Prospective Study of Saline Infusion Sonography and Office Hysteroscopy

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Abstract

Background: To evaluate the diagnostic potential of saline infusion sonography to pick up uterine cavity lesions and compare it with the gold standard office hysteroscopy.

Methods: Study population consisted of women scheduled for office hysteroscopy for various indications. Uterine cavity of 208 women of the study group were evaluated first by saline infusion sonography and then by office hysteroscopy by two separate examiners. Findings were recorded separately for both procedures and compared. Pain rating was also noted after each procedure. **Result:** In eight patients either or both the procedures could not be performed for various reasons, hence were excluded from the analysis. With saline infusion sonography, pathological findings were identified in 93 (46.5%) patients and hysteroscopy detected lesions in 88 (44%) patients. For all findings combined sensitivity of saline infusion sonography was 90.9%, specificity 88.3%, positive predictive value 86.0% and negative predictive value 92.5% as compared to hysteroscopy. Former was less painful and easier to perform than the latter.

Conclusion: The findings of saline infusion sonography and office hysteroscopy did not differ significantly. Thus saline infusion sonography is an excellent option for uterine cavity evaluation.

MJAFI 2009; 65 : 332-335

Key Words: Hysteroscopy; Saline infusion sonography; Uterine cavity abnormality

Introduction

Hysterectomy is the commonest surgery performed by gynaecologists in our country after caesarean section. Abnormal uterine bleeding is one of the commonest conditions for gynaecological consultation in the outpatient clinical setting and hysterectomy [1]. In such cases further evaluation to establish the cause of her symptom should be undertaken [2]. One area which remains unsatisfactorily evaluated is uterine cavity. Intracavitary pathology constitutes a substantial number towards the cause of woman's symptomatology. A hysteroscopy evaluation of uterine cavity with endometrial curettage remains gold standard so far to diagnose intracavitary pathology of uterus [1,3,4]. Diagnostic hysteroscopy is a highly specialized procedure requiring costly equipment, specialized training to perform, besides being a invasive procedure with its inherent disadvantages [3,4]. Ultrasonography is an excellent method for imaging uterine and endometrial abnormalities. Transvaginal ultrasound (TVS) improves visualization of the endometrium and ovaries as compared with transabdominal imaging. However, evaluation of the uterine cavity is limited. Small structural abnormalities can be missed and endometrial and

myometrial abnormalities cannot always be differentiated. This can be over come by saline infusion into the uterine cavity and then performing a TVS. Saline infusion sonography (SIS) is a valuable diagnostic procedure to evaluate intracavitary pathological condition of uterus which is easy to perform, cheap and widely available in our setup. Hence this study is taken up to evaluate the efficacy of saline infusion sonography and to determine its accuracy to pick up uterine cavity lesions and applicability in a OPD setup vis a vis the gold standard office hysteroscopy.

Material and Methods

The study was carried out at a tertiary care teaching hospital. Study population consisted of women scheduled for diagnostic office hysteroscopy. Women with abnormal uterine bleeding (both pre and post menopausal) with normal cervical cytology were included in the study. Women with active infection of genital organs, pregnancy, large fibroids and those who refused to undergo office hysteroscopy or SIS were excluded from the study. Total of 208 women were included in the study.

All examinations were done in the first half of the menstrual cycle. Procedure was explained to the women and consent taken on a prepared consent form. SIS and office hysteroscopy were performed by two specialists on each case, the findings

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were recorded separately without the knowledge of each other's observations.

Saline infusion sonography was done first. After bimanual pelvic examination conventional TVS was performed on Wipro GE Medical system USG machine with a transvaginal probe of 5.0 MHz. Uterus and adenexae were observed in both coronal and sagittal plane. Endometrial thickness was measured. Sims speculum was introduced and vagina and cervix were inspected for any signs of infection. Those having no signs of any infection were subjected for further evaluation. A sterile disposable balloon catheter (size Foley's 08/10) was introduced through the cervical canal into the uterus. Speculum was then withdrawn and TVS probe introduced. A 50 ml disposable syringe was attached to the catheter and saline solution infused slowly until uterine cavity could be clearly observed. Uterine cavity was then observed in coronal and sagittal plane and findings were recorded in a data sheet.

Another specialist then performed office hysteroscopy with a 4 mm rigid hysteroscope (Karl Storz) and normal saline as distending media. Findings were recorded in a separate data sheet.

At the conclusion of each procedure pain rating was obtained from each woman. A table was shown and she was asked to select an appropriate number for level of discomfort experienced during each procedure. Minimal discomfort-1, acceptable discomfort-2, tolerable pain-3, severe intolerable pain-4.

No prophylactic antibiotic was used unless indicated by any pre-existing risk factor. The patients were advised to report back if they had a temperature more than 100°F or foul smelling discharge/abnormal bleeding per vaginum or persistent pelvic/abdominal pain.

SIS finding were classified as normal cavity, endometrial polyp, submucous myoma, hyperplasia, endometrial cancer and intrauterine synechiae on the basis of criteria described by Parsons et al [5].

Data collected were analysed. SIS findings were compared with hysteroscopy findings. The sensitivity, specificity, positive and negative predictive values were calculated.

Results

The study was carried out in the OPD complex of the department. Total of 258 patients scheduled for office hysteroscopy were asked to participate in the study. Of these 208 consented and were enrolled. In eight (3.84%) patients either or both procedures could not be performed. In two (0.96%) patients neither of the procedure was possible because of cervical stenosis. In five (2.4%) patients SIS was performed but office hysteroscopy could not be successfully performed due to severe pain. In one (0.48%) patient SIS could not be successfully performed due to poor visualization of the uterine cavity as it failed to distend by the fluid media. On hysteroscopy dense synechiae (Asherman's) was detected. Hence these eight patients were not included in the analysis. The age of the patients ranged from 21 to 55 years, mean (39.1 years). The presenting symptoms were menorrhagia in 120 (60%), metrorrhagia 9 (4.5%), menometrorrhagia 25

(12.5%), polymenorrhoea 22 (11%), polymenorrhagia 24 (12%) cases.

Both procedures were performed in 200 patients. Gold standard office hysteroscopy identified 112 (56%) normal uterine cavity and 88 (44%) were detected to have abnormalities in uterine cavity. Findings of SIS and office hysteroscopy are listed in Table 1.

Hysteroscopy findings were compared with the findings of SIS. Table 1 shows the findings of hysteroscopy as well as SIS and their number in respect of normal cavity, polyp, myoma, hyperplasia, products of conception and uterine synechiae. In some cases more than one lesion was detected by either or both procedure. False positive, false negative and findings of SIS which differed with gold standard Office hysteroscopy are shown in Table 2.

The diagnostic potential of SIS in respect of office hysteroscopy is analysed in Table 3. When the abnormal lesion in the uterine cavity was polyp, SIS has sensitivity of 93.0%, specificity of 94.1%, Positive Predictive Value (PPV) of 72.9% and Negative Predictive Value (NPV) of 98.1%. For evaluation of myoma, SIS has sensitivity of 88.2%, specificity of 97.3%, PPV of 91.8% and NPV of 96.0%. Similarly for hyperplasia the sensitivity, specificity, PPV and NPV are 100%, 97.9%, 42.8% and 100 % respectively. Findings are similar in

Table 1
Findings of SIS and Hysteroscopy

Findings	SIS (%)		Hysteroscopy (%)	
Normal	107	(53.5)	112	(56)
Polyp	34	(17)	28	(14)
Myoma	45	(22.5)	49	(24.5)
Hyperplasia	06	(3)	03	(1.5)
Polyp + Myoma	03	(1.5)	02	(1)
Myoma + Hyperplasia	01	(0.5)	Nil	(0)
Uterine synechiae	03	(1.5)	03	(1.5)
Products of conception	01	(0.5)	03	(1.5)
Total	200	(100)	200	(100)

Table 2
SIS versus Hysteroscopy

No of cases	SIS	Hysteroscopy
<i>False positive results</i>		
5	Polyp	Normal
2	Polyp	Blood clot
2	Polyp + Myoma	Myoma + Blood clot
1	Multiple Polyp	Product of conception
1	Myoma + Hyperplasia	Myoma
3	Hyperplasia	Normal
3	Myoma	Normal
<i>False negative results</i>		
1	Myoma	Polyp + Myoma
1	Normal	Product of conception
3	Normal	Polyp
4	Normal	Myoma
<i>Polyp versus Myoma</i>		
1	Myoma	Polyp
2	Polyp	Myoma

Table 3**Diagnostic potential of SIS compared with Hysteroscopy (n=200)**

Characteristic tested	Polyp	Myoma	Hyperplasia	Uterine Synechiae	Product of conception	All lesions
Abnormalities SIS / Hysteroscopy	37/30	49/51	07/03	03/03	01/03	93/88 *
Sensitivity	93.0%	88.2%	100%	100%	33.3%	90.9% (82.87 – 95.98)
Specificity	94.1%	97.3%	97.9%	100%	100%	88.3% (80.98 – 93.67)
Positive predictive value	72.9%	91.8%	42.8%	100%	100%	86.0% (77.28 – 92.34)
Negative predictive value	98.1%	96.0%	100%	100%	98.9%	92.5% (85.79 – 96.71)

*Figures in bracket denotes CI (confidence interval)

Table 4**Diagnostic potential of SIS compared to Hysteroscopy**

	Our study	Widrich et al [3]	Krampl et al [1]	Kamel et al [6]
Total lesions SIS / Hysteroscopy	93 / 88	61 / 56		56 / 53
Sensitivity	90.9%	96%	94%	93.1%
Specificity	88.3%	88%	84%	93.9%
Positive predictive value	86.0%	89%	89%	94.6%
Negative predictive value	92.5%	96%	98%	92.0%
Significance (Mc nemar's Test)	p = 0.76	p = 0.18		

other lesions too (Table 3). When all findings are combined the sensitivity, specificity, PPV and NPV of SIS are 90.9%, 88.3%, 86.0% and 92.5 % respectively. If false positive and false negative results are considered, the two procedures do not differ significantly in detecting polyp, myoma and other uterine cavity abnormalities as well as all findings combined. From above observations and statistical evaluation it is seen that both procedures are almost in perfect agreement in detecting various uterine cavity abnormalities.

Table 5 shows the level of pain associated with the two techniques differed significantly. Pain rating was higher for hysteroscopy than SIS.

There were no infections or any other complication encountered during the study while performing SIS or office hysteroscopy.

Discussion

In this study we directly compared SIS with office hysteroscopy, which is currently the state of art technique for uterine cavity evaluation. Our most important finding is that, compared with office hysteroscopy, SIS is an excellent technique with a very high sensitivity for detecting intrauterine abnormalities. It is also less uncomfortable for patients than office hysteroscopy.

Various studies have also found normal uterine cavity in almost half or more than half of the patients studied [1,2]. Our findings and detection rate of various lesions are in agreement with various other studies [3,6,7,10]. Krampl et al [1] compared the findings with histology and found sensitivity and specificity of SIS is better than hysteroscopy and in detection of focal lesion their accuracy is similar. Widrich et al [3], also found greater

Table 5**Pain rating**

Nature of pain	Score	SIS (No. of patients)	Hysteroscopy (No. of patients)
Minimal discomfort	1	136	66
Acceptable discomfort	2	60	94
Tolerable pain	3	4	26
Severe intolerable pain	4	00	14

correlation between SIS and hyperplasia as compared to hysteroscopy. They also found no significant statistical difference between SIS and hysteroscopy in detecting various other intrauterine lesions. Endometrial histopathology was beyond the scope of our study, though above studies found better correlation between pathological result and SIS than hysteroscopy. Diagnostic accuracy of SIS in comparison to hysteroscopy in terms of both sensitivity and specificity are 90.9% and 88.3% respectively in this study. Diagnostic potential of SIS compared with hysteroscopy in various other studies are in agreement with the present study (Table 4).

SIS is a minimally invasive procedure. It does not lead to post procedure complications [3,6]. The level of pain associated with the two techniques differs significantly [3]. In our study SIS caused minimal discomfort in 136 patients, acceptable discomfort in 60 patients, tolerable pain in four patients and none had severe intolerable pain, whereas in hysteroscopy the figures were 66, 94, 26 and 14 respectively. Hysteroscopy definitely causes more discomfort to the patient than SIS specially when rigid hysteroscope is

used, which is commonly available in our setup.

Other advantages of SIS are that it can be performed in presence of heavy bleeding and offers additional information about myometrium and adenexae [3]. It is a relatively inexpensive procedure in comparison to hysteroscopy. It is more widely available, easy to perform and does not require much expertise.

In conclusion SIS is widely available, cost effective, more patient friendly. It is less invasive with negligible complication rate in comparison to generally available office hysteroscopy in our setup. Beside these advantages the diagnostic potential and accuracy of SIS makes it an excellent option in most of our hospitals where it can be performed easily and conveniently for evaluation of intrauterine abnormalities. Therefore in the absence of a flexible hysteroscope, SIS is an excellent choice in the evaluation of intrauterine abnormalities.

Conflicts of Interest

None identified

Intellectual Contribution of Authors

Study Concept : Brig S Rudra, Col BS Duggal

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References

1. Krampl E, Bourne T, Hurlen-Solbakken H, Istre O. Transvaginal ultrasonography, sonohysterography and operative hysteroscopy for the evaluation of abnormal uterine
2. bleeding. *Acta Obstet Gynecol Scand* 2001; 80: 616-22.
3. Mihm LM, Quick VA, Brumfield JA, et al. The accuracy of endometrial biopsy and saline sonohysterography in the determination of the cause of abnormal uterine bleeding. *Am J Obstet Gynecol* 2002; 186: 858-60.
4. Widrich T, Bradley LD, Mitchinson AR, Collins RI. Comparison of saline infusion sonography with office hysteroscopy for the evaluation of endometrium. *Am J Obstet Gynecol* 1996; 174: 1327-34.
5. Cornelis D, de Kroon. Technology assessment of saline contrast hysterosonography. *Am J Obstet Gynecol* 2003; 188: 945-9.
6. Parsons AK, Lense JJ. Sonohysterography for endometrial abnormality: preliminary results. *J Clin ultrasound* 1993; 21: 87-95.
7. Kamel HS, Darwish AM, Mohamed AR. Comparison of transvaginal ultrasonography and vaginal sonohysterography in the detection of endometrial polyp. *Acta Obstet Gynecol Scand* 2000; 79: 60-4.
8. Soares SR, Batista MM, Camargos AF. Diagnostic accuracy of sonohysterography, transvaginal sonography, and hysterosalpingography in patients with uterine cavity diseases. *Fertility and Sterility* 2000; 73: 406-11.
9. Campo R, Van Belle Y, Rombauts I, Brosens I, Gerdt S. Office mini-hysteroscopy. *Hum Reprod Update* 1999; 5: 73-81.
10. De Vries LD. Comparison of transvaginal sonography, Saline infusion sonography and hysteroscopy in perimenopausal women with abnormal uterine bleeding. *J Clin Ultrasound* 2000; 28: 217-23.
11. Pelin E, et al. Comparison of transvaginal sonography, saline infusion sonography and hysteroscopy in the evaluation of uterine cavity pathologies. *Aust Nz J Obst & Gyn* 2005; 45: 30-5.

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