

Evaluating the role of saline infusion sonohysterography in the assessment of the uterus after hysteroscopic metroplasty: A retrospective cohort study

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SUMMARY

AUTHORS' CONTRIBUTION: (A) Study Design · (B) Data Collection · (C) Statistical Analysis · (D) Data Interpretation · (E) Manuscript Preparation · (F) Literature Search · (G) No Fund Collection

Background: Hysteroscopic metroplasty is considered the standard treatment of the uterine septum. Incomplete removal of the septum is usually evaluated by a second-look office hysteroscopy.

Aim: To compare the efficacy of Saline Sonohysterography (SS) against office hysteroscopy in diagnosing incomplete resected septum. **Methods:** We performed a retrospective cohort observational study on 56 patients in a private hospital in Saudi Arabia from January 2020 to December 2022. The patients were diagnosed with uterine septum by transvaginal ultrasound and were operated upon by Hysteroscopic resection of the uterine septum. Eight weeks later, Saline sonohysterography was done during the postmenstrual phase for all patients. The primary outcomes were the residual septum length. The secondary outcomes were the residual cavity length and the intrauterine adhesions.

Results: our study showed no significant differences between the results of Saline Sonohysterography and office hysteroscopy regarding the length of the fundal notch (P-value=0.317) and residual cavity length (P-value=0.560), and it showed very good agreement between their results (P-value <0.001). Regarding intrauterine adhesions detection, Saline Sonohysterography showed a sensitivity of 55.5%, specificity of 100%, positive predictive value of 100%, and negative predictive value of 91%, 92% accuracy (P-value <0.001) with good agreement with the results of the office hysteroscopy by Kappa method (K=0.672).

Conclusion: Saline Sonohysterography is as effective as office hysteroscopy in diagnosing incomplete uterine septum excision.

Keywords: Uterine septum; Hysteroscopic septum resection; Office hysteroscopy; Saline sonohysterography; Residual length

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INTRODUCTION

Congenital uterine malformations include Mullerian tube anomalies resulting in the uterine septum, which may also result in the vaginal septum [1]. The uterine septum can affect the fertility of the woman in the form of defective implantation due to the defective endometrium and its response to the hormones. The presence of the septum affects placental development leading to recurrent abortion, malpresentation, and preterm deliveries [2-5].

The hysteroscopic resection of the septum is now the most popular treatment modality. Incomplete removal of the septum depends on the size of the septum, which may acquire a second session. The incomplete septum is usually diagnosed by office hysteroscopy, which is expensive, invasive, and needs special equipment [6,7].

Saline Sonohysterography can diagnose incomplete septum or postoperative adhesions without another surgical procedure. Saline Sonohysterography has the advantage of being easy, inexpensive, and relatively less painful to the patient [8,9].

AIM

To compare the efficacy of Saline Sonohysterography (SS) against office hysteroscopy in diagnosing incomplete resected septum.

Design: We performed a retrospective cohort observational study on 56 patients who attended our private hospital in Saudi Arabi from January 2020 to December 2022.

PATIENTS AND METHODS

The study was approved by the ethical committee of our private hospital.

The study included 56 patients with uterine septum complaining of infertility or recurrent miscarriages according to the following inclusion criteria: Patients of reproductive age (20-39), Patients with a history of recurrent abortion or infertility.

The septate uterus or sub-septate diagnosis was confirmed *via* Saline Sonohysterography. We used the American Society for Reproductive Medicine classification (ASRM) for classifying and diagnosing cases of uterine.

Saline sonohysterography was used to diagnose septate, arcuate, and bicornuate uterus cases. The diagnosis of the septate uterus was confirmed if the depth of the external fundal indentation was absent or less than 1 cm.

Pregnant ladies were excluded from the study. Other exclusion criteria are maternal age of less than 20 years or more than 39 years, all cases of organic uterine lesions as myomas were also excluded from the study.

The technique of saline sonohysterography

The machine used in the examination was GE Voluson E10, GE Medical System, Zipf, Austria. Insertion of 12 FG catheter in the cervix was done under speculum inspection. A 60 ml syringe was used to slowly inject the saline into the uterus under ultrasound guidance to observe gradual filling. An average of 5–10 ml of fluid was used for uterine distention. At this stage, the morphology of the uterine cavity was observed. In cases of uterine septum, the septum's length, width, and residual cavity lengths (Distance from the tip of the septum to the internal os) were assessed.

A hysteroscopic resectoscope ((Karl Storz GmbH & Co KG, Tuttlingen, Germany) was used to excise the uterine septum under general anesthesia. Post-resection by eight weeks, Saline Sonohysterography was done on the same day immediately before the second look office hysteroscopy. The same consultant did it for all patients (all are consultants with the same experience).

The same preoperative parameters were assessed; Length and width of the residual septum and cavity length and the presence or absence of intrauterine adhesions.

Primary outcome: Residual septum length.

Secondary outcomes: Residual cavity length and uterine adhesions.

Statistical methods

Data were coded and entered using the statistical

package for the Social Sciences (SPSS) version 26 (IBM Corp., Armonk, NY, USA). Data were summarized using mean, standard deviation, median, minimum, and maximum in numerical data and using frequency (count) and relative frequency (percentage) for categorical data. The non-parametric Wilcoxon signed-rank test was used (Chan, 2003a). For comparing categorical data, Chi-square (χ^2) test was performed. The exact t-test was used when the expected frequency was less than 5. The 3D US and hysteroscopy agreement was tested using the Intra Class Coefficient (ICC) and Cronbach's alpha reliability coefficient with their 95% confidence interval (95%CI). The Kappa measure of agreement was used to test agreement between categorical variables. Standard diagnostic indices were calculated, including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic efficacy. P- Values less than 0.05 were considered statistically significant.

RESULTS

According to the patient's data, it was found that the mean age of the patients was 27.79 years old with an SD of 5.87 years. **Tab. 1.** showed a statistically significant difference between preoperative and postoperative septum length, septum width, and residual cavity length. **Tab. 2.** shows the agreement between the notch lengths and residual length by SS and Office hysteroscopy. **Tab. 3.** demonstrates the Adhesions by SS *vs.* Office hysteroscopy. **Tab. 4.** demonstrates the accuracy of SS in the detection of adhesions postoperatively.

DISCUSSION

The results of the present study and their interpretation

The present study showed no significant differences between the results of SS and office hysteroscopy regarding the length of the fundal notch (P-value 0.215) and residual cavity length (P-value 0.661), with very good agreement

Tab. 1. Postoperative assessment of the patients by 3D SIS and office hysteroscopy.

3D SIS	Pre-operative Assessment		Post-operative Assessment		
	Mean	Sd	Mean	Sd	p-value
Septum Length	1.8	0.29	0.61	0.23	<0.001
Septum Width	2.56	0.39	0.9	0.44	<0.001
Residual Cavity Length	2.39	0.32	3.55	0.31	<0.001
Postoperative Assessment	3D SIS		Office Hysteroscopy		p-value
	Mean	Sd	Mean	Sd	
Length Notch	0.61	0.23	0.63	0.22	0.317
Residual Cavity Length	3.55	0.31	3.54	0.34	0.560

Tab. 2. Agreement between lengths of the notch and residual length by 3D SIS and office hysteroscopy.

Variables	Value	95% Confidence Interval		p-value	
		Lower Bound	Upper Bound		
Length Notch	Intraclass Correlation Coefficient	0.924	0.869	0.956	<0.001
	Cronbach's Alpha	0.960	0.930	0.977	<0.001
Residual Length	Intraclass Correlation Coefficient	0.932	0.884	0.961	<0.001
	Cronbach's Alpha	0.965	0.938	0.980	<0.001

Tab. 3. Adhesions by 3D SIS vs. office hysteroscopy.

Variables		Adhesions (Postoperative Assessment by Office Hysteroscopy)				p-value
		Yes		No		
		Count	%	Count	%	
Adhesions (Postoperative Assessment By 3D SIS)	Yes	5	55.6%	0	0.0%	<0.001
	No	4	44.4%	41	100.0%	

Tab. 4. Accuracy of 3D SIS in the detection of adhesions postoperatively.

Statistic	Value	95% CI
Sensitivity	55.56%	21.20% to 86.30%
Specificity	100.00%	91.40% to 100.00%
Positive Predictive Value	100.00%	-
Negative Predictive Value	91.11%	83.16% to 95.51%
Accuracy	92.00%	80.77% to 97.78%

between their results (P-value <0.001). Regarding intrauterine adhesions, SS showed a sensitivity of 55.5%, specificity of 100%, positive predictive value of 100%, and negative predictive value of 91%, with 92% accuracy (P-value <0.001) with good agreement with the results of the office hysteroscopy by Kappa method (K=0.672).

Comparison of current results with similar studies

Many studies have evaluated uterine cavity pathologies that present with infertility, recurrent miscarriages, and recurrent implantation failure. The current study is comparable to a study done in 2014 [10]. This prospective observational study included one hundred forty-one women undergoing hysteroscopic metroplasty for a septate uterus with a history of miscarriage and/or infertility. Uterine abnormalities were detected using hysteroscopy in 18 (12.8%) of 141 women. Saline Sonohysterography was highly accurate (97.2%), sensitive (97%), and specific (100%), with a positive predictive value of 100% and a negative predictive value of 85%. The diagnostic values of hysteroscopy and Saline Sonohysterography were not significantly different. Saline Sonohysterography showed substantial interrater/interrater agreement regarding overall uterine cavity evaluation ($\kappa=0.79$ and 0.78 , respectively). Saline Sonohysterography demonstrated substantial interrater/interrater agreement for the postoperative uterine cavity evaluation, as diagnostically accurate as hysteroscopy. The use of second-look hysteroscopy was limited to cases that required reoperation [10].

A study was done in 2016 [12] as a prospective cohort study on 60 sub-fertile women with recurrent implantation failure. Overall uterine abnormalities were significantly less likely to be identified with SIS than with hysteroscopy (P=0.002). Still, analysis of each finding separately demonstrated a comparable difference between SIS and hysteroscopy (P > 0.05). It was found that the sensitivity, specificity, positive predictive value, and negative predictive value of SIS to detect intrauterine pathology were 41.2%, 100%, 100%, and 81.1%, respectively. Hence, findings suggested a good role of SIS in the workup for recurrent implantation failure saving more invasive procedure for selected cases [11].

However, in a study done in 2017 [12] to compare saline infusion sonography vs. hysteroscopy in the evaluation of uterine cavity in women with unexplained infertility where 50 patients were included in the study, patients were subjected to an ultrasound assessment of uterine cavity using saline as the contrast medium (SIS) and then followed by hysteroscopy on a later date. The examination was performed after the cessation of menstruation but before the 10th day of the menstrual cycle. The uterine cavity was inspected for irregularities such as synechiae, polyps, submucous myomas, and uterine malformations. Sensitivity, specificity, accuracy, and positive and negative predictive values of SIS and diagnostic hysteroscopy to detect intracavitary abnormalities were compared. In this study, hysteroscopy was more sensitive (100 vs. 85%). Specificity (100 vs. 100%) and more accuracy (100 vs. 94%) than SIS. Hysteroscopy also had the same predictive value (100 vs. 100%) positive predictive value as SIS (100 vs. 90% negative predictive value) as SIS during the evaluation of patients with unexplained infertility. They concluded that hysteroscopy is still considered the gold standard for diagnosing intrauterine pathology as it is more sensitive and accurate than SIS. They found that diagnostic hysteroscopy with biopsy is considered the "gold standard" to diagnose intrauterine abnormalities.

A retrospective observational data was collected from 223 patients 14 of whom underwent TVS, SIS, and hysteroscopy Regarding endometrial polyps, TVS: sensitivity was 60.53%, specificity was 97.06%, positive predictive value (PPV) was 95.83%, negative predictive value (NPV) was 68.75% and SIS: sensitivity was 95%, specificity was 97.14%, and PPV was 97.44%, and NPV was 94.44%. Submucous Leiomyoma, TVS: sensitivity was 57.14%, specificity was 93.48%, PPV was 84.21%, NPV was 78.18%, and SIS sensitivity was 96.55%, specificity was 100.00%, PPV was 100.00%, and NPV was 97.92% [12].

STRENGTHS AND WEAKNESS OF THE STUDY

Strengths of this study include that the same investigator performed every procedure for all patients (SIS, office hysteroscopy), the investigator for every

procedure was blinded to the results of the other procedure, and the prospective nature of the study. Among the weak points of the study are the small sample size and the evaluation of the uterine cavity (panoramic view) and residual septum by office hysteroscopy, depending on the investigator's subjective impression. So proper estimation of the reproducibility of hysteroscopy was not performed. This is a common disadvantage of most studies that use hysteroscopy as the reference standard. Therefore, we used calibrated instruments during hysteroscopy to allow objective hysteroscopic assessment of uterine cavity shape and fundal length. The same consultant performed all patients to improve the reproducibility of hysteroscopy.

CLINICAL IMPLICATION OF THE PRESENT STUDY

The less invasive Saline Sonohysterography can be used in the postoperative assessment of residual septum length and residual cavity length, presence or absence of intrauterine adhesions eight weeks after hysteroscopic septum resection instead of the more invasive second look office hysteroscopy.

RECOMMENDATIONS FOR FURTHER STUDIES

Further studies are needed with increased sample size and follow-up with the patients after septum resection to detect the obstetric outcome and its relation to the residual septum length (fundal notch) so that we could detect

a cut-off length of the residual septum that will impair implantation and accordingly need reoperation.

CONCLUSION

Saline Sonohysterography can be used after hysteroscopic septum resection to assess the uterine cavity instead of the more invasive second-look office hysteroscopy to assess residual septum length, residual cavity length, and the presence or absence of intrauterine adhesions.

ETHICS APPROVAL

Study approved by Ethical Committee.

CONSENT FOR PUBLICATION

Non applicable.

AVAILABILITY AND DATA MATERIAL

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

COMPETING INTERESTS

The author reports there are no competing interests to declare

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