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A comparative study of three-dimensional saline infusion sonohysterography and diagnostic hysteroscopy for the classification of submucous fibroids

R.Salim, C.Lee, A.Davies, B.Jolaoso, E.Ofuasia and D.Jurkovic[1]

Department of Obstetrics and Gynaecology, King's College Hospital, London, UK

[1]To whom correspondence should be addressed at: Early Pregnancy and Gynaecology Assessment Unit, Suite 8, Golden Jubilee Wing, King's College Hospital, London SE5 8RX, UK. E-mail: davor.jurkovic@kcl.ac.uk

BACKGROUND: The purpose of this study was to compare three-dimensional saline infusion sonohysterography (3D SIS) and diagnostic hysteroscopy for the diagnosis and classification of submucous uterine fibroids. METHODS: This was a prospective double-blind study of 49 women who presented with a history of menorrhagia, diagnosed on non-enhanced two-dimensional ultrasonography with submucous fibroids. Fibroids were classified on 3D SIS according to the proportion of fibroid contained within the endometrial cavity, using the European Society of Hysteroscopy Classification of Submucous Fibroids. These results were then compared with the findings at diagnostic hysteroscopy. RESULTS: A total of 61 submucous fibroids was identified in 49 symptomatic women. Diagnostic hysteroscopy confirmed these findings in all cases. There was agreement between the two methods in 11/12 cases of Type 0 fibroids (92%), 34/37 (92%) of Type I fibroids and 9/12 (75%) of Type II fibroids. The overall level of agreement was good with a kappa value of 0.80. CONCLUSIONS: There is a good overall agreement between 3D SIS and diagnostic hysteroscopy in classification of submucous fibroids. Agreement is better in cases where a greater proportion of the fibroid is contained within the uterine cavity.

Key words: hysteroscopy/saline infusion sonohysterography/submucous fibroids/three-dimensional ultrasound

Introduction

Submucous fibroids are the most common anatomical cause of excessive menstrual blood loss in women of reproductive age. Advances in operative hysteroscopy have enabled removal of these lesions with a significant reduction in morbidity, post-operative recovery time and costs compared to open abdominal myomectomy (Emanuel *et al.*, 1999; Feng *et al.*, 2002). However, accurately identifying those fibroids suitable for hysteroscopic resection remains difficult. The main determining factor in successful hysteroscopic fibroid resection appears to be the proportion of the fibroid contained within the uterine cavity. Diagnostic hysteroscopy is currently regarded as the pre-operative investigation of choice in determining resectability of submucous fibroids prior to the scheduling of an operative hysteroscopy (Wamsteker *et al.*, 1993a,b; Corson, 1995). This procedure enables direct visualization of the uterine cavity and accurate identification of intracavitary pathology. However, diagnostic hysteroscopy is an invasive and costly procedure, which is associated with risks such as uterine perforation and ascending genito-urinary infection (Brooks, 1992; Indman, 1995; Julian, 2002). Furthermore, it provides only subjective assessment of fibroid size and indirect information regarding the depth of myometrial extension. Video recording of hysteroscopic findings may be used for quality control purposes, but the recorded data cannot be modified and the final diagnosis is determined by the initial findings at the operation.

Two dimensional (2D) B-mode transvaginal ultrasound with sterile saline instillation into the endometrial cavity provides a clear view of the uterine cavity (Cicinelli *et al.*, 1995; Widrich *et al.*, 1996; de Kroon *et al.*, 2003). This enables accurate detection of structural pathology affecting the uterine cavity including submucous fibroids, comparable to diagnostic hysteroscopy (Farquhar *et al.*, 2003). In addition, ultrasound enables accurate measurement of the size of the uterine fibroids. However, 2D ultrasound is not an accurate method of assessing the extent of submucous fibroid protrusion into the uterine cavity (Vercellini *et al.*, 1997; Dueholm *et al.*, 2001a,b).

Three-dimensional (3D) transvaginal ultrasound has been commercially available for >10 years. This technique allows detailed evaluation of pelvic organs by collecting a series of sequential ultrasound images and converting them into an ultrasound volume. This information is digitally stored as a dataset, which may then be analysed on line. The dataset is reconstructed in such a way as to allow visualization of an organ from any chosen angle and in any arbitrary plane (Jurkovic, 2002).

In this study, we compared 3D transvaginal ultrasound combined with saline instillation into the uterine cavity to diagnostic hysteroscopy for the assessment of submucous fibroids. In particular we examined the assessment of myometrial extension of fibroids by the two techniques.

Materials and methods

This was a prospective double-blind study set in a tertiary gynaecology ultrasound unit at a London teaching hospital. Symptomatic women referred to the unit underwent a non-enhanced B-mode 2D ultrasound scan. Those women found to have submucous fibroids were invited to join the study, provided there was no other identifiable cause for their symptoms. Informed consent was obtained and three-dimensional saline infusion sonohysterography (3D SIS) was performed in all cases. A sterile Cuscoe speculum was passed, the cervix visualized and cleaned with sterile chlorhexidine solution. A 3.3 mm soft plastic paediatric naso-gastric suction catheter was then passed through the cervix into the uterine cavity without grasping the cervix. The speculum was removed and a 5 MHz transvaginal 3D ultrasound probe inserted into the vagina (Voluson 730; KretzTechnik, Austria). The uterine cavity was visualized and the position of the catheter within the uterine cavity confirmed. A longitudinal view of the uterus was obtained and the catheter was withdrawn to a level just above the internal cervical os. A volume of 5–10 ml of sterile saline solution was then instilled into the uterine cavity. A 3D volume was generated by the automatic sweep of the mechanical transducer. The acquired volume was the shape of a truncated cone, with a depth of 4.3–8.6 cm and a vertical angle $a = 90°$. The volumes were stored digitally (Magneto-Optic 3.0′; 640MB Olympus Europe, Germany) and analysed using multiplanar visualization (Figure 1). With this technique it was possible

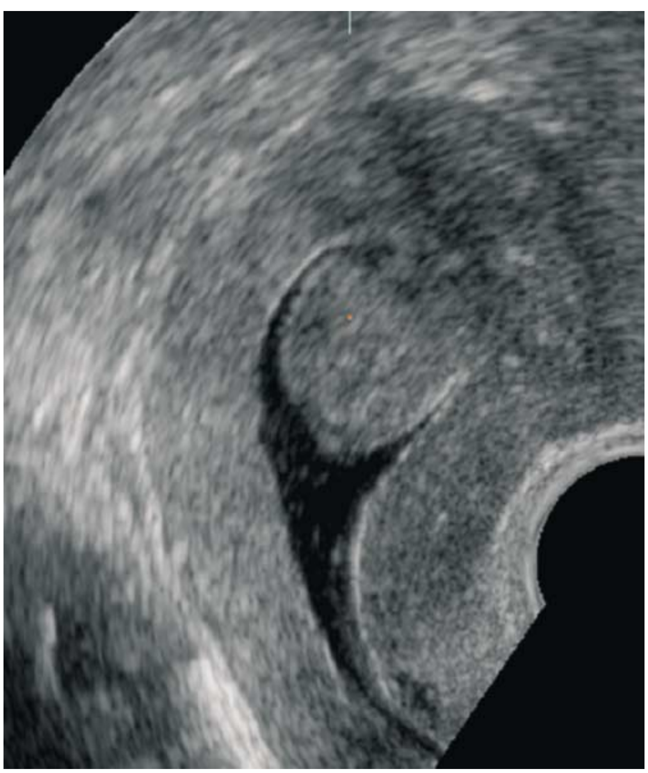

Figure 1. A fibroid polyp visualized on three-dimensional saline infusion sonohysterography using the technique of planar reformatted section.

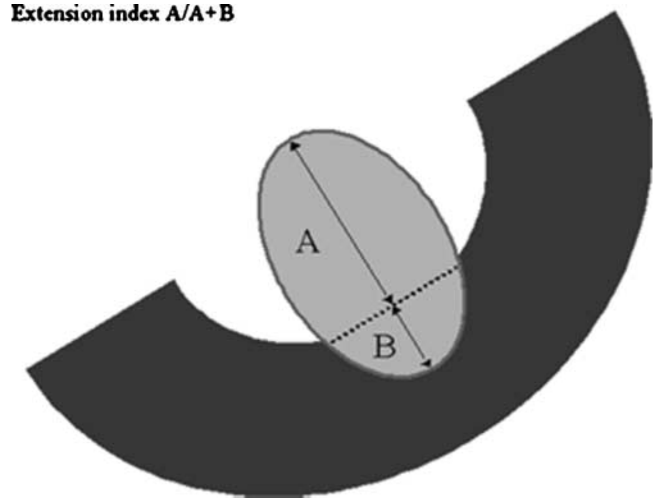

Figure 2. Schematic representation of measurement of myometrial extension of a submucous fibroid.

to examine the uterine cavity in three orthognal planes. This enabled the operator to achieve planes that were not necessarily possible with the original 2D ultrasound. The 3D ultrasound volume was manipulated to visualize the fibroid in its widest diameter in a plane perpendicular to the endometrium. Measurements were then taken as shown in Figures 2 and 3. Both measurements traversed the centre of the fibroid. The fibroid diameter was compared with the measurement of intracavitary fibroid protrusion, to calculate the percentage of fibroid volume confined to the myometrium. The fibroid was then classified according to the European Society of Hysteroscopy Classification of Submucous Fibroids (Wamsteker, 1993) as Type 0 (fibroid polyp), Type I (<50% contained within the myometrium) or Type II (>50% contained within the myometrium).

Diagnostic hysteroscopy was performed under general anaesthesia in all women, with a rigid 30° hysteroscope and a 5 mm diameter diagnostic sheath (Storz Endoscopy, Germany) by a single experienced operator (A.D.) who was blinded to the ultrasound findings. Aseptic technique was observed throughout the procedure. Normal saline was used to distend the uterine cavity. Infusion pressure was elevated by a pneumatic cuff under manometric control at a pressure of 100–120 mmHg. A high intensity cold light source and fibre optic cable were used to illuminate the uterine cavity. The procedure was monitored using a single chip video camera and the image was displayed on a monitor visible to the operator. The approximate size of the fibroid was determined by visualization of the fibroid and comparison with the length of the hysteroscope. The protrusion into the cavity was determined by visualization of the angle between the fibroid and the uterine wall.

A dedicated database was set up for data collection and Cohen's kappa for inter-observer agreement was calculated (Cohen, 1960).

Results

Forty-nine symptomatic women with submucous fibroids were invited to join the study, all of whom consented to take part. None of the recruited women withdrew from the study. The mean women's age was 39 years (range 25–55). Twenty-one women were nulliparous and in parous women the parity ranged from 1 to 5. Primary indications for assessment were: menorrhagia in 34 (69%), intermenstrual bleeding in eight (16%), infertility in six (12%) and history of second

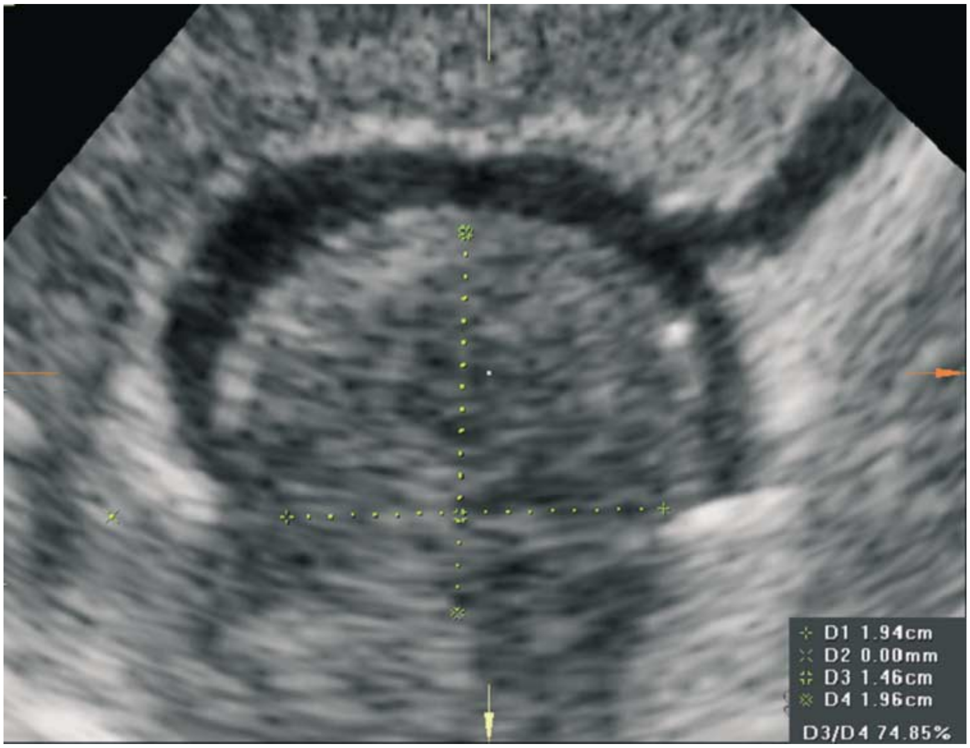

Figure 3. Three-dimensional saline infusion sonohysterography showing the calculation of intracavitary fibroid extension.

trimester miscarriage in one (2%) woman. 3D SIS was successful in all 49 women, providing clear views of the uterine cavity. Mild discomfort was the only reported side-effect of the procedure. Diagnostic hysteroscopy was also successful in all cases; clear views of the uterine cavity were obtained with both tubal ostia identified in each case. There were no operative complications associated with the diagnostic hysteroscopies.

A total of 61 submucous fibroids was identified by both 3D SIS and diagnostic hysteroscopy. The results are summarized in Table I. Overall, there was agreement in the classification of 54/61 (89%) fibroids (kappa 0.80). Eleven fibroids were classified as Type 0, 34 as Type I and 9 as Type II by both 3D SIS and hysteroscopy. One fibroid classified as Type I on 3D SIS was described as Type 0 on hysteroscopy. In a further six cases of discordant findings, 3D SIS indicated deeper myometrial involvement in half of the cases and hysteroscopy in the other half.

Table I. Comparison between three-dimensional saline infusion sonohysterography (3D SIS) and diagnostic hysteroscopy for classification of submucous fibroids

Hysteroscopy	3D SIS			Total
	Type 0	Type I	Type II	
Type 0	11	1	0	12
Type I	0	34	3	37
Type II	0	3	9	12
Total	11	38	12	61

Type 0: fibroid polyp.
Type I: <50% contained within the myometrium.
Type II: >50% contained within the myometrium.

Discussion

This study showed good overall agreement between diagnostic hysteroscopy and transvaginal ultrasound in the diagnosis of submucous fibroids. Every woman scheduled for a hysteroscopy for suspected submucous fibroids had the diagnosis confirmed at operation. This high accuracy is consistent with several previous studies, which compared non-enhanced transvaginal ultrasound with hysteroscopy (Fedele *et al.*, 1991; Cicinelli *et al.*, 1995; Dueholm *et al.*, 2001a,b). Similar results were also obtained using saline infusion sonohysterography (Fukuda *et al.*, 1993; Bronz *et al.*, 1997; Valenzano *et al.*, 1999; Dijkhuizen *et al.*, 2000; Bernard *et al.*, 2001; Dueholm *et al.*, 2001a,b; Nanda *et al.*, 2002; Lindheim *et al.*, 2003).

There was also good overall agreement between diagnostic hysteroscopy and 3D ultrasound in the assessment of myometrial extension of fibroids. Using the European Society of Hysteroscopy Classification of Submucous Fibroids (Wamsteker, 1993a) the best level of agreement was achieved in women with fibroid polyps (Type 0). These are the fibroids in which hysteroscopic resection is likely to be relatively simple and successful. The level of agreement decreased with increasing degree of myometrial involvement. This is not surprising as hysteroscopy can only assess the segment of the fibroid protruding into the cavity, whilst ultrasound can also provide information about the part of the fibroid buried within the myometrium. In cases of discordant findings the differences were random with no clear tendency of either method to overestimate myometrial involvement. These results are better than findings by Vercellini *et al.* (1997), who reported less agreement between non-enhanced 2D transvaginal ultrasound and hysteroscopy, with the methods giving discordant results in 55/228 cases (24.1%). In their study there was also no clear pattern of differences between the methods and discordant results were randomly distributed.

A more recent study by Leone and Lanzani (2003) using 2D SIS showed complete agreement with diagnostic hysteroscopy in all cases of submucous fibroids. They used the angle formed between the intracavitary portion of the fibroid and the endometrium to classify the fibroids. Although these results were impressive, the reproducibility of the angle measurements used in the study has not been tested. In addition the angle measurement is based on the assumption that all fibroids are spherical in shape, which is clearly not always the case. Therefore it remains to be seen whether these results will be successfully reproduced by other investigators.

This raises the issue of which method should be considered as the gold standard for the evaluation of myometrial involvement of submucous fibroids. Although most studies use diagnostic hysteroscopy as the gold standard, the value of this approach has been questioned by others. Dueholm *et al.* (2001b) compared the accuracy of magnetic resonance imaging (MRI), non-enhanced transvaginal ultrasound, SIS and hysteroscopy in the evaluation of abnormalities of the uterine cavity using hysterectomy specimens as the gold standard. Although all the methods performed reasonably well in the detection of uterine cavity lesions, for the assessment of submucous fibroids MRI and SIS were superior to hysteroscopy. The authors' conclusion was that MRI, rather than hysteroscopy, should be used for pre-operative assessment of submucous fibroids.

However, the critical issue when evaluating submucous fibroids is not the relative accuracy of different diagnostic methods, but the prediction of the success of hysteroscopic resection in symptomatic women. This subject has been less extensively investigated and there is only limited data on the predictive value of hysteroscopy in the pre-operative selection of submucous fibroids for hysteroscopic resection. In a study by Vercellini *et al.* (1997) only 69% of women deemed suitable for endoscopic fibroid resection on hysteroscopic assessment had fibroids successfully removed using this technique. Although the cause of this discrepancy was not addressed in the paper, it does suggest that diagnostic hysteroscopy may not be the optimal method for pre-operative assessment of submucous fibroids.

A classification of submucous uterine fibroids into three sub-types (0, I and II) depending on the degree of myometrial extension was adopted by the European Society of Hysteroscopy in order to improve pre-operative selection of women for hysteroscopic resection. However, a prospective study conducted by the team which designed this classification showed that the degree of myometrial involvement had very little influence on the success of hysteroscopic resection of submucous fibroids (Wamsteker, 1993b). In a subgroup of women with Type I fibroids ($<50\%$ myometrial extension), complete resection was achieved in 12/20 (60%) of the procedures compared to 10/20 (50%) in Type II fibroids ($>50\%$ myometrial extension). Taking into account repeated procedures, complete resection was achieved in 12/14 cases (85.7%) of Type I fibroids, which was almost identical to 10/12 (83.3%) in Type II fibroids.

In clinical practice it is not uncommon to find multiple fibroids affecting the uterine cavity. Apart from the number of fibroids, their size is also likely to be a factor in determining the success of hysteroscopic resection. None of the current methods used in routine clinical practice is able to assess more complex distortion of uterine cavity in sufficient detail.

Three-dimensional ultrasound may overcome some of the limitations associated with fibroid classification using a 2D model (Weinraub and Herman, 1998). 3D ultrasound enables us to examine the uterus from any angle and in any arbitrary plane and it is possible to assess both the size and the depth of myometrial extension in each individual fibroid. The saved volume can be manipulated in such a way as to provide measurements of the depth of myometrial extension exactly at the widest fibroid diameter, taken in a plane perpendicular to the endometrium. This cannot be achieved by using 2D ultrasound or any other conventional diagnostic technique. Further research will show whether this increased diagnostic capability of 3D ultrasound may be translated into a more meaningful system of classification of submucous fibroids, which could predict the success of hysteroscopic fibroid resection with a high degree of accuracy.

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