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Saline infusion in comparison to gel infusion sonohysterography

Abstract

Aim of the work: To compare both types sonohysterography in delineation of the cavity of endometrium.

Patients and methods: A prospective kasralainy hospital, Egypt

Patients: We included 200 women, coming to obstetrics and Gynecology department complaining from infertility

Interventions: women were divided into 2 groups, group A subjected to saline sonohysterography and group B subjected to gel sonohysterography.

Results: The time needed for uterine distention was significantly longer in the gel group (4.5s±3.39), while in the saline group it was 9.3±3.48 (P-value =0.014).

The pain score was higher in the second group (mean= 1.56±0.942) compared to 1.24±0.80 in the first (P-value of 0.007).

The specificity and sensitivity of testing with saline was 100% and also in the gel group they were 100 % and 100 %, respectively.

Conclusion: Saline instillation was better in decreasing the time needed for distension of the uterine cavity, in decreasing technique time and in decreasing post procedure pain but both are accurate in diagnosing intracavitary lesions.

Keywords: saline infusion, gel infusion, sonohysterography

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Mahmoud Alalfy,[1] Ahmed azklani[2]

[1]Reproductive Health and Family Planning department, National Research Centre, Egypt

[2]Obstetrics and Gynecology Department, Kasralainy Faculty of Medicine, Cairo University, Egypt

Correspondence: Mahmoud Alalfy, Reproductive health and Family planning department, National Research Centre, Egypt, Tel +20 1002611058, Email A_askalani@hotmail.com

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Introduction

Endometrial cavity could be precisely evaluated by using a low cost method which is a sono hysterography. A previous a meta-analysis revealed that sonohysterography using saline infusion has a sensitivity of Ninty percent in diagnosing uterine cavitary lesions as polyps.[1]

One of the drawbacks of saline sonohysterography is it can cause a leakage of saline if the used catheter is small as suction catheter causing inadequate filling, this can be prevented by using larger volumes.[2]

Infertility that is caused uterine cavity lesions accounts for ten to fifteen percent couples coming for treatment. Also abnormal uterine findings accounts for thirty four percent to sixty two percent of infertile ladies.[3]

Our focus was to compare the feasibility, accuracy, specificity and sensitivity of the gel versus saline infusion sonohysterography in delineation and diagnosis of intracavitary lesions.

Aim of the study

To compare both types sonohysterography in delineation of the cavity of endometrium.

Materials and methods

A prospective observational study was made in the Ultrasound unit of Obstetrics and Gynecology, kasralainy, Cairo University.

A total of 240 women participated in the study; their age was between 20 and 40 years, coming to outpatient clinic complaining from primary infertility. Exclusion criteria were presence of cervical cancer, a risk of pelvic inflammatory disease, presence of pregnancy and patients with excessive vaginal discharge.

(2D) transvaginal ultrasound scan of the uterus and endometrium was made to all women. women were divided into 2 groups, in group 1 120 women were exposed to saline infusion sonography with 20mL of sterile NaCl 0.9% solution injected using a 2-mm- sterile disposable catheter, that is used for IUI. While in the second group, in which women exposed to GIS using the same above mentioned catheter, through which 20mL of gel (Endosgel_; Farco-Pharma GmbH, Ko¨ ln, Germany) warmed to 37_C was infused, it contains chlorhexidine gluconate, sodium lactate, methyl hydroxybenzoate, propyl hydroxybenzoate, hydroxyethylcellulose and purified water.

Every woman was put in the dorsal lithotomy position; a sterile vaginal speculum was introduced. A prophylactic antibiotics were given, disinfection of the vagina and ectocervix with Povidone Iodine was done. A sterile disposable plastic syringe of 20mL capacity for each woman. The limiting point of instillation was the first appreciation of a clear delineation between the anterior and posterior uterine walls.

The procedure was made postmenstrual. All cases were performed using a GE Voluson 730 ultrasound system equipped with a 6–12MHz 3D endovaginal probe.

The mean time needed for the technique was recorded for each case, the time during which the cavity to distend. The degree of pain was evaluated by using a visual analog scale (VAS), which is a measure of pain severity, with 0 equivalents to no pain and 3 equivalent to severe pain.

2D Transvaginal sonohysterography technique

After putting the Cusco speculum, an intrauterine sperm catheter was introduced into the cervix till reaches the upper part of uterine cavity, then injection of saline was made till cavity distension occurs, and evaluation of the cavity for presence of any intracavitary lesion was performed.

2D transvaginal scan was performed using the gray scale. The findings were noted and intracavitary lesions were measured.

All women were referred to the hysteroscopy clinic, where diagnosis was confirmed and proper management was offered. A written informed consent was obtained from every woman participated in this study. We got the acceptance of the local ethical committee of our institute.

Statistical methods

Results were expressed as means±standard deviation (SD) or number (%). Comparison between categorical data was performed using Chi square test. Standard diagnostic indices including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and diagnostic accuracy were calculated as described by Galen (1980). The data were considered significant if p-values was ≤0.05 and highly significant if p<0.01. Statistical analysis was performed with the aid of the SPSS computer program (version 19 windows).

Sample size calculation

Sample size calculation was done to compare both types sonohysterography in delineation of the cavity of endometrium. As reported in previous studies, the specificity of testing with saline was 100% and the sensitivity was 64.28%, whereas in the gel group they were 97.22% and 81.81%, respectively. . Accordingly, we calculated that the minimum proper sample size to be 216 patients to be able to reject the null hypothesis with 80% power (β=0.2) and 95% significance level (α=0.05). Sample size was increased 10% to allow for drop out. Therefore, the total sample size needed is 240 patients.

Results

In the present study, the demographic data of the study groups showed no statistically significant difference. The time needed for uterine distention was significantly longer in the gel group (4.5s±3.39), while in the saline group it was 9.3±3.48 (P-value =0.014) (Tables 1–4).

Table 1 Descriptive statistics of patients' characteristics

	Number and percentage
Age (years)	
20-30	135
30-40	105
Mean SD	29.43±4.32
Body mass index	
20-25	142
More than 25	98
Mean SD	24.72±2.73

Table 2 Pain score according to visual analog scale (VAS) during 3D saline infusion in comparison to gel infusion

Degree of pain	3D Gel infusion	3D saline infusion	P value
No	103	80	0.014
Mild	9	19	
Moderate	8	11	
Severe	3	10	
		\	

Table 3 Time needed for distension of cavity

	3D GIS	3D SIS	P value
Mean Time needed for cavity distension	4.5 second	9.3 seconds	<0.001

Table 4 shows Sensitivity, specificity, negative and positive predictive values for 3D GIS in diagnosing uterine cavity lesions

	Total number	Sensitivity GIS	Sensitivity SIS	Specificity GIS	Specificity SIS	+ve PV GIS	PV SIS	-Ve PV GIS	PV SIS	Accuracy GIS	Accuracy SIS
Arcuate uterus	5	100%	100%	100%	100%	100%	100%	100%	100%	3/3 100%	2/2 100%
Subseptate uterus	4	100%	100%	100%	100%	100%	100%	100%	100%	3/3 100%	1/1 100%
Endometrial polyp	6	100%	100%	100%	100%	100%	100%	100%	100%	2/2 100%	4/4 100%
myoma	4	100%	100%	100%	100%	100%	100%	100%	100%	1/1 100%	3/3 100%

GIS, gel instillation sonography; SIS, saline instillation sonography

The pain score was higher in the second group (mean=1.56 ±0.942) compared to 1.24±0.80 in the first (P-value of 0.007).

The specificity and sensitivity of testing with saline was 100% and also in the gel group they were 100 % and 100 %, respectively.

Discussion

The simplest diagnostic tool for abnormalities of the uterus is transvaginal ultrasound.[4]

The inaccuracy of 2D transvaginal ultrasonography comes from that the delineation of uterine cavity could not be properly established because the anterior and posterior uterine walls are touching each others so masking the intracavitary space.

The usually used fluid for infusion sonography is 0.9 percent NA CL for evaluation of intracavitary lesions.[4–6]

Office hysteroscopy bypass this difficulty as it distend the uterine cavity and allows for visualization of the intracavitary lesions.[4,7,8] but

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hysteroscopy is more difficult to do ,needs experience, needs more time and more expensive than Transvaginal US.[9]

In the present study, the time needed for uterine distention was significantly longer in the gel group (4.5s±3.39), while in the saline group it was 9.3±3.48 (P-value=0.014).

Then gel instillation sonography was introduced.[10,11] In agreement to the current study, a previous study made by El-Faisal Y et al.[12] women, they compared saline as distension medium, in comparison to sterile gel, they revealed that gel needs more time, causes more post procedure pain.[12]

In the present study, the demographic data of the study groups showed no statistically significant difference.

This difference in time is explained by the time needed to load gel in the syringe and the injection of gel is more difficult than the saline, with a higher resistance, and it requires more power from the examiner, so the injection rate was slower.

The rate of leakage was more in the saline infusion group, but with no statistically significant difference with (P-value=0.2). This comes in accordance with a previous study made by Van Den Bosch et,al in 2011, they also concluded that to balance this leakage, more amount of saline was used in comparison to the gel.[13] Also El-Faisal Y et al.[12] showed that there was more leakage in saline group but with no statistically significant difference.[12]

Mean procedure time was significantly shorter in the saline group than in the gel group (10.23±1.69 and 14.45±1.62min, respectively, P-value=0.0001).[12]

We think that the pain score that was increased in gel group might be due to a longer distension time and the length of the technique, which were more in the gel group.

In a previous study made in 2014, revealed that all women were subjected to office hysteroscopy and compared to either saline or gel instillation sonography, the specificity was one hundred percent for saline and 97.7 percent for gel instillation.[12]

A previous research made by Farya khan et al.[15] revealed that gel instillation was better in sensitivity than saline with less false negative results with gel infusion.[1,13–15]

A previous study made by Kroon et al.[1] showed that the sensitivity of saline and gel infusion sonography was Ninty five percent.[1]

Limitation of the study

The limitation of this study was occurrence of pain during the procedure that sometimes causes patient discomfort and woman may move during injection of saline or gel that could make the image hazy.

Conclusion

Sonohysterography is an accurate simple procedure, easy to perform for diagnosing intrauterine lesions.

Both saline and gel infusion sonohysterography could be performed but the gel needs more time, causes more post procedure pain but with less leakage.

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None.

Conflicts of interest

Author has no any conflict of interest to declare.

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