization, hence we believe that women with equivocal results or apparently non-patent tubes should still be advised to have L&D.

MRI is a complementary imaging technique to HyCoSy that is under-utilized in gynaecological practice. The pelvis is an ideal site for obtaining high quality multiplaner images, with minimal motion artefact from respiration or large blood vessels. Although considered expensive (£200) and not as easily accessible as ultrasound, the technique provides more information; it is also cheaper and safer than the surgical alternative, L&D±H (average cost £548, range £360–720). MRI has been shown to reduce total health care expenditure in gynaecology by reducing the number of invasive surgical procedures (Schwartz *et al.*, 1994), a major benefit in the current drive towards providing cost effective care. In this pilot study, minimal–mild endometriosis in four women with patent Fallopian tubes was not detected by MRI but this finding of 'mild disease' made no difference clinically as the women were not offered specific treatment for endometriosis and were managed essentially as cases of unexplained infertility. All the cases of moderate–severe endometriosis were identified by MRI and the technique differentiated the pathologies of the ovarian cysts that were detected using TVS. In one case, a diagnosis of a haemorrhagic corpus luteum was made at laparoscopy, but the cyst had the appearence of an endometrioma on MRI. Given that there were periovarian adhesions also present and the serum CA 125 concentration was mildly elevated (41.4 IU/ml) in this case, it is possible that the MRI diagnosis was more accurate. This highlights the fact that direct inspection of the pelvis at laparoscopy may not always be the 'gold-standard' investigation.

It is clear that the combined use of HyCoSy and MRI was as sensitive as L&D ± H in the detection of clinically

significant lesions (Table II). The imaging techniques failed to detect minimal–mild endometriosis and mild adhesions not compromising tubal patency but these laparoscopic findings did not affect the clinical management. We suggest there is a need in a larger study to confirm our impression that L&D ± H can be avoided in infertile women with normal HyCoSy with or without MRI findings. The role of MRI is uncertain and it may be more cost effective to reserve the technique for those women with abnormality detected using TVS. Lastly, an additional advantage of screening with imaging techniques is that it should allow better pre-operative counselling and scheduling of operating time for those women with abnormality as, at present, many women have to undergo a definitive second procedure following diagnostic L&D ± H.

Acknowledgements

Thanks are due to Schering Health Care Ltd for supplying Echovist® contrast medium and the Akrad intrauterine catheters, and to the Economics Advisory Group (Ltd), 38 Spring Street, London, for the costing of the procedures.

References

American Fertility Society (1985) Revised American Fertility Society classification of endometriosis. *Fertil. Steril*., **43,** 351–352.

Ayida, G., Harris, P., Kennedy, S. *et al.* (1996) Hysterosalpingo–contrast sonography in the outpatient investigation of infertile women. *Br. J. Radiol*., **69**, 910–913.

Balen, F., Allen, C., Siddle, N. and Lees, W. (1993) Ultrasound contrast hysterosalpingography-evaluation as an outpatient procedure. *Br. J. Radiol*., **66,** 592–599.

Campbell, S., Bourne, T., Tan, S. and Collins, W. (1994) Hysterosalpingo-contrast sonography (HyCoSy) and its future role within the investigation of infertility in Europe. *Ultrasound Obstet. Gynecol.*, **4,** 245–253

Crosignani, P. and Rubin, B. (1996) Guidelines to the prevalence, diagnosis and management of infertility. *Hum. Reprod*., **11,** 1775–1807.

Degendarht, F., Jibril., Eisenhauer B. *et al.* (1993) Vaginal hysterosalpingo-contrast-sonography. *BMUS Bull.*, Nov., pp. 36–37.

Deichart. U., Sclief. R., Van de sandt. M. and Juhnke, I. (1989) Transvaginal hysterosalpingo-contrast-sonography (HyCoSy) compared with conventional tubal diagnostics. *Hum. Reprod.*, **4,** 418–424.

Dudiak, C., Turner, D., Patel, S. *et al.* (1988) Uterine leiomyomas in the infertile patient: preoperative localization with MR Imaging versus US and Hysterosalpingography. *Radiology,* **167,** 627–630.

Fertility Committee of RCOG (1992) *Infertility Guidelines for Practice.* RCOG, London, UK.

Forman, R., Robinson, J., Mehta, Z. and Barlow, D. (1993) Patient history as a simple predictor of pelvic pathology in subfertile women. *Hum. Reprod*., **8**, 53–55.

Gabos, P. (1976) A comparison of hysterosalpingography and endoscopy in evaluation of tubal function in infertile women. *Fertil. Steril.*, **27,** 238–242.

Hughes, E., Ferdorkow, D., Collins, J. and Vandekerckhove, P. (1996) Ovulation suppression vs placebo in the treatment of endometriosis. In Lilford, R., Hughes, E. and Vandekerckhove, P. (eds), *Subfertility Module of The Cochrane Database of Systematic Reviews.* BMJ Publishing Group, London, UK.

Koninckx, P. (1994) Is mild endometriosis a condition occurring intermittently in all women? *Hum Reprod.*, **9**, 2202–2205

Mitchell, D., Mintz, M., Spritzer, C. *et al.* (1987) Adenexal masses: MR Imaging observations at 1.5T, with US and CT correlation. *Radiology,* **162,** 319–324.

Moghissi, K. and Sim, G. (1975) Correlation between hysterosalpingography and endoscopy for the evaluation of tubal function. *Fertil. Steril*., **26**, 1178–1181.

Pellerito, J., Mccarthy, S., Doyle, M. *et al.* (1992) Diagnosis of uterine anomalies: relative accuracy of MR imaging, endovaginal sonsography and hystersalpingography. *Radiology,* **183,** 795–800.

Schlief, R. and Deichart, U. (1991) Hysterosalpingo-contrast sonography of the uterus and Fallopian tubes: results of a clinical trial of a new contrast medium in 120 patients. *Radiology,* **178,** 213–215.

Schwartz, L., Panageas, E., Lange, R. *et al.* (1994) Female pelvis: impact of MR imaging on treatment decisions and net cost analysis. *Radiology,* **192,** 55–60.

Sugimura, K., Imaoka, I. and Okizuka, H. (1996) Pelvic endometriosis: impact of magnetic resonance imaging on treatment decisions and costs. *Acta Radiol*., **3,** S66–S68.

Swolin, K. and Rosencrantz, M. (1972) Laparoscopy vs hysterosalpingography in sterility investigations. A comparative study. *Fertil. Steril.*, **23,** 270–273.

Takahashi, K., Okada, S., Ozaki, T. *et al.* (1994) Diagnosis of pelvic endometriosis by magnetic resonance imaging using 'fat-saturation' technique. *Fertil. Steril.*, **62,** 973–977.

Togashi, K., Nishimura, K., Kimura, I. *et al.* (1991) Endometrial cyst: diagnosis with MR imaging. *Radiology,* **180,** 73–78.

van der Weiden, R. and van Zijl, J. (1989) Radiation exposure of the ovaries during hysterosalpingography. Is radionuclide hysterosalpingography justified? *Br. J. Obstet. Gynecol.*, **96,** 471–472.

Received on October 7, 1996; accepted on April 25, 1997