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Original Article

Agreement between transvaginal ultrasound and saline contrast sonohysterography in evaluation of cesarean scar defect



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ABSTRACT

Objectives: to assess the agreement between saline contrast sonohysterography (SCSH) and transvaginal sonography (TVS) in the evaluation of cesarean section scar defect (CSD) regarding its width, depth, and shape and also in assessing the anterior myometrium, and residual myometrium related to the scar.

Material and methods: a prospective study during the period between August 2017 and January 2018 was conducted in which 102 consecutive participants underwent primary cesarean section in Ain Shams University Maternity Hospital were assessed six weeks after CS to evaluate for CSD presence by using both SCSH and TVS.

Results: CSD could be detected only in 59.8% of women by TVS and 70.5% by SCSH with good agreement strength (Cohen kappa = 0.805). TVS was 84.72% sensitive and 100.00% specific in identifying CSD diagnosed by SCSH. The PPV, NPV, and accuracy of TVS were 100.00%, 73.17%, and 89.21%, respectively. The mean anterior myometrial thickness (AMT) did not differ when assessed by both TVS and SCSH, while the mean niche width was 2.56 ± 1.98 mm with SCSH compared to 2.17 ± 1.63 mm with TVS ($r = 0.954$), and its mean depth was 2.76 ± 2.02 mm for SCSH and 1.57 ± 1.51 mm in TVS ($r = 0.812$). The mean residual myometrium was 10.09 ± 2.74 mm in SCSH while was 11.18 ± 2.50 mm for TVS ($r = 0.914$).
Conclusion: cesarean scar defects in non-pregnant women are better evaluated at SCSH than at unenhanced TVS as more defects detected by SCSH and better evaluation of its shape, borders and size.

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Introduction

In past decades the cesarean section (CS) rate has markedly increased [1]. It is well known that cesarean section scar site act as the nidus for many conditions in subsequent pregnancies, namely cesarean scar pregnancy (CSP), morbidly adherent placenta (MAP), and scar dehiscence/rupture. These conditions have the potential to cause significant maternal and perinatal morbidity [2]. In their Systematic Review Roberge and colleagues found that large uterine scar defects, detected before next pregnancy, represent a high risk of uterine rupture in subsequent pregnancies [3]. moreover, postmenstrual spotting, dysmenorrhea, dyspareunia, or chronic pelvic pain are noticed to be more frequent in women with CSD, with theoretical concerns that health care providers can face many difficulties in gynecological procedures as intrauterine device

placement, evacuation, and embryo transfer with CSD presence [4]. CS scar defect was first described using hysterosalpingography in 1961 [5], and then was detected by trasabdominal sonography (TAS) in 1982 [6] and TVS in 1990 [7].

Naji et al. reported that the prevalence of CSD ranges between 6.9% and 69% as no consensus exists regarding the gold standard for the detection and measurement of a niche and each study uses different methods for niche measurement [8].

Improvements in the imaging procedures have facilitated the evaluation of CS scars both before and during pregnancy with identifying women prone to the aforementioned complications in subsequent pregnancies and providing a clinical guide for the management of pregnancy and delivery [3]. Evaluating CSD can be done by various tools including transvaginal sonography (TVS) [8] and contrast enhanced sonography (using gel or saline) [9,10], fewer reports of hysteroscopy [11,12] hysterosalpingography [13] and 3D ultrasonography [14].

However, there are controversial results regarding the efficacy of different techniques and their ability to detect uterine scar

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defects as well as related outcomes during later pregnancies [15]. But contrast enhanced sonography and TVS were the most feasible, cost effective requiring less training [3], it is possible to detect CSD without SCSH, but many authors found that SCSH facilitates the detection and measurement of scar defects [16–18].

The saline contrast sonohysterography (SCSH) procedure is a quick and minimally invasive procedure which can be performed in the physician's office with virtually no patient discomfort [19]. It can be performed 6–12 weeks after cesarean section using gel or saline instillation with an overall accuracy of 96% in the diagnosis of CSD [20].

Taking into consideration the growing importance of this subject, with no consensus regarding the gold standard method for the detection and measuring CSD, it is of interest to identify the degree of agreement between transvaginal sonography and SCSH in the detection of cesarean scar defect.

Materials and methods

The participants in this study were a group of women included in another study that aimed to determine the effect of alpha lipoic acid on Cesarean section uterine wound healing. [21] Here we report the results of comparison of TVS and SCSH in evaluation of CSD.

This study was conducted as a prospective observational clinical trial during the period between August 2017 and January 2018 in which a consecutive series of participant attended Ain Shams University Maternity Hospital emergency room who were informed about the purpose of the trial, the operational modalities, and their benefits as well as the potential risks. After being assessed for eligibility, 102 women aged 18–35 years with singleton term pregnancy undergoing prelabor uncomplicated lower segment cesarean section for the first time were included into the trial. While Women used intrauterine device as a contraceptive method inserted during CS and women with any structural uterine abnormality as cervical stenosis or fibroid uterus, or having any previous uterine incision were excluded from the study.

Six week after CS, the participants were reassessed for any contraindication to perform SCSH as pelvic infection or unexplained pelvic tenderness, which could be due to pelvic inflammatory disease and after obtaining an informed written consent sonographic examination was performed using Samsung H60 EV 4–9 MH vaginal probe by a well-trained expert sonographer, both TVS followed by SCSH in the same visit. The participant lied in the lithotomy position with an empty bladder; the uterus was examined in the longitudinal section, with and without contrast enhancement, for the presence of a cesarean section scar defect.

As there are no clear criteria for diagnosing a cesarean scar defect, any visible defect or indentation in the scar, however small, was classified as a defect. For performing SCSH a sterile vaginal speculum was inserted and the cervix was cleaned with an antiseptic solution. A size CH 8 Foley's catheter was introduced into the internal cervical os and for stabilization and occlusion of the internal cervical os its balloon was inflated with 5 mL of sterile saline. Before introducing the ultrasound probe into the posterior vaginal fornix the speculum was removed and 20 mL plastic syringe containing sterile saline was attached to the catheter; the incision site was viewed longitudinally then 10–20 mL of saline was infused by pushing the syringe plunger, using similar pressure in all cases. The appropriate volume of saline was determined individually by the ultrasound examiner performing the SCSH.

The following measurements were recorded; the thickness of the myometrium bordering the scar (from the serosal surface of the uterus to the apex of the niche), the depth (distance between

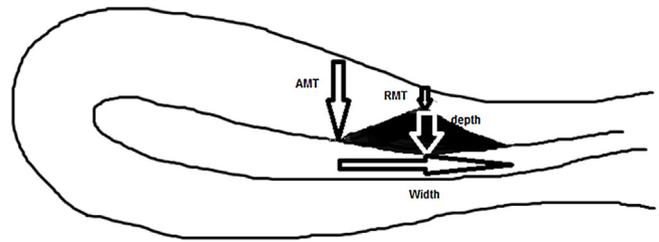


Fig. 1. the recorded measures in both Saline contrast sonohysterography and transvaginal sonography.

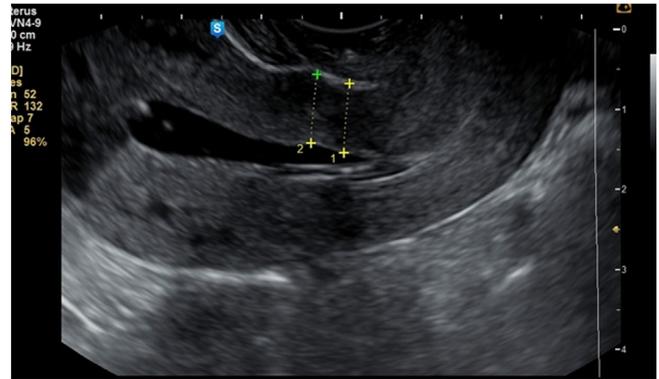


Fig. 2. Saline contrast sonohysterography showing intact myometrium at the site of previous scar with no Cesarean scar defect.

apex of the niche and the estimated middle of the niche base), width(perpendicular to the line between middle of the niche base and apex), and shape of the CSD and healing ratio (the thickness of residual myometrium covering the defect divided by the sum of the thickness of residual myometrium cover the defect and the depth of the defect) Fig. 1.

The study was approved by the Ethical and Research Committee of the Council of Obstetrics and Gynecology Department, Ain Shams University in August 2017. The study methodology was registered on clinical trials: NCT03257514. The study was reported according to the guidelines for reporting studies of reliability and agreement (GRRAS) Figs. 2 and 3.

Sample size justification

The required sample size has been calculated using the IBM© Sample Power© software version 3.0.1 (IBM© Corp., Armonk, NY).

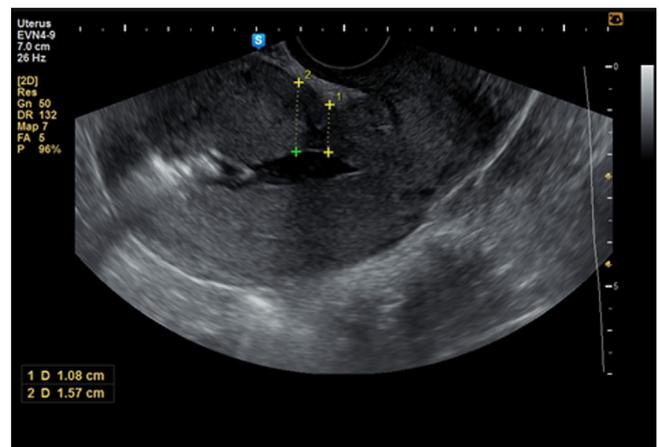


Fig. 3. Saline contrast sonohysterography showing Cesarean scar defect.

The main outcome measure was the agreement between TVS and SCSH regarding the detection of CSD in women with previous one CS and according to previous study by Osseer et al. [18] the lowest limit of kappa (K0) was 0.56 With 0.8 proportion of outcome. Consequently, it was estimated that a sample size of 95 patients achieves a power of 90% (type 2 error, 0.10) to detect with the expected Kappa (K1) 0.90 using a confidence level of 95% (type 1 error, 0.05) and assuming a dropout rate of about 6%, 102 patients were included in the study.

Statistical analysis

Data were analyzed using IBM® SPSS® Statistics version 23 (IBM® Corp., Armonk, NY, USA). Description of all data was in the form of mean (M) and standard deviation (SD) for all quantitative variables, frequency and percentage for all qualitative variables. Agreement between TVS, SCSH for evaluation of CSD formation and shape was performed using Cohen kappa test. The following judgement of Cohen's kappa was used: kappa < 0.41 reflects poor strength of agreement between the observers; 0.41–0.60 reflects moderate strength; 0.61–0.80 reflects good strength; 0.81–1.0 reflects excellent strength. The diagnostic accuracy of TVS in detecting CSD was calculated by sensitivity, specificity, positive and negative predicative values. The Correlation of scar defect parameters evaluated by TVS, and SCSH was assessed by Spearman's correlation with the following judgement was used: < 0.2 reflects very weak correlation; 0.2 – 0.39 weak; 0.4 – 0.59 moderate; 0.6 – 0.79 strong; 0.8–1 very strong correlation.

Results

During the period between August 2017 and January 2018 a total of 102 women underwent prelabor CS for the first time were reassessed six weeks after CS for the presence of CSD. The clinical characteristics of women with and without CSD by SCSH are shown in (Table 1). there was significant difference between those with and without CSD regarding age but not regarding parity, and anterior myometrial thickness.

The prevalence of CSD was 59.8% (61/102) by TVS and 70.5% (72/102) by SCSH. TVS was 84.72% sensitive and 100.00% specific in identifying CSDs diagnosed by SCSH. The PPV, NPV, and accuracy of TVS were 100.00%, 73.17%, and 89.21%, respectively. There is with good agreement strength between SCSH and TVS regarding evaluation of CSD presence (Cohen's kappa coefficient=0.805, 95% CI=0.685 to 0.924) (Table 2).

The mean anterior myometrial thickness was 12.7 ± 2.04 when assessed by both TVS and SCSH while The mean niche width was 2.56 ± 1.98 mm with SCSH compared to 2.17 ± 1.63 mm with TVS,

Table 2

Agreement between TVS, SCSH for evaluation of CSD formation.

	SCSH		TVS	
	NO Niche	niche	No niche	niche
Weighted kappa	30(29.4%)	72(70.6%)	41 (40.2%)	61 (59.8%)
Standard error	0.805			
Confidence interval	0.061			
TVS diagnostic performance	0.685 to 0.924			
sensitivity	84.72%			
Specificity	100.00%			
PPV	100.00%			
NPV	73.17%			
accuracy	89.21%			

and its mean depth was 2.76 ± 2.02 mm for SCSH and 1.57 ± 1.51 mm in TVS

The mean residual myometrium was 10.09 ± 2.74 mm in SCSH while was 11.18 ± 2.50 mm for TVS. There is a very strong correlation between TVS, SCSH in measuring anterior myometrial, residual myometrial thickness, niche width, niche depth, and healing ratio Table 3.

Most CSD diagnosed by SCSH were triangular in shape (40.2%) and the second common was irregular shape (15.7%), followed by linear niche (14.7%). While according to TVS, most defects were linear in shape (24.5%), and the second common was triangular shape (20.6%), followed by irregular shape (14.7%). There is good agreement between SCSH, and TVS regarding evaluation of CSD shape (Cohen kappa=0.682*) Table 4.

Discussion

In this study we evaluated the effectiveness of TVS in detecting CSD and measuring its dimensions compared to SCSH. Both techniques are feasible, easily accessible, cost effective, and widely used non-invasive methods to diagnose the CSD as there is no method is considered the gold standard for CSD detection and not all women with a history of CS develop a defect, also not all women with CSD will be symptomatic so it is important to identify the best screening modality.

Results from our study showed that TVS leaves 11 cases with CSD undiagnosed; confirm that CSD detection increases using SCSH and that most scar defects appear to be larger than with TVS, although all of the undiagnosed defect were less than 2 mm till now, there has been no clear criteria for diagnosing a CSD some consider it as a thinning of the myometrium, while others define it as anechoic area with a depth of at least 1 mm or an indentation of the myometrium of at least 2 mm depth. [22], moreover the CSD

Table 1

Clinical characteristics of cases with and without scar niche by SCSH.

variable	No niche 30	Niche 72	The difference	P value	95% Confidence Interval
age	26.93 ± 5.15	24.52 ± 5.09	2.41	0.033	0.20,4.61
PG	11(36.67%)	26(36.11%)		0.468	
P1	7(23.33%)	12(16.67%)			
P2	7(23.33%)	12(16.67%)			
P3	2(6.67%)	15 (20.83%)			
P4	3(10.00%)	7(9.72%)			
BMI(kg/m ²)	26.7 ± 3.1	26.2 ± 2.6		0.429	
Anterior myometrial	12.56 ± 1.95	12.86 ± 2.08	0.30	0.51	–1.17,0.58
Residual myometrial	12.56 ± 1.95	9.06 ± 2.35	3.5	0.000	2.52,4.46
Niche width	–	3.63 ± 1.28		–	–
Niche depth	–	3.79 ± 1.23		–	–
Healing ratio	–	69.81 ± 10.74		–	–

Table 3
TVS and SCSH measured parameters and their correlation.

	SCSH	TVS	The difference	Paired t test P value	95% Confidence Interval of the Difference	
					lower	upper
Anterior myometrial	12.7 ± 2.04	12.7 ± 2.04	0.00	–	–	–
Residual myometrial	10.09 ± 2.74	11.18 ± 2.50	1.088	0.000	–1.30	–0.87
Niche width	2.56 ± 1.98	2.17 ± 1.63	0.40	0.000	0.291	0.508
Niche depth	2.76 ± 2.02	1.57 ± 1.51	1.09	0.000	0.88	1.31
Healing ratio	78.68 ± 16.49	87.37 ± 12.80	8.68	0.000	–10.40	–6.96

the Spearman rank correlation		Correlation coefficient (Spearman rho)	P value
Anterior myometrial		1.00	0.000
Residual myometrial		0.914	0.000
Niche width		0.954	0.000
Niche depth		0.812	0.000
Healing ratio		0.824	0.000

Table 4
Different CSD shapes by TVS and SCSH.

CSD shape	SCSH	TVS
triangular	41 (40.2%)	21(20.6%)
linear	15 (14.7%)	25(24.5%)
irregular	16 (15.7%)	15(14.7%)
Weighted kappa	0.682	
Standard error	0.067	
Confidence interval	0.5501 to 0.815	

size may not be correlated with women symptoms; as a previous study found that the depth of CSD did not differ between asymptomatic women and those with postmenstrual spotting (p value = 0.50) [23].

In this study, TVS had 84.72% sensitivity, 100% Specificity with accuracy of 89.21% with a good agreement between SCSH, and TVS regarding evaluation of CSD formation. (Cohen's kappa = 0.805). In the same line Baranov et al., results showed that there was 96.4% agreement in detection of any scar defect by conventional TVS and SCSH (kappa, 0.93). [24], also Roberge et al. [3] in their systematic review reported that TVS and SCSH were good tools to detect uterine scar defects. While Osser et al found that TVS showed intact scars in 26 cases, 12 of them had a defect in SCSH. They reported an agreement between the two techniques of 81%; Cohen's kappa was 0.560. [18]

Moreover, Antila Långsjö et al. [25] found that the agreement between TVS and SCSH was not good; half of the CSD diagnosed with SCSH was missed by TVS.

The number and size of scar defects or the RMT may better be assessed by SCSH [18] as with SCSH, the endometrial cavity is filled with saline which outlines the niche and clearly delineates its borders; allowing for accurate detection and measurement of defect dimensions and shapes that is considered to be the best predictors for potential complications [26].

Also Menada Valenzano et al., found that CSD was found in 59.5% of women with previous CS and the scar defect seen on TVS may appear smaller than the defect seen on SCSH. [16]

Regarding the different shapes of CSD in the current study, (40.2%) of scar defects diagnosed by SCSH was triangular in shape and irregular shape was reported in (15.7%), followed by linear niche (14.7%). According to TVS, most scar defects were linear in shape (24.5%), followed by triangular shape (20.6%). There was a moderate agreement between SCSH and TVS regarding evaluation of CSD shapes (Cohen kappa = 0.682). The discrepancy between TVS, SCSH in detecting the shape of CSD could be due to increased

intrauterine pressure during SCSH which makes scar defects appear larger, changing its shape from linear to triangular and helps to delineate the defect borders with appearance of its irregular borders.

The frequencies of different CSD shapes were variable in different studies. Osser et al. [18] found that most scar defects were triangular in shape and the shape did not change at SCSH, but the ultrasound examiner found it easier to delineate the borders of scar defects at SCSH than at unenhanced ultrasound examination. While Bij de Vaate and colleagues reported that most niches had a semicircular (50.4%) or triangular shape (31.6%). [23]

In our study the mean anterior myometrial thickness (AMT) did not differ when assessed by both TVS and SCSH (12.7 ± 2.04 mm) (r = 1.00), while regarding the mean niche width, the mean depth and the mean residual myometrium there was very strong correlation between TVS and SCSH (r = 0.914, 0.954, and 0.812 respectively), and the defects seems larger with SCSH than they appear with TVS.

Antila Långsjö and colleagues found that median niche depth was 3.0 (2.0–7.3) by TVS and 3.3 (2.0–11.0) by SCSH with underestimation of 1.1 mm (range 0.0–7.9) for TVS compared to SCSH, with 95% limits of agreement from –1.9 to 4.1 mm. while its width range between (0.9–11.4) in TVS with median 3.5 and was 4.9 (1.0–14.3) by SCSH, and median RMT was 3.3 and 3.7 for TVS and SCSH respectively showing underestimation of RMT by 0.3 mm in TVS compared to SCSH (range 0.00–15.55) with 95% limits of agreement from –3.8 to 3.2 mm. [25]

While Osser and colleagues found that the width and the length of the defects and AMT were significantly larger by SCSH. There was no significant difference in RMT or healing ratio between TVS, SCSH for women underwent one Cesarean section. [18]

Conclusion

Cesarean scar defects in non-pregnant women are better evaluated at SCSH than at unenhanced TVS as more defects detected by SCSH and better evaluation of its shape, borders and size.

A main strength of this study that we used two methods for CSD detection (TVS and SCSH), both were performed by the same operator at the same time point. Thus, the circumstances and the menstrual cycle effects on endometrial thickness were constant and avoiding the effect of interobserver variation. Both methods are easily performed, non-invasive, widely available, reproducible, can be performed as an office based procedure.

This study lacks an objective reference when comparing these two methods. At present there is no consensus regarding the gold

standard for the detection and measurement of CSD. Hysteroscopy could have provided as a reference method. However, hysteroscopy is also operator dependent; thus it is not totally objective, it is expensive procedure not widely available in low resources countries as Egypt limited to tertiary centers or some private settings, needs special training while it is preferred to screen for CSD at routine ultrasound. Moreover, hysteroscopy cannot detect both anterior and residual myometrial thicknesses which must be evaluated prior to hysteroscopic niche resection. Another limitation of this study we did not report symptoms associated with CSD however; early assessment six weeks after CS where most symptoms cannot be reported and this is main question to be answered in our ongoing research.

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Conflict of interest

We declare that we have no conflict of interest.

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