Original research

Prospective evaluation of the ultrasound signs proposed for the description of uterine niche in non-pregnant women

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ABSTRACT (250 max)

Objectives To prospectively evaluate the new ultrasound-based signs for the diagnosis of post-cesarean section uterine niche in non-pregnant women and their relationship with clinical factors.

Methods We investigated prospectively a cohort of 160 consecutive women with one previous term cesarean delivery (CD) between December 2019 and 2020. All women had a detailed transvaginal ultrasound examination at 4-12 months after CD and were separated into two subgroups according to different stages of labour at the time of their CD: subgroup A (n=109;68.1%) for elective CD and CD performed in latent labour at a cervical dilatation (≤ 4 cm) and subgroup B (n=51;31.9%); for CD performed during the active stage of labour (> 4 cm).

Results Overall, 41 women (25.6%) were diagnosed with a uterine niche and the incidence of a uterine niche was significantly (P<0.001) higher in women who had an elective (20/45; 44.4%) compared to those who had an emergent (21/115; 18.3%) CD. Compared to subgroup B, subgroup A presented with a significantly (P=0.027) higher incidence of uterine niche located above the vesicovaginal fold and with a significantly (P=0.0002) lower proportion of cesarean scar positioned below the vesicovaginal fold. There was a significantly (P<0.001) higher proportion of women with a residual myometrial thickness (RMT) > 3 mm in subgroup A than in subgroup B and a significant negative relationship was found between the RMT and the cervical dilatation at CD (r=-0.22; P=0.008).

Conclusions Sonographic cesarean section scar assessment indicate that the type of CD and the stage of labour at which the hysterotomy is performed has an impact on the location of the scar and the scarification process including the niche formation and RMT.

Key Words - Cesarean delivery; uterine niche; uterine scar; residual myometrial thickness; preterm labor.

Cesarean delivery (CD) rates have increased exponentially around the world in the last two decades.[1] The development of cesarean scar defect or 'niche' also called isthmocele, is considered as one of the key factors associated with secondary obstetrics and gynecologic complications. This phenomenon has been indirectly associated with an increase in iatrogenic obstetric complications in subsequent pregnancies including cesarean scar pregnancies and accreta placentation[2,3] and more recently preterm birth.[4-6] The tethering of the endometrium in a niche can serve as a reservoir for intermenstrual blood and fluid and several studies have shown that niches are the causative factor of long-term gynecology morbidity including postmenstrual spotting and dysmenorrhea, and possibly subfertility.[7-12]

Muscles in general do not heal by regenerating muscle fibers, but by forming "foreign" substances including collagen. The myometrial scar tissue often presents with myofibre disarray, tissue edema, inflammation and elastosis.[13] In large caesarean scar defect, there is often an absence of re-epithelialisation in large uterine scar area and the leucocyte recruitment to the endometrium during the secretory phase is affected.[14] A recent study has also shown that smooth muscle volume density is decreased in the lower uterine segment after cesarean birth and the number of apoptotic nuclei increased up to 3 years after surgery.[15] A Doppler study of the uterine circulation has shown that the uterine vascular resistance is increased, and the volume blood flow is decreased, in women with a prior CD compared to controls with a previous vaginal birth.[16] Experiments in mice have also shown that differences in regenerative ability translate into histological, proliferative and functional differences in biomechanical properties of the scarred myometrium after cesarean section.[17] These findings highlight the long-term impact of a cesarean scar tissue

on both the endometrial biology and the overall uterine vascularization and can explain the development of a uterine niche and the secondary gynecologic symptoms and the higher risk of scar implantation[18] and abnormal placentation.[19,20]

The incidence of uterine niche after prior CD varies widely in the literature ranging between 24% and 70%.[10, 21-23] This is due to differences in population demographics including the numbers of prior CDs, the gestational age at delivery and the incidence of emergent versus elective CD and assessment methodology the timing of the assessment in relation to the last CD and the use of 3D imaging and sonohysterography. Furthermore, many cohort studies are small, retrospective and have not use a uniform ultrasound definition for the uterine niche. In 2019, experts of the European Niche Taskforce participated in a Delphi procedure to standardise uterine niche evaluation in non-pregnant women including a description of ultrasound signs reached by consensus.[24] The aim of this study was to prospectively evaluate these ultrasound signs and their relationship with clinical factors in women with a history of one prior CD.

Materials and Methods

This prospective cohort study was conducted at the Department of Obstetrics & Gynecology, Shamir Medical Centre, Israel between December 2019 and December 2020. The study was approved by the local institutional ethics committee (# 0180-19; approval 24-11-2019) and written informed consent was obtained from all participants. We enrolled woman with one previous term (≥37 weeks) CD. All CDs were performed with a low transverse uterine incision and the uterus was closed in two unlocked layers. Exclusion

criteria were, multiple gestations, more than one prior CD or a previous cesarean section incision other than a low transverse incision.

All women were invited for a sonographic follow-up examination between 4-12 months after CD using a Samsung WS80A or Voluson™ E10 ultrasound systems equipped with a V5–9 MHz endovaginal probe. The diagnosis of niche was defined according to the recent Delphi consensus as an indentation at the site of the cesarean scar with a depth of at least 2 mm.[24] All niches were classified as a simple niche. Basic ultrasound measurements of the niche included length, depth, and residual myometrial thickness (RMT) in the sagittal plane. In addition, we measured the distance between the niche or scar and the vesicovaginal fold, and the distance between the niche or scar and the external os in the sagittal plane. Patients' demographics and obstetrical data were recorded at the time of the ultrasound examination.

SPSS (SPSS Inc., version 25 Chicago, IL, USA) data analysis and statistical software package (Manugistics, Rockville, MD) was used to analyse the data. A standard Kurtosis analysis indicated that the demographic values were normally distributed and the data are therefore presented as mean and standard deviation (SD). To evaluate the impact of the stage of labour on the development of a uterine niche after CD we separated the patients were into two subgroups according to different stages of labour at the time of their CD. Subgroup A included women had an elective CD or an emergent CD at a cervical dilatation $\leq$ 4 cm (latent phase) and subgroup B included women who had their CD at any stage > 4 cm (active phase) as previously described[25]. Categorical variables were compared between subgroups using the Two-tailed t-tests, Fisher's Exact tests and Pearson's Chi-square (χ^2)

tests. Correlations between RMT and the cervical dilatation at CD were performed using the Pearson coefficient. A *P* value <0.05 was considered significant.

Results

During the study period, a total of 160 women with a history of one prior CD at term were recruited. The demographic characteristics of the study population and ultrasound findings are presented in Table 1. There were 45 (28.1%) elective and 115 (71.9%) emergent cesarean deliveries. The mean time interval between CD and the ultrasound examination was 9.6±4.6 months. In 6/118 (5.1%) patients it was impossible to identify the position of the scar relative to the vesicovaginal fold (distance above or below) on ultrasound examination. Overall, 41 women (25.6%) were diagnosed with a uterine niche (Figure 1). The incidence of a niche was significantly (χ^2 11.6; P<0.001) higher in women who had an elective (20/45; 44.4%) compared to those who had an emergent (21/115; 18.3%) CD.

Table 2 displays and compares the ultrasound findings in the subgroups. There were 109 (68.1%) women in subgroup group A (Elective CD and emergent CD performed at ≤ 4 cm cervical dilatation) and 51 (31.9%) in subgroup B (CD at >4 cm cervical dilatation). The mean distance between the uterine scar and the external os and between the uterine scar and the vesicovaginal fold were significantly (P<0.05) longer in subgroup A than in subgroup B. The RMT was significantly larger in subgroup A than in subgroup B (7.2 ± 2.6 vs. 6.3 ±2.7 mm; P = 0.045). There was a significantly (P<0.001) higher proportion of women with an RMT > 3 mm in subgroup A than in subgroup B and a significant negative relationship was found between the RMT and the cervical dilatation at

CD (r=-0.22; P=0.008). There was a significantly (P=0.027) higher incidence for a niche to be positioned in the uterus above the vesicovaginal fold in subgroup A than in subgroup B. A significantly (P=0.0002) higher proportion of women in subgroup A had their cesarean scar positioned above the vesicovaginal fold then in subgroup B.

Discussion

Using the standardised criteria of the European Niche Taskforce we found that women who had an elective CD are more likely to present within 4-12 months after deliver with a uterine niche than those who had an emergency cesarean section and that both simple scars and niches are more often located above the vesicovaginal fold when the hysterotomy is performed at a cervical dilatation ≤ 4 cm.

In the present study, the incidence of uterine niche after one CD at term following double-layer unlocked closure of the myometrium was 25.6%. Several factors have been found to have a direct impact on subsequent niche development including a retroverted uterus, multiple CDs, split thickness suturing technique (excluding the endometrial layer) and/or single-layer versus to double-layer closure the hysterotomy incision.[9,10,26] Overall systematic reviews and meta-analyses of randomised control trials (RCTs) comparing single-layer with to double-layer myometrial closure have found a similar incidence of uterine niche in women suggesting that type of uterine closure has little influence on uterine scar healing after CD.[27-29] Double-layer unlocked sutures seem to be preferable to single-layer locked sutures regarding RMT,[27] healing ratio and secondary dysmenorrhoea[28] but outcomes were considered inaccurate because the studies reviewed had included relatively few patients and events.[27] A larger RCT is ongoing and should

provide insight in the outcomes of single- compared to double-layer closure technique, including postmenstrual spotting and subfertility.[30]

There is limited data on the impact of the type of CD i.e. elective versus emergent and timing during labour. A recent cohort study has found that elective and early labour CD at cervix dilatation < 2cm is associated with an increased prevalence of a scar above the internal cervical os as well as a scar niche.[31] In the present study, we found a significantly (P<0.001) higher incidence of a uterine niche in women who had an elective compared to those who had an emergent CD. When the CD was performed at a cervical dilatation ≤ 4 cm there was a significantly (P=0.027) higher incidence of a uterine niche located above the vesicovaginal fold and a significantly (P=0.0002) lower proportion of cesarean scar below the vesicovaginal fold compared to those who had their CD at active stage of labour. Intrapartum emergency CD are more likely to involve the cervix cervical tissue[31,32] and the risk increases as labour progressed and the lower segment is further stretched by the descent of the fetal presentation.[33,34] As the labour progresses, full cervical effacement causes the smooth muscle of the internal sphincter to migrate into the lower uterine segment[35] making it difficult for the surgeon to localise the upper cervix. This can explain the higher incidence of scars and niches below the vesicovaginal fold in the subgroup who had an emergent CD at > 4 cm in the present study (Table 2).

Injury to the cervical morphology during CD performed late in labor may contributing to preterm birth in subsequent pregnancies.[4,6,34] Recent data have indicated that the uterine cervix is made a specialized sphincter at the internal os and the cervical smooth-muscle cells may play a role in cervical remodelling as well as initiating and/or disseminating uterine contractility.[36] We found that women who had an emergency CD at

cervical dilatation > 4 cm presented with a significantly higher incidence of both their scar or a niche to be located below the vesicovaginal fold (Table 2) suggesting that this subgroup of women could be at higher risk of premature delivery in subsequent pregnancies. This subgroup of women also had a significantly higher incidence RMT ≤ 3 mm and presented with a smaller mean RMT compared to women who had an elective CD or their CD in latent stage of labour suggesting that they may also be at higher of lower uterine segment dehiscence and possibly uterine rupture in labour in subsequent pregnancies.

The incidence of a uterine niche was significantly (P<0.001) higher in women who had an elective (20/45; 44.4%) compared to those who had an emergent (21/115; 18.3%). Elective CD have been associated with a higher incidence of accreta placentation in subsequent pregnancies.[37,38] This could be due to the development of a niche and the higher risk of cesarean scar pregnancy[2,3] after elective CD. There is mounting evidence that a niche can be associated postmenstrual spotting and dysmenorrhea.[9-11] Although there is limited evidence that closing the niche surgically improves the gynaecological symptoms and no evidence that is prevents the development of a cesarean scar pregnancy, several techniques have been proposed.[39] The hysteroscopic correction of niche may be the strategy in those patients with adequate RMT overlying the niche (≥ 2.5–3.5 mm), given the risk of balder injury.[12] Laparoscopic surgery may be the preferred options for patients with a thinner residual myometrium over the defect (< 2.5 mm) and when hysteroscopic treatment is inconclusive.[40] However, the comparison of these different techniques is limited by the lack standardised sonographic protocol in assessment of the uterine scar before surgery.

Our study has several strengths. First the prospective design of the study allowed standardised TVS examination of all study participants with one previous CD at term during the study period. Second, all our measurements were made using the consensus criteria of the European Niche Taskforce.[24] Previous authors have used various definitions of niche and reported different outcomes, making it difficult to compare series and probably introducing selection bias. The limitations of our study the single-institution study design which limits the generalizability of our results and the variable time intervals between delivery and the follow-up scan during Covid-19 pandemic. Also we do not have longitudinal data on the possible changes of the cesarean scar remodelling and uterine niche development with advancing time after hysterotomy. A randomised controlled trial on the impact of one- versus two-layer closure with ultrasound follow-up has shown that uterine scar thickness remains increased even at 6 weeks post-partum, suggesting that the process of uterine scar remodelling extends beyond the traditional postpartum period.

With the increasing incidence of CD, ultrasound evaluation of the uterine scarification process has become essential in understanding the impact of different type of cesarean section and different techniques of uterine closure on the risks of long-term obstetrics and gynaecological complications. The use of standardise sonographic criteria for the assessment of cesarean section scar is crucial for the development of management protocols and follow-up of patients with a history of CD.

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353 **Table 1**. Demographic characteristics of the study population (n=160). Results are
354 shown as mean (±SD) or number of subjects (percentage).

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Parameter	Results
Maternal age (years)	32.0±5.6
Obstetric history	
Gravidity	2.2±1.7
Parity	1.6±1.1
Gestational age at cesarean delivery (weeks)	38.6±1.6
Cervical dilatation at the time of cesarean delivery (cm)	2.7±3.4
Elective cesarean delivery	45 (28.1)
Indication for elective cesarean delivery	
Fetal malpresentation	37 (82.2)
Large for gestational age	8 (17.8)
Emergent cesarean delivery	115 (71.9)
Indications for emergent cesarean delivery	
Fetal malpresentation	16 (13.9)
Fetal distress	63 (54.8)
Dystocic labor	36 (31.3)
Time period from CD to ultrasound examination (months)	9.6±4.6
Ultrasound parameters	
Uterine position	26.3±5.1
Anteflexed	123 (83.1)
Retroflexed	25 (16.9)
No of cases with a niche	41 (25.6)
Niche length (mm)	7.3±4.1
Niche depth (mm)	4.5±2.8
Residual myometrial thickness of scar or niche (mm)	7.6±2.6
Distance from scar to external os (mm)	33.3±9.2
Distance from scar to vesicovaginal fold (mm)	9.0±9.8

Table 2. Comparison of ultrasound findings between according to cervical dilatation at the time of CD. Data are presented as the number (%) or as the mean ± standard deviation.

	Subgroup A (Elective & CD at 0-4 cm) N=109	**Subroup B (CD at 5-10 cm) N= 51**	**P value**
No of cases presenting with a simple scar	86	32	
No of cases presenting with a niche	23	19	
Scar position identified	82	30	
Above vesicovaginal fold	74 (90.2%)	17 (56.7%)	
At or below vesicovaginal fold	8 (9.8%)	13 (43.3%)	0.0002[#]
Distance between scar and external os (mm)	32.9±9.1	29.5±7.3	0.027[&]
Distance between scar and vesicovaginal fold (mm)	9.7±9.8	-3.6±8.1	0.020[&]
Niche position			
Above vesicovaginal fold	17 (73.9%)	7 (36.8%)	
At or below vesicovaginal fold	6 (26.1%)	12 (63.2%)	0.027[#]
RMT (mm)			
> 3 mm	103 (94.5%)	32 (62.7%)	<0.0001[#]
≤ 3 mm	6 (5.5%)	19 (37.2%)	
Mean RMT (mm)	7.2±2.6	6.3±2.7	0.045[&]

CD = cesarean delivery; RMT= residual myometrial thickness.

[#] Fisher's exact test.

[&] Student's t-test.

Figure legend

Figure 1. Transvaginal midsagittal ultrasound image of the uterus. (A) Niche location at the level of the vesicovaginal fold. (B) Niche location below the level of the vesicovaginal fold.