Diagnostic Correlation Between Saline Infused Sonohystrography and Three Dimensional Transvaginal Ultrasound in the Assessment of Cesarean Section Scar Defect. A Study of a Diagnostic Test Accuracy

E. Ahmed Mortada[1], Rania Gamal[1], Israa Bahaa Hassan Sherif[2], Aliaa Mohamed Maaty[2]

1 Ain Shams University

2 Ain Shams University Hospital

Funding: No specific funding was received for this work.

Potential competing interests: No potential competing interests to declare.

Abstract

Background: The evolution of sonohysterography over the past years has contributed significantly to the assessment of uterine cavity. Saline infused sonohysterography (SHG) may be recommended as an alternative to Diagnostic Hysteroscopy for the assessment of the uterine cavity and uterine scar in women with previous Cesarean Section. Three-dimensional (3D) ultrasonography that enhances visualization of the lower uterine segment (LUS), myometrial thickness and the size of uterine diverticulum is a more recent tool used to diagnose post-cesarean section uterine diverticulum.

Objective: To compare accuracy of three-dimensional transvaginal ultrasound versus the “gold standard” saline infused sonography for assessing the characteristics, frequency of caesarean scar defects in symptomatic patients with a history of cesarean section.

Patients and Methods: This study was conducted with 72 women. patients were recruited from the ultrasound unit underwent both threedimentional transvaginal ultrasound and saline infused sonohysterography. This study, conforming to the declaration of Helsinki, was approved by the ethical committee of Obstetrics and Gynecology department, Ain Shams University, ethical committee number FMASU M D 52 \2021.

Results: 3D transvaginal ultrasound and sonohysterography showed almost good agreement regarding prevalence of niche with kappa (κ) 0.780 with p-value ($p<0.001$). Both imaging modalities show statistically significant higher mean value of volume in SIS was 591.67±271.05 comparing to 3D TVUS was 444.36±219.42, with p-value ($p=0.004$).

Conclusion: There is a substantial agreement between 3D TVUS and SIS in evaluating various niche characteristics, encompassing depth, length, width, volume, AMT and RMT. The data strongly supports the advantages of 3D TVUS over SIS for assessing Cesarean scar defects, commonly known as "Niche." These benefits encompass cost-effectiveness, improved time efficiency, enhanced patient tolerability, and heightened patient satisfaction associated with the 3D TVUS procedure.

Mortada El Sayed Ahmed, MD[1], **Magdy Hassan Kolaib, MD**[2], **Rania Gamal Anwar, MD**[3], **Israa Bahaa Hassan Sherif, Msc**[4], and **Aliaa Mohamed Maaty, MD**[5]

Department of Obstetrics and Gynecology, Faculty of Medicine, Ain Shams University, Cairo, Egypt

*Corresponding author: Rania G. El sakaan Cairo, Egypt, ORCID iD: 0000-0003-1338-7470, Tel: +201283262383, Email: dr.raniagamal2015@yahoo.com.

Running title: Diagnostic correlation between Saline infused sonohystrography and three dimensional transvaginal ultrasound.

Keywords: Saline infused sonohysterography, transvaginal ultrasonography, NICHE, Three-dimensional ultrasonography, cesarean section scar defect.

Introduction

Women delivered by cesarean section are prone to some complications, one of which is the presence of a Cesarean scar defect (CSD) which is defined as any uterine dimpling 2 mm or more at the cesarean scar site that could be visualized by ultrasound.[1][2]

It has been associated with adverse pregnancy outcome, higher risk of complications during gynecologic procedures as well as clinical symptoms such as postmenstrual bleeding. [3][4][5][6]

Caesarean niche is best demonstrated using saline infused sonography (SIS), with higher detection rates compared with two dimentional transvaginal ultrasound (2DTVUS).[4]

More recently, three dimentional transvaginal ultrasound (3DTVUS) has been reported to have a very high accuracy rate in diagnosing congenital anomalies of the uterus.[7]

It is a non-invasive and reproductive procedure that assesses both the internal and external contour of the uterus by displaying the coronal plane of the uterus.[8]

It is now recommended as the first diagnostic step in the assessment of the uterine cavity.[9]

The aim of this study was to compare accuracy of three dimensional transvaginal ultrasound versus the “gold standard” saline infused sonography for assessing the characteristics, frequency and appearance of caesarean scar defects in symptomatic patients with a history of cesarean section.

Methods

This study was a prospective study of diagnostic test accuracy conducted on 72 symptomatic women with history of cesarean section during the period from July 1st, 2021 to October 2023, at Feto-maternal Medicine unit (FMU), Ain Shams University Maternity Hospital, Cairo, Egypt to compare 3DTVUS versus SIS in diagnosis and assessment of cesarean scar defect.

This study, conforming to the declaration of Helsinki, was approved by the ethical committee of Obstetrics and Gynecology department, Ain Shams University, ethical committee number FMASU M D 52 \2021.

The study was registered on ClinicalTrials.gov, with the following number: NCT05996926

389 women attending FMU who fulfilled the inclusion criteria, which were, age between 20 and 45 years; with Previous 1-3 CS(s); and duration from the last CS ranging from 6 months to 5 years complaining of abnormal uterine bleeding (intermenstrual, postmenstrual bleeding), lower abdominal pain, pelvic pain, infertility, recurrent pregnancy loss or women who were evaluated preconception for the possibility of having a morbidly adherent placenta or a trial vaginal birth after cesarean section (VBAC) in next pregnancy; in the period between July 2021 to October 2023, were asked to participate. 81 women, agreed to participate in our study, 9 women were excluded due to presence of uterine polyp and submucous fibroid.

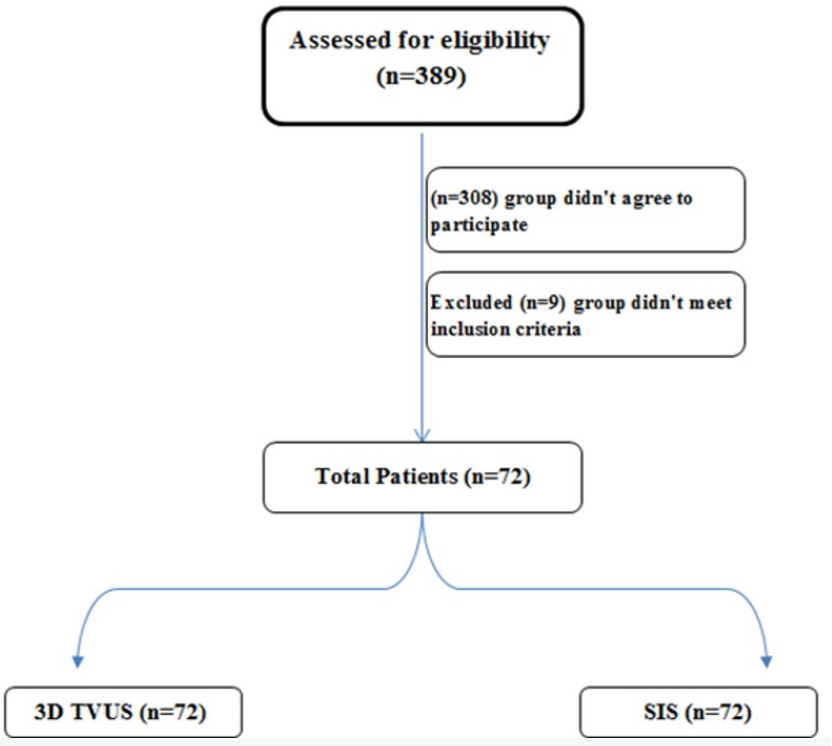

Fig. 1. Flow Chart.

Informed consent was obtained before enrollment of the participants. the exclusion criteria included a Pregnancy (Positive pregnancy test), active or Recent pelvic infection or surgery on the tubes or the uterus. Active vaginal bleeding. Suspected malignancy, intrauterine device in situ.

All participants in the study were subjected to detailed history taking, thorough pelvic examination, each was asked about the symptoms, severity and duration of symptoms and the main bothersome complain.

The participant then underwent conventional 2D ultrasound to exclude pelvic pathology.

3DTVUS was done with the patient in the lithotomy position using ultrasound machine (Samsung WS80A), transvaginal 2-11 MHz probe.

Identification of niche, as a hypo or anechoic defect at site of previous C.S scar of at least 2 mm associated with a residual myometrial thickness of <5 mm.

When niche was identified, measurements were taken following Delphi criteria**Jordans et al.** [10] as follows: In the sagittal plane, the niche length and depth, residual and adjacent myometrial thicknesses were measured. The depth of the defect is measured, starting from uterine cavity to the apex of the defect. The residual myometrium is measured from the apex of the defect to the serosa.

In the transverse plane, the width of the niche was measured and any branches can be assessed. Niche Volume was estimated. procedure time was estimated.

Afterwards SIS was performed with the patient in the lithotomy position and empty bladder, sterile cusco specutum was inserted in the vagina, the cervix anterior lip was hold by vorcellum, the cervix was cleansed with betadine solution. then silicon's catheter fr 9 was inserted into uterine cervix and the balloon infalated with 3 ml sterile saline solution, for stabilization and occlusion of the internal cervical os. Before introducing the ultrasound probe into the posterior vaginal fornix the speculum was removed a 60 ml sterile syring was attatched to the foly's catheter and sterile Na Cl 0.9% solution was injected till cavity was filled and the site of the cesarean scar was visualized. the volume injected varied from 7- 10 ml.

In SIS, if niche was identified, criteria were applied for measurements as described before. Procedure time was estimated.

Both procedures were performed by same personnel. After completion of both procedures, a questioner was handed to the study participant to measure her tolerability and satisfaction with each procedure.

Statistical methods

Recorded data were analyzed using the statistical package for social sciences, version 23.0 (SPSS Inc., Chicago, Illinois, USA). The quantitative data were presented as mean± standard deviation and ranges. Also qualitative variables were presented as number and percentages.

The following tests were done: Independent-samples t-testof significance was used when comparing between two means. ***A one-way analysis of variance (ANOVA)***when comparing between more than two means. Post Hoc test: Tukey's test was used for multiple comparisons between different variables. The Comparison between groups with

qualitative data was done by using ***Chi-square test*** and ***Fisher's exact test*** instead of Chi-square test only when the expected count in any cell less than 5. ***Intra class Correlation coefficient:*** Was used for the agreement between actual birth weight and other formula. The ICCs were classified using a system suggested By Koo and Li (2016) as follows: less than 0.50 Z poor agreement; 0.50 to less than 0.75 Z moderate agreement; 0.75 to less than 0.90 Z good agreement; 0.90 or greater Z high agreement. A P value less than 0.05 was considered statistically significant **Bland Altman:** For agreement was used Bland Altman plot. **Evaluation of Diagnostic Performance:** Accuracy was represented using the terms sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy. ***The confidence interval was set to 95%*** and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following: **Probability (P-value):** P-value <0.05 was considered significant. P-value <0.001 was considered as highly significant. P-value >0.05 was considered insignificant.

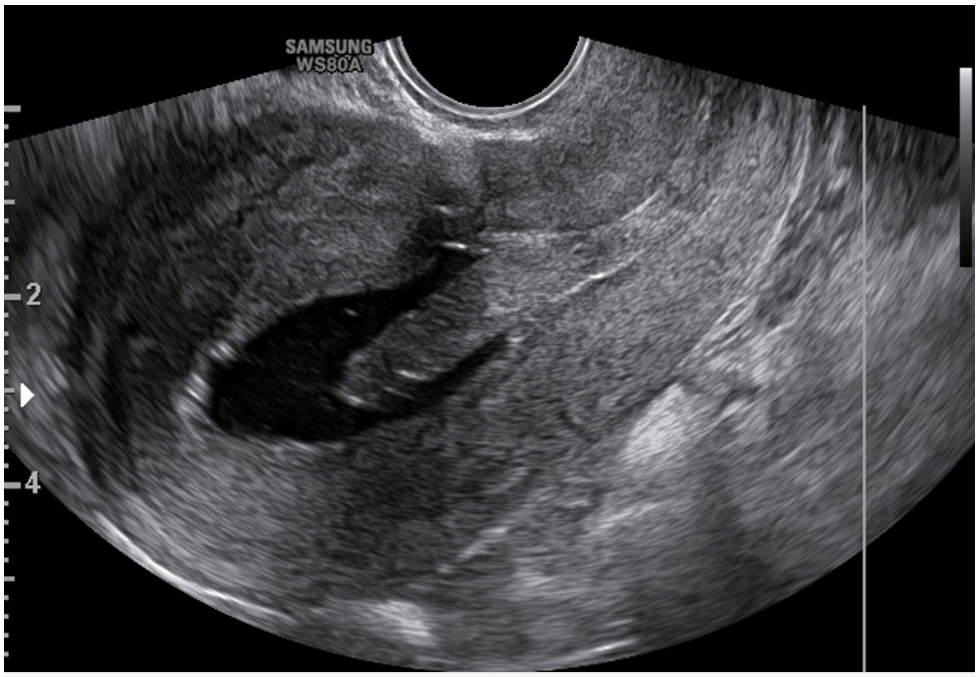

Fig. 2. SIS Showing CSD and intrauterine blood clot.

Results

Table 1. Demographic data distribution among study group.

Demographic data	Total (n=72)
Age (years)	
Range	22-48
Mean±SD	32.04±6.14
Number of previous CS	
Range	1-3
Median (IQR)	2 (2-3)
Duration since last CS	
Range	6-60
Mean±SD	21.28±17.04
BMI [wt/ (ht)^2]	
Range	24.2-33.9
Mean±SD	28.62±2.93

The study was conducted on a wide age group ranging from 22 to 48 years, (mean age of 32.04±6.14 years); while ranged of Number of previous CS was 1-3 and median of 2 (2-3); while ranged of Duration since last CS was 6-60 with mean 21.28±17.04; while ranged of BMI [wt/ (ht)^2] was 24.2-33.9 with mean of 28.62±2.93.

Table 2. Symptoms distribution among study group.

Symptoms	Total (n=72)
Post menstrual bleeding	53 (73.6%)
Intermenstrual bleeding	49 (68.1%)
Lower abdominal pain	40 (55.6%)
Dysmenorrhea	20 (27.8%)
Pelvic pain	20 (27.8%)
Recurrent pregnancy loss	8 (11.1%)
Infertility	7 (9.7%)

This table shows that the majority of patients were in the 53 patients (73.6%) were post menstrual bleeding, followed by 49 patients (68.1%) were intermenstrual bleeding; then 40 patients (55.6%) were lower abdominal pain; followed by 20 patients (27.8%) were dysmenorrhea; 20 patients (27.8%) were pelvic pain; 8 patients (11.1%) were recurrent pregnancy loss and 7 patients (9.7%) were infertility among symptoms.

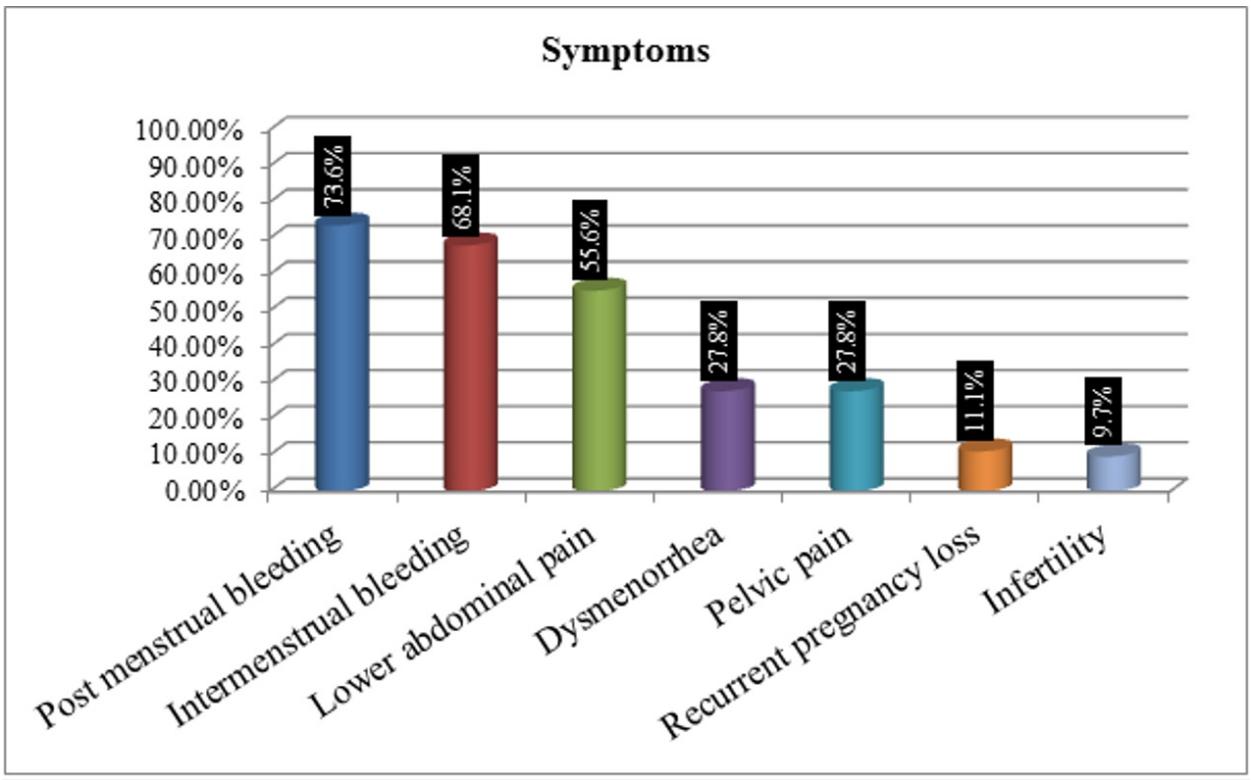

Fig. 3. Par chart Symptoms distribution among study group.

Table 3. Severity of symptoms distribution among study group.

Severity of symptoms	Total (n=72)
Mild	21 (29.2%)
Moderate	28 (38.9%)
Severe	23 (31.9%)
Duration of symptoms	
Range	2-33
Mean±SD	11.08±4.00

Regarding severity of symptoms, there was 21 patients (29.2%) were mild symptoms, 29 patients (38.9%) were moderate symptoms and 23 patients (31.9%) were severe symptoms; As for the duration of symptoms ranged 2 to 33 with mean 11.08±4.00.

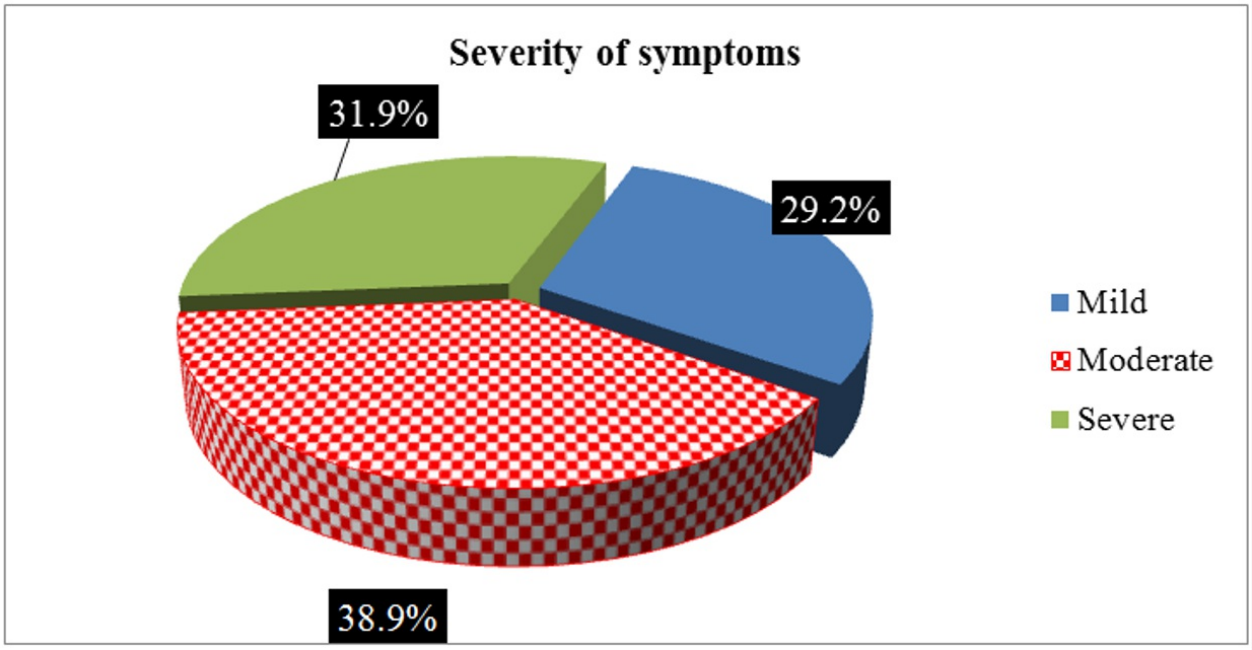

Fig. 4. Pie chart Symptoms distribution among study group.

Table 4. Comparison between 3D TVUS and SIS according to outcome.

	3D TVUS (n=72)	SIS (n=72)	Test value	P-value
Depth of niche (mm)				
Mean±SD	4.63±1.44	5.18±1.30	-1.968	0.052
Range	2-8.2	3-8.3		
Length of niche (mm)				
Mean±SD	10.64±2.56	11.49±2.42	-1.689	0.094
Range	5.9-16.6	6.1-16.8		
Width of niche (mm)				
Mean±SD	9.84±2.57	10.50±2.46	-1.293	0.199
Range	5.1-15	5.1-15.5		
Volume				
Mean±SD	444.36±219.42	591.67±271.05	-2.932	0.004*
Range	126-960.4	157-1580		
AMT				
Mean±SD	7.81±1.99	7.81±1.79	-0.013	0.990
Range	4.1-12.8	4.8-12.8		
RMT				
Mean±SD	3.29±1.14	3.23±1.02	0.269	0.789
Range	1.1-6	1.1-5		

*Using: t-Independent Sample t-test for Mean±SD; p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

This table shows statistically significant higher mean value of volume in SIS was 591.67±271.05 comparing to 3D TVUS was 444.36±219.42, with p-value (p=0.004).

While, there is no statistically significant difference between 3D TVUS and SIS according to depth of niche (mm), length of niche (mm), width of niche (mm), Anterior myometrial Thickness(AMT) and Residual myometrial thickness (RMT), with p-value (p>0.05).

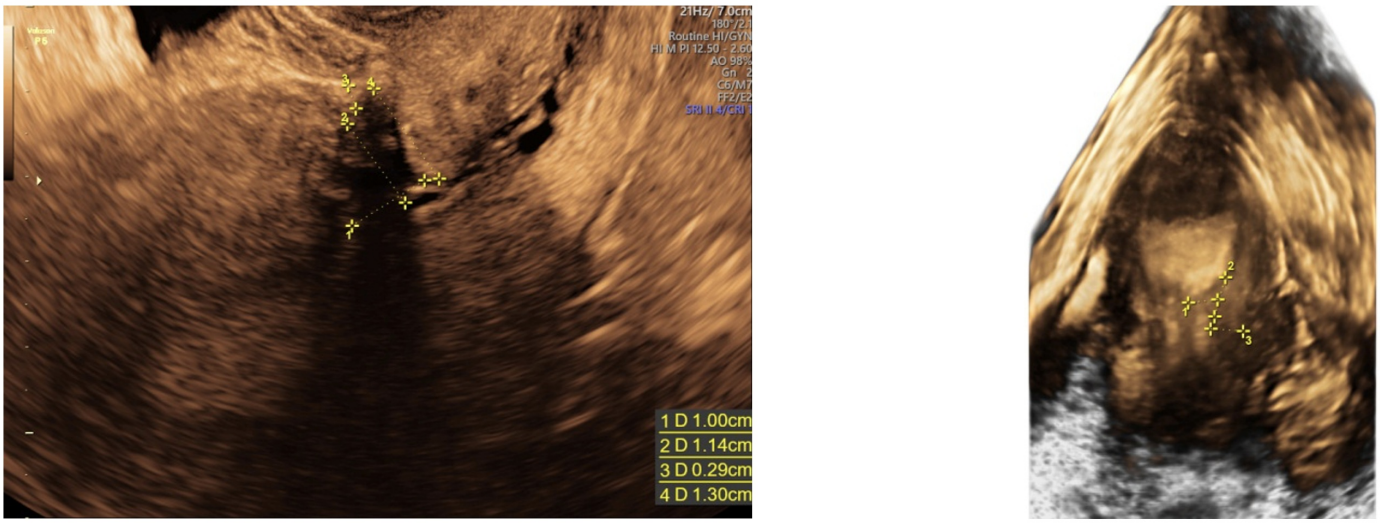

Fig. 5. 3D TVU/S showing CSD.

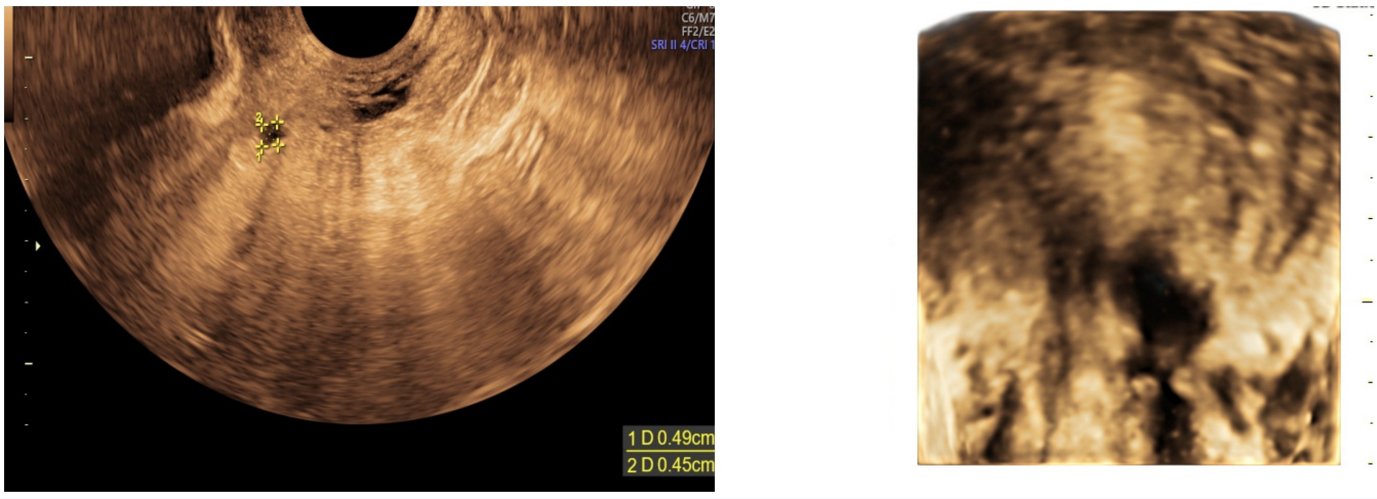

Fig. 6. SIS Showing CSD.

Table 5. Agreement between 3D TVUS and SIS according to prevalence of niche.

SIS: Niche	Cesarean scar defect (Niche)	Total		
	No	Yes		
No	No.	20	1	21
	%	76.9%	2.2%	29.2%
Yes	No.	6	45	51
	%	23.1%	97.8%	70.8%
Total	No.	26	46	72
	%	100.0%	100.0%	100.0%

Using: (κ) Kappa agreement

3D transvaginal ultrasound and sonohysterography showed almost good agreement regarding prevalence of niche with kappa (κ) 0.780 with p-value ($p<0.001$).

This table shows statistically significant diagnostic performance of SIS in the diagnosis of Niche, there was sensitivity 97.8%, specificity 76.9%, positive predictive value 88.2% and negative predictive value 95.2% and accuracy 90.3%

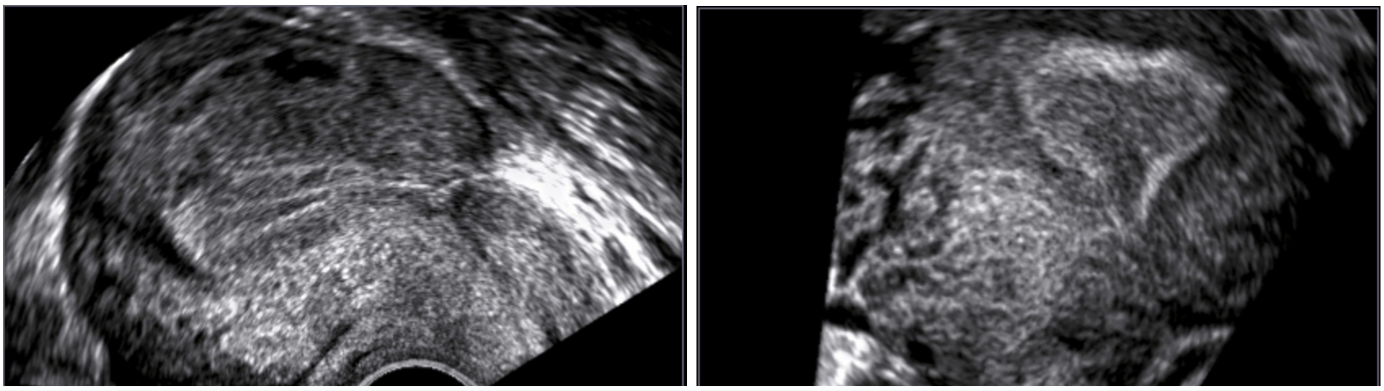

Fig. 7. 3D TVU/S showing CSD.

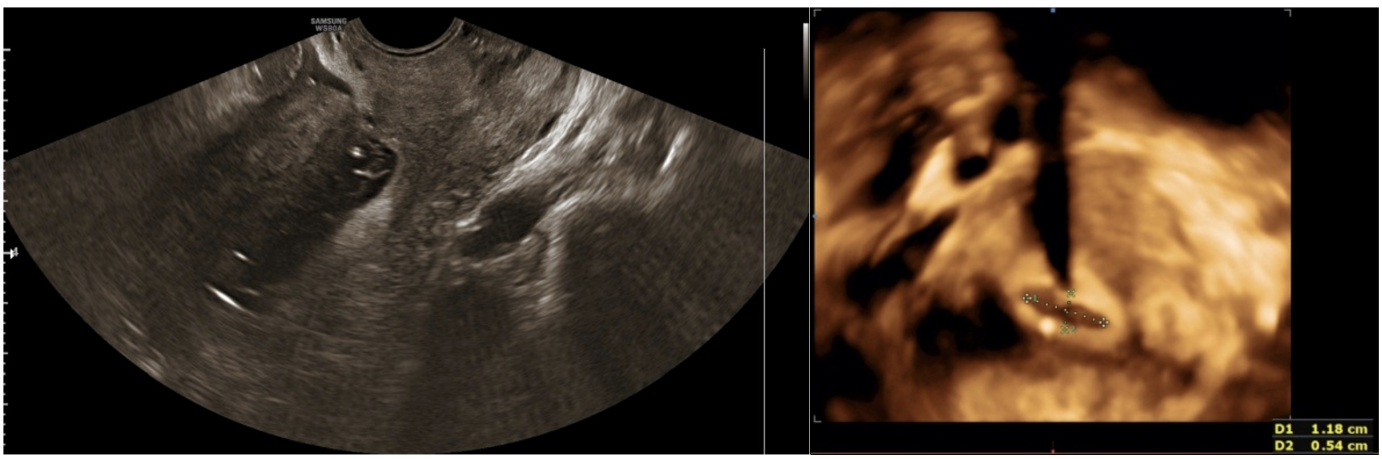

Fig. 8. SIS Showing CSD.

Table 6. Intra class Correlation coefficient for Depth of niche (mm), Length of niche (mm), Width of niche (mm), Volume, AMT and RMT between 3D transvaginal ultrasound and Saline infused sonohysterography.

Finding	ICC coefficient	95% C.I	P-value	Level of agreement
Depth of niche (mm)	0.844	0.719-0.914	<0.001**	Good
Length of niche (mm)	0.970	0.946-0.984	<0.001**	Excellent
Width of niche (mm)	0.977	0.958-0.987	<0.001**	Excellent
Volume	0.872	0.770-0.929	<0.001**	Good
AMT	0.978	0.961-0.988	<0.001**	Excellent
RMT	0.951	0.912-0.973	<0.001**	Excellent

ICC: Intra class Correlation coefficient

CI: Confidence interval; LL: Lower limit; UL: Upper Limit

**: Statistically significant at p ≤ 0.05*

This table shows statistically significant good agreement between 3DTVUS and SIS, regarding measuring depth with (ICC coefficient 0.844 “0.719-0.914” & p-value <0.001) and Volume with (ICC coefficient 0.872 “0.770-0.929” & p-value <0.001).

Also, statistically significant excellent agreement between 3DTVUS and SIS for measured length, width, RMT and AMT of CSD (mm), with (ICC coefficient 0.970 “0.946-0.984” & p-value <0.001), (ICC coefficient 0.977 “0.958-0.987” & p-value <0.001), (ICC coefficient 0.978 “0.961-0.988” & p-value <0.001) and (ICC coefficient 0.951 “0.912-0.973” & p-value <0.001), respectively.

Thus, it is considered that 3D transvaginal ultrasound is closer to the saline infused sonohysterography.

Table 7. Comparison between 3D TVUS and SIS according to secondary outcome.

	3D TVUS (n=72)	SIS (n=72)	Test value	P-value
Total cost (LE)				
Mean±SD	300.00±0.00	231.11±31.65	18.470	<0.001**
Range	300-300	170-270		
Total time (min)				
Mean±SD	5.94±0.79	14.85±1.32	-49.242	<0.001**
Range	5-7	12-17		
Tolerability				
Low	0 (0.0%)	11 (15.3%)	121.846	<0.001**
Moderate	0 (0.0%)	55 (76.4%)		
High	72 (100.0%)	6 (8.3%)		
Satisfaction				
Not Satisfied	0 (0.0%)	7 (9.7%)	7.358	0.007*
Satisfied	72 (100.0%)	65 (90.3%)		

Using: t-Independent Sample t-test for Mean±SD;

x^2: Chi-square test for Number (%) or Fisher's exact test, when appropriate

*p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

This table shows statistically significant higher mean value of total cost (LE) in 3D TVUS was 300.00±0.00 Egyptian pounds comparing to SIS was 231.11±31.65, with p-value (p<0.001). As well as a highly statistically significant higher mean value of total time (min) in SIS group was 14.85±1.32 comparing to 3D TVUS was 5.94±0.79, with p-value (p<0.001).

As for the tolerability, there was higher frequency of high tolerability in 3D TVUS was 72 patients (100%) comparing to SIS was 6 patients (8.3%), with p-value (p<0.001).

While, there was all patients (100%) were satisfaction in 3D TVUS comparing to SIS was 65 patients (90.3%), with p-value (p=0.007).

Table (8). Association between severities of symptoms with outcome in cases which showed niche in 3D TVUS.

3D transvaginal ultrasound	Severity of symptoms			Test value	p-value
	Mild *(n=21)*	Moderate *(n=28)*	Severe *(n=23)*		
Cesarean scar defect (Niche)					
No	4 (19.0%)	7 (25.0%)	15 (65.2%)	12.594	0.002*
Yes	17 (81.0%)	21 (75.0%)	8 (34.8%)		
Depth of niche (mm)	4.05±1.28B	4.67±1.51B	5.76±0.94A	4.405	0.018*
Length of niche (mm)	10.17±2.96	10.98±2.30	10.76±2.43	0.472	0.627
Width of niche (mm)	8.98±2.46	9.96±2.32	11.35±2.96	2.526	0.092
Volume	335.6±166.6C	458.4±215.3B	638.5±203.1A	6.563	0.003*
AMT	8.00±1.40	7.90±2.40	7.14±2.01	0.544	0.584
RMT	3.34±1.16	3.32±1.14	3.11±1.26	0.114	0.892

Using: One way Analysis of Variance test was performed for Mean±SD & Multiple comparison between groups through Post Hoc test: Tukey's test

x2: Chi-square test for Number (%) or Fisher's exact test, when appropriate

Different capital letters indicate significant difference at (p<0.05) among means in the same row

*p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

This table shows statistically significant association between severity of symptoms according to Cesarean scar defect (Niche), Depth of niche (mm) and Volume, with p-value (p=0.002; p=0.018 and p=0.003).

Table 9. Association between severities of symptoms with outcome in cases which showed niche in SIS.

Saline infused sonohysterography	Severity of symptoms			Test value	p-value
	Mild *(n=21)*	Moderate *(n=28)*	Severe *(n=23)*		
Niche					
No	5 (23.8%)	4 (14.3%)	12 (52.2%)	9.186	0.010*
Yes	16 (76.2%)	24 (85.7%)	11 (47.8%)		
Depth of niche	4.51±1.00C	5.20±1.41B	6.15±0.85A	6.428	0.003*
Length of niche	10.88±2.74	11.78±2.34	11.81±2.05	0.814	0.449
Width of niche	9.52±2.34	10.71±2.37	11.54±2.49	2.552	0.088
Volume	452.44±201.5C	600.07±280.4B	788.50±230.6A	6.208	0.004*
AMT	8.11±1.36	7.91±2.12	7.15±1.53	1.030	0.365
RMT	3.17±0.94	3.33±1.09	3.11±1.04	0.224	0.800

Using: One way Analysis of Variance test was performed for Mean±SD & Multiple comparison between groups through Post Hoc test: Tukey's test

x2: Chi-square test for Number (%) or Fisher's exact test, when appropriate

Different capital letters indicate significant difference at (p<0.05) among means in the same row

*p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

This table shows statistically significant association between severity of symptoms according to Cesarean scar defect (Niche), Depth of niche (mm) and Volume, with p-value (p=0.010; p=0.003 and p=0.004).

Table (10): Association between main complain with outcome in cases which showed niche in 3D TVUS.

Finding by 3D TVUS	Main Complain							Test value	p-value
	Dysmenorrhea	Infertility	Intermenstrual bleeding	Lower abdominal pain	Pelvic pain	Post menstrual bleeding	Reccurent pregnancy loss		
Niche									
No	3 (75.0%)	2 (28.6%)	5 (33.3%)	1 (14.3%)	1 (14.3%)	11 (44.0%)	3 (42.9%)	6.548	0.365
Yes	1 (25.0%)	5 (71.4%)	10 (66.7%)	6 (85.7%)	6 (85.7%)	14 (56.0%)	4 (57.1%)		
Depth of niche (mm)	7.40±0.0 A	4.84±1.15B	4.12±1.37B	4.35±1.53B	6.30±1.18A	4.24±1.26B	4.25±0.83B	3.125	0.013*
Length of niche (mm)	10.70±0.0	9.74±2.39	10.56±2.46	10.38±1.66	11.58±4.19	10.60±2.32	11.10±3.40	0.246	0.958
Width of niche (mm)	9.10±0.0	9.90±3.24	9.55±2.57	11.37±2.32	11.92±2.26	8.84±2.15	8.75±2.77	1.643	0.161
Volume	291.90±0.0	394.78±217.42	406.19±190.00	485.06±282.06	691.57±128.50	388.26±217.34	404.40±164.25	1.836	0.117
AMT	5.20±0.0	7.80±2.32	8.40±1.30	7.88±1.31	7.62±1.76	7.94±2.76	6.70±1.02	0.625	0.709
RMT	2.10±0.0	3.46±1.52	3.60±1.11	3.45±0.59	3.25±0.85	3.29±1.45	2.43±0.21	0.694	0.656

Using: One way Analysis of Variance test was performed for Mean±SD & Multiple comparison between groups through Post Hoc test: Tukey's test

x2: Chi-square test for Number (%) or Fisher's exact test, when appropriate

*p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

This table shows statistically significant association between main complain with depth of niche (mm), with p-value (p=0.013); while there is no statistically significant association between main complain and other finding by 3D TVUS, with p-value (p>0.05).

Table 11. Association between main complain with outcome in cases which showed niche in SIS.

Finding by SIS	Main Complain							Test value	p-value
	Dysmenorrhea	Infertility	Intermenstrual bleeding	Lower abdominal pain	Pelvic pain	Post menstrual bleeding	Reccurent pregnancy loss		
Niche									
No	2 (50.0%)	1 (14.3%)	5 (33.3%)	1 (14.3%)	1 (14.3%)	8 (32.0%)	3 (42.9%)	3.949	0.684
Yes	2 (50.0%)	6 (85.7%)	10 (66.7%)	6 (85.7%)	6 (85.7%	17 (68.0%)	4 (57.1%)		
SIS: Depth of niche	5.35±1.48B	5.15±1.04B	4.65±1.17B	4.93±1.27B	6.90±0.88A	5.18±1.30B	4.35±0.91B	2.860	0.019*
SIS: Length of niche	11.65±0.35	10.17±2.21	11.52±2.36	11.52±1.23	12.08±4.13	11.57±2.31	12.08±2.92	0.374	0.892
SIS: Width of niche	9.50±2.55	10.38±2.71	10.67±2.60	11.80±2.42	12.50±2.08	9.59±2.14	9.58±2.50	1.597	0.170
SIS: Volume	583.15±290.97	491.48±194.73	563.96±213.15	645.90±345.01	897.53±360.15	541.41±243.31	495.83±182.42	1.807	0.119
SIS: AMT	6.00±1.13	7.97±1.71	8.39±1.47	7.77±1.49	7.70±1.36	7.89±2.31	6.80±1.28	0.742	0.619
SIS: RMT	2.55±0.49	3.63±1.21	3.51±1.01	3.35±0.56	3.33±0.98	3.10±1.18	2.45±0.42	0.897	0.505

Using: One way Analysis of Variance test was performed for Mean±SD & Multiple comparison between groups through Post Hoc test: Tukey's test

x2: Chi-square test for Number (%) or Fisher's exact test, when appropriate

*p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

This table shows statistically significant association between main complain with depth of niche (mm), with p-value (p=0.019); while there is no statistically significant association between main complain and other finding by SIS, with p-value (p>0.05).

Discussion

A Cesarean Section Scar Defect (CSD) is a structural anomaly that can occur in the uterus following a cesarean section (C-section) delivery, due to incomplete healing or abnormal tissue formation, leading to a localized defect within the uterine wall. CSDs is often associated with various gynecological symptoms and reproductive health issues, including abnormal uterine bleeding, pelvic pain, infertility, and recurrent pregnancy loss [11].

The present study was a prospective, diagnostic test accuracy study, aimed to compare accuracy of three-dimensional transvaginal ultrasound (3DTVUS) versus the "gold standard" saline infused sonography (SIS) for assessing the characteristics, frequency of caesarean scar defects in symptomatic patients with a history of cesarean section.

In this study, participants underwent both 3DTVUS and SIS, the prevalence of CSD was 63.9% when assessed by 3DTVUS, while SIS detected a slightly higher prevalence of 70.8%. Both methods highlighted a relatively high prevalence of scar niches in this group of symptomatic patients with a history of cesarean sections.

In a study done by **Antila-langsjo et al.** [12] that compared Two dimentional transvaginal ultrasound (2DTVUS) to SIS in the diagnosis of CSD, the prevalence of CSD was 22.4% By 2DTVUS and 45.6% by SIS. Sensitivity and specificity for 2DTVUS was 49.1 and 100%, respectively, compared with SIS.

The study used unselected population of women who delivered by CS, the study aim was to determine the prevalence of CSD and, more specifically, to compare 2DTVUS with SIS in the detection of CSD. Ultrasound examinations were performed six months post C.S.

Rasheedy et al. [13] that was conducted on 102 women underwent prelabor CS for the first time and were reassessed six weeks after CS for the presence of CSD using 2DTVUS and SIS. The results showed The prevalence of CSD was 59.8% (61/102) by 2DTVUS and 70.5% (72/ 102) by SIS.

In this comparative analysis between two diagnostic methods, 3D TVUS and SIS, for assessing CSD, there were notable differences in certain aspects of scar defect assessment between the two methods. Specifically, the depth of the niche was slightly lower in the 3D TVUS group compared to the SIS group, although this difference was not statistically significant ($p = 0.052$). Similarly, the length and width of the niche were slightly smaller in the 3D TVUS group compared to the SIS group, although again, these differences were not statistically significant ($p = 0.094$ and $p = 0.199$, respectively). However, significant differences were observed in niche volume, with 3D TVUS showing a significantly lower mean volume compared to SIS ($p = 0.004$). Notably, there was no significant difference between the two methods in assessing anterior myometrial thickness (AMT) or residual myometrial thickness (RMT).

In the study done by **Antila-Långsjö et al.** [12] revealed that the depth, width, and length of CSD were assessed using 2DTVUS and SIS. 2DTVUS yielded a median depth of 3.0 mm, while SIS resulted in a slightly larger median depth of 3.3 mm. Similarly, the width of CSD, as determined by 2DTVUS, had a median of 3.5 mm, whereas SIS indicated a wider median width of 4.9 mm. Additionally, the length of isthmoceles measured by 2DTVUS had a median of 7.7 mm, while SIS measurements showed a slightly longer median length of 8.2 mm (P=0.290). These findings suggest that SIS tends to provide slightly larger dimensions of CSD compared to 2DTVUS.

It should be noted that the majority of the studies compared 2DTVUS to SIS in the detection and assessment of CSD. While in our study we compared 3DTVUS to SIS.

Furthermore, in this analysis we evaluated the agreement between 3D TVUS and SIS for detecting CSD among those with the condition, this represents a sensitivity of 97.8% and 76.9% for SIS and 3D TVUS, respectively and Specificity of SIS and 3DTVUS was 76.9%, and 97.8% respectively. The overall agreement between the two methods appears to be good, suggesting that both modalities have their strengths and limitations in diagnosing C.S defect.

Rasheedy et al. [13] found that 2DTVUS had 84.72% sensitivity, 100% Specificity with accuracy of 89.21% with good agreement between SIS, and 2DTVUS . In the same line **Baranov et al.** [14] results showed that there was 96.4% agreement in detection of any scar defect by conventional 2DTVUS and SIS.

On the contrary, **Antila-Långsjö et al.** [12] revealed that the agreement between 2DTVUS and SIS is not good. Half of the

CSD diagnosed with SIS remained undiagnosed with 2DTVUS.

In another study conducted by **de Vaate et al.** [15] assessed the reproducibility of 3D TVUS in the assessment of a CSD. The authors found that various niche parameters, including depth (both perpendicular to niche base andmaximal depth), maximal width, width at niche base, RMT and volume, can be measured with a high level of agreement.

Interestingly, there do not appear to be any reproducibility studies performed to compare the diagnostic accuracy between 3D TVUS and SIS.

The comparison between Three-Dimensional Transvaginal Ultrasound (3D TVUS) and Saline Infused Sonography (SIS) for secondary outcomes related to cost, time, tolerability, and patient satisfaction reveals several noteworthy findings. Firstly, the total cost associated with the procedures significantly favored SIS, with a mean cost of 231.11 LE (Egyptian Pounds) compared to 300 LE for 3D TVUS ($p < 0.001$). Additionally, 3D TVUS was considerably more time-efficient, with a mean procedure time of 5.94 minutes, compared to 14.85 minutes for SIS ($p < 0.001$). In terms of tolerability, 3D TVUS was rated as highly tolerable by all 72 participants (100%), whereas SIS was rated as having moderate tolerability by the majority (76.4%) and low tolerability by a smaller portion (15.3%) of participants. Furthermore, patient satisfaction was significantly higher with 3D TVUS, with all 72 participants (100%) reporting satisfaction, compared to 65 participants (90.3%) for SIS ($p = 0.007$). These findings collectively suggest that 3D TVUS offers advantages in terms of efficiency, tolerability, and patient satisfaction compared to SIS, making it a potentially preferred diagnostic method for assessing Cesarean scar defects in clinical practice.

Similar findings is recognized in a study done by **Seshadri et al.** [16] demonstrated that SIS is an established, reliable and cost-effective method of diagnosing intrauterine abnormalities. Also **Seshadri et al.** [16] revealed that 3D TVUS is generally considered a well-tolerated procedure by patients it is a relatively shorter examination, less invasive.

The data indicates a significant association between the severity of symptoms and the presence of the Niche among cases that showed a Niche in 3D TVUS and SIS ($p = 0.002$) ($p=0.010$) respectively.

Furthermore, the depth of the Niche, measured by 3DTVUS exhibited significant variation across symptom severity categories ($p = 0.018$), with cases of severe symptoms having a deeper Niche (mean depth of 5.76 mm) compared to those with moderate (4.67 mm) or mild symptoms (4.05 mm). Similarly, the volume of the Niche showed significant differences based on symptom severity ($p = 0.003$), with cases of severe symptoms having a larger Niche volume (638.5 mm^3) compared to those with moderate (458.4 mm^3) or mild symptoms (335.6 mm^3). These findings suggest that the severity of symptoms may be indicative of the size and depth of Cesarean scar defects.

Additionally, the association between the severity of symptoms and depth and volume measured with SIS were statistically significant ($P=0.003$), ($p=0.004$) respectively, with more severe symptoms being associated with deeper niches and greater volume. However, no significant differences were observed in the length and width of the niche or in AMT and RMT across different symptom severities.

In a study done by **Antila et al**. [17] the subgroup analysis revealed an even stronger association for postmenstrual

spotting in cases of large isthmoceles (25.9% vs. 9.5%), further emphasizing the link between isthmocele and these gynecological symptoms.

The current study results provide insights into the association between the main complaints and outcomes in cases with detected CSD, using both 3D TVUS and SIS. The depth of the niche, as measured by 3D TVUS, shows a significant variation across complaints, with deeper niches associated with complaints like pelvic pain and postmenstrual bleeding (6.90±0.88 mm). Again, the depth of the niche measured by SIS varies significantly, with deeper niches associated with certain complaints (e.g., pelvic pain and postmenstrual bleeding). These findings suggest that while the presence of CSD may not be directly related to specific complaints, the depth of the niche appears to differ based on the nature of the symptoms, highlighting the potential importance of niche characteristics in symptom management strategies for individuals with a history of cesarean sections.

In a study by **McGowan et al.** [18] which focused on the diagnosis and management of uterine niche, no association was found between niche presence and abnormal uterine bleeding in a random population using TVUS and SHG

The results of our study suggest that 3D TVUS and SIS both have their strengths in assessing Cesarean section scar defects (CSDs) in patients with a history of cesarean sections. Both imaging modalities demonstrated good to excellent agreement in measuring various CSD parameters such as depth, length, width, volume, AMT and RMT.

Points of weakness

This study had some limitations. the unfamiliarity and the invasive nature of saline infused sonohysterography made it unacceptable to many women. Additionally, a trained personnel to perform saline infused sonohysterograhply was not readily available which prolonged the study period.

Points of strength

The study was unique as it compared three dimensional transvaginal ultrasound to the gold standard saline infused sonohysterography in the evaluation of C.S scar defect.

Furthermore, clear criteria for diagnosing and assessment of a cesarean scar defect was followed.

It can also be regarded as a strength that all participants were examined by both TVUS and SHG at the same time point. Thus, the circumstances and the menstrual cycle point were constant.

Conclusion

The study's results highlight the significant prevalence of Cesarean scar defects among symptomatic patients, underscoring the need for heightened awareness and comprehensive evaluation in individuals with a history of cesarean deliveries, particularly those presenting gynecological concerns. The data strongly supports the advantages of 3D TVUS

over SIS for assessing Cesarean scar defects, commonly known as "Niche." These benefits encompass cost-effectiveness, improved time efficiency, enhanced patient tolerability, and heightened patient satisfaction associated with the 3D TVUS procedure.

Furthermore, the study demonstrates substantial agreement between 3D TVUS and SIS in evaluating various niche characteristics, encompassing depth, length, width, volume, AMT and RMT. While minor differences in niche measurements exist between the two methods, the overall consensus suggests that 3D TVUS serves as a dependable alternative to SIS for diagnosing Cesarean scar defects. In light of these findings, it is reasonable to consider 3D TVUS as a viable substitute for SIS in Cesarean scar defect assessments, especially in clinical settings prioritizing cost-efficiency, streamlined procedures, patient comfort, and contentment.

References

1. ^*Betran AP, Torloni MR, Zhang JJ, Gülmezoglu AM. WHO working group on caesarean section WHO statement on caesarean section rates. BJOG. 2015; 123(5):667–670.*
2. ^*Naji O, Abdallah Y, Paterson-Brown S. Cesarean birth: Surgical techniques. Glob Libr Women's Med. 2010.*
3. ^*van der Voet LF, Bij de Vaate AM, Veersema S, Brolmann HAM, Huirne JAF. Long-term complications of caesarean section. The niche in the scar: a prospective cohort study on niche prevalence and its relation to abnormal uterine bleeding. BJOG. 2014;121:236–44.*
4. a, b*Bij de Vaate AJM, van der Voet LF, Naji O, Witmer M, Veersema S, Brolmann HAM, et al. Prevalence, potential risk factors for development and symptoms related to the presence of uterine niches following Cesarean section: systematic review. Ultrasound Obstet Gynecol. 2014;43: 372–82.*
5. ^*Tower AM, Frishman GN. Cesarean scar defects: an underrecognized cause of abnormal uterine bleeding and other gynecologic complications. J Minim Invasive Gynecol. 2013;20:562–72.*
6. ^*Vikhareva Osser O, Valentin L. Clinical importance of appearance of cesarean hysterotomy scar at transvaginal ultrasonography in nonpregnant women. Obstet Gynecol. 2011;117:525–32.*
7. ^*Gouhar GK, Siam S. Uterine septum structure and reproductive performance: Role of 3D TVUS and MRI. The Egyptian Journal of radiology and nuclear Medicine. 2013; 44(2):357-65.*
8. ^*Ghi T, Casadio P, Kuleva M, Perrone AM, Savelli L, Giunchi S, Meriggiola MC, Gubbini G, Pilu G, Pelusi C, Pelusi G. Accuracy of three-dimensional ultrasound in diagnosis and classification of congenital uterine anomalies. Fertility and Sterility. 2009; 92(2):808-13.*
9. ^*Salim R, Woelfer B, Backos M, Regan L, Jurkovic D. Reproducibility of three-dimensional ultrasound diagnosis of congenital uterine anomalies. Ultrasound Obstet Gynecol. 2003; 21:578-82.*
10. ^*Jordans IP, De Leeuw R, Stegwee SI, Amso NN, Barri-Soldevila PN, Van den Bosch T, Bourne T, Brolmann HA, Donnez O, Dueholm M, Hehenkamp WJ. A practical guideline for examining a uterine niche using ultrasonography in non-pregnant women: a modified Delphi method amongst European experts. Ultrasound in Obstetrics & Gynecology. 2018; 53(1):107-15.*

11. ^*Rosa F, Perugin G, Schettini D, Romano N, Romeo S, Podestà R, Guastavino A, Casaleggio A, Gandolfo N. Imaging findings of cesarean delivery complications: cesarean scar disease and much more. Insights into imaging. 2019; 10:1-4.*
12. a, b, c*Antila-Långsjö R, Mäenpää JU, Huhtala H, Tomás E, Staff S. Comparison of transvaginal ultrasound and saline contrast sonohysterography in evaluation of cesarean scar defect: a prospective cohort study. Acta obstetricia et gynecologica Scandinavica. 2018; 97(9):1130-6.*
13. a, b*Rasheedy R, Sammour H, Elkholy A, Fadel E. Agreement between transvaginal ultrasound and saline contrast sonohysterography in evaluation of cesarean scar defect. Journal of gynecology obstetrics and human reproduction. 2019; 48(10):827-31.*
14. ^*Baranov A, Gunnarsson G, Salvesen KÅ, Isberg PE, Vikhareva O. Assessment of Cesarean hysterotomy scar in non-pregnant women: reliability of transvaginal sonography with and without contrast enhancement. Ultrasound in Obstetrics & Gynecology. 2016; 47(4):499-505.*
15. ^*de Vaate AM, Linskens IH, van der Voet LF, Twisk JW, Brölmann HA, Huirne JA. Reproducibility of three-dimensional ultrasound for the measurement of a niche in a caesarean scar and assessment of its shape. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2015; 188:39-44.*
16. a, b*Seshadri S, Khalil M, Osman A, Clough A, Jayaprakasan K, Khalaf Y. The evolving role of saline infusion sonography (SIS) in infertility. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2015; 185:66-73.*
17. ^*Antila RM, Mäenpää JU, Huhtala HS, Tomás EI, Staff SM. Association of cesarean scar defect with abnormal uterine bleeding: the results of a prospective study. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2020; 244:134-40.*
18. ^*McGowan S, Goumalatsou C, Kent A. Fantastic niches and where to find them: the current diagnosis and management of uterine niche. Facts, Views & Vision in ObGyn. 2022; 14(1):37.*