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The B-mode sonographic evaluation of the post-caesarean uterine wall and its methodology: A study protocol

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Abstract

Aim: The aim of this study is to utilize the niche measurement guidelines outlined by Jordans *et al.* in order to establish normal values and accurate description of caesarean section scars in a normal population. After defining the normal distribution, abnormal pregestational scar characteristics will be identified for predicting adverse pregnancy outcomes.

Methods: This is a prospective observational multicenter clinical study where women with a history of only one caesarean section and yet open family planning are enrolled. The uterine length, cervical length, niche length, niche depth, niche width, residual myometrial thickness, endometrial thickness, scar to internal os distance, anterior myometrial thickness superior and inferior to the scar and the posterior myometrial thickness opposite the scar, superior and inferior to it are measured in a pregestational uterus. The lower uterine segment is measured over a length of 3 cm during subsequent pregnancy and followed up until delivery.

Results: Data from 500 patients will yield normal distribution curves for all predefined measurements. Establishing a correlation between deviations from the normal measures and adverse events would be instrumental for counseling women regarding subsequent pregnancy and mode of delivery.

Conclusion: This study will demonstrate the changes of the post-caesarean scar from a non-pregnant uterus until delivery and can confirm the importance of the scar characteristics in predicting pregnancy outcome.

Key words: caesarean scar, caesarean section, post-caesarean uterus, sonography, uterine wall.

Introduction

There is no doubt that caesarean section (CS) is an important surgical intervention which improves both maternal and fetal obstetrical outcomes given the right circumstances. These circumstances are met when an indication for performing a CS due to either fetal or maternal causes is fulfilled.^{1,2} Even though the immediate postoperative maternal morbidity is decreasing because of improved perioperative management,³ there are severe long-term risks to a CS including extrauterine pregnancies, subfertility,

abnormally invasive placenta (AIP), repeated CS, as well as uterine rupture and hysterectomy.⁴

The past two decades show continuous increase of CS rates especially in middle- and high-income countries without a parallel improvement in maternal and fetal outcomes. Despite efforts to limit unnecessary CS, many developed countries fail to keep their rate below 30%.⁵ Deeper knowledge of the CS scars and their healing is required in order to appropriately advise the increasing number of pregnant women with a history of CS. Thus far, our recommendations have been based on statistical data, but we believe

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that tailored risk-assessment for each patient can be achieved. Several groups have studied the sonographic assessment of the lower uterine segment for a safe vaginal delivery after a CS. A normal lower uterine segment after CS was associated with a sonographic anterior wall thickness of more than 3.2 mm around delivery and thus assumed to be safe for a trial of labor.⁶ Similar results were shown by Basic et al. where scar thickness of more than 3.5 mm was regarded as a quality of good healing that can withstand vaginal delivery.⁷ Naji et al. studied the scar during subsequent pregnancy and considered an anterior myometrial wall thickness of 2.5 mm as a cut-off point for normal thickness. They concluded that the scar was visible in 88.8% and the reproducibility of the scar measurement decreased with advancing gestational age.⁸ Similarly, a cut-off value of less than 2.5 mm was associated with a translucent lower uterine segment.⁹ The measurement of the lower uterine segment with ultrasound was shown to be highly reproducible when predetermined standardized measuring criteria are implemented.¹⁰ The value of ultrasound in predicting uterine rupture and mode of delivery in a pregnancy following a CS remains controversial, thus current guidelines do not recommend ultrasound for this purpose.¹¹

The CS scar is easy to visualize in a non-pregnant uterus and its measurement is more accurate than during pregnancy. While a hypoechogenic triangular defect 'niche' at the site of the scar is the most commonly described change, a universally accepted definition of the normal scar appearance remains lacking. Transvaginal ultrasound represents the gold standard method for evaluating niches which are present in 24–70% after a CS.¹² Large niches are associated with gynecological complaints such as chronic pelvic pain, postmenstrual spotting, and abnormal uterine bleeding.¹³ Especially large niches are expected to be associated with obstetrical complications in subsequent pregnancies such as uterine rupture and abnormal placentation, however, this effect has not been established because a definition of a large niche does not exist.¹⁴ Jordans *et al.* published guidelines in order to standardize the examination, measurement and description of the niche in non-pregnant women. These guidelines were based on a Delphi method and should help to generate universally understandable evaluation of CS scars for future clinical studies. Transvaginal ultrasound with either 2D or 3D can be used for the measurement, and a niche is defined as an indentation of more than 2 mm at the site of the

CS scar. The length, width and depth of the niche should be measured on the planes where they reach their maximum, while the residual myometrial thickness (RMT) should be measured on a sagittal plane. Additional information such as the adjacent myometrial thickness, the distance between the niche and the external os or the vesicovaginal fold are also considered to be important in the evaluation.¹⁵

The aim of this study is to utilize the measurement guidelines outlined by Jordans *et al.* in order to establish normal values and accurate description of CS scars in a normal population.

Methods

This is a prospective observational multicenter clinical study where consenting women over the age of 18 with a history of only one CS, regardless of reason for the CS or the gestational age at delivery, and yet open family planning are enrolled. Exclusion criteria are completed family planning and a history of more than one CS or other uterine surgeries. The study was approved by the Ethics Committee at the Hesse State Chamber of Physicians, reference number 2019-1138-evBO. Voluson E10 with a 5-13 MHz GE RIC6-12-D microconvex transvaginal transducer as well as a curved array 8 MHz GE RAB4-8-D transabdominal probe are used for the examinations (GE Healthcare GmbH, Munich, Germany). Vaginal ultrasound will be utilized to visualize the uterus and the CS scar with an empty bladder one year postoperatively. Three-dimensional volumes from each uterus are saved for an offline assessment, during which several measurements will be acquired. The uterine length (UL), cervical length (CL), niche length (L), niche depth (D), niche width (W), RMT, endometrial thickness (EM), scar to internal os distance (SO), anterior myometrial thickness superior (sAMT) and inferior (iAMT) to the scar and the posterior myometrial thickness opposite the scar (PMT), superior (sPMT) and inferior to it (iPMT) as shown in Figure 1 are documented and their reproducibility will be tested.

A survey of gynecological findings such as dysmenorrhea, postmenstrual spotting and abnormal uterine bleeding is conducted at the time of this examination.

Furthermore, the study participants will undergo serial ultrasound examinations at the 5th-8th gestational week, first, second and third trimester upon starting a subsequent pregnancy. The first examination includes measurements similar to those shown in

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Figure 1 The measurable variables for evaluating the caesarean section scar in a non-pregnant uterus on (a) sagittal and (b) transverse planes. (UL) uterine length, (CL) cervical length, (L) niche length, (D) niche depth, (W) niche width, (RMT) residual myometrium thickness, (EM) endometrial thickness, (SO) scar to internal os distance, (sAMT) anterior myometrial thickness superior to the scar, (iAMT) anterior myometrial thickness inferior to the scar, (PMT) posterior myometrial thickness inferior to the scar, (iPMT) posterior myometrial thickness inferior to the scar.

Figure 1 in addition to identifying scar pregnancies which are believed to be precursors for AIP.¹⁶

The rest of the follow-up examinations will be performed with a combination of transvaginal and transabdominal transducers. The lower uterine segment will be measured over a length of 3 cm starting from the most inferior identifiable part of the myometrium as shown in Figure 2. All of the transabdominal examinations are performed with a full bladder and bladder volume will be noted.

The myometrium is identified as a relatively hypoechogenic layer between two bright hyperechogenic lines representing the peritoneum and the chorioamniotic membrane.¹⁰ The RMT at the scar location will be documented if the CS scar is identifiable during pregnancy such as in Figure 3.

Pregnancy outcome, mode of delivery and adverse events such as AIP, uterine rupture during labor in a subsequent pregnancy and uterine dehiscence during



Figure 2 Sagittal view of a normal post-caesarean lower uterine segment for measuring the myometrium thickness along 3 cm in the 20th gestational week (A inferior, D superior).

repeated CS are documented and will be correlated to the sonographic properties of the scar. Our consensual definition of uterine dehiscence is an unruptured translucent lower uterine segment during a repeated CS.

Results

Data from 500 patients will allow the definition of a 95% reference interval where the upper and lower bounds will have a precision of at least 2% with a probability of 95% pregestationally and during the first trimester. It is expected that only part of the patients yields reliable measurements during the second and third trimester, the precision of the respective reference interval bounds will then still be at least 2.4% with a probability of 95%. If possible, parametric approaches will be preferred for defining reference intervals. A bar-chart will be established in order to demonstrate the means and the 95% confidence intervals for the measurements collected from the 500 patients.

Furthermore, inter- and intra-observer variability will be evaluated. Moreover, interclass correlation will demonstrate the congruence between the transvaginal and transabdominal measurements of the lower uterine segment during pregnancy.

ROC-curve analysis will be performed to evaluate the predictive information of different measurements and adverse events, such as dysmenorrhea, abnormal uterine bleeding, subfertility, subsequent AIP, uterine rupture, dehiscence and emergency CS. Furthermore, a multivariable logistic regression model will be used to assess and combine the diagnostic and predictive value of the measurements for aforementioned outcomes.

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Figure 3 Visible caesarean section scar during pregnancy (a) red arrow showing the scar as an indentation in the sagittal view of the myometrium; (b) green arrow showing thinning at the caesarean section scar like an hourglass. (RMT) residual myometrium thickness.

Discussion

In order to recognize abnormal CS scars, a definition of normal scarring needs to be created. A populationwide screening for all women after a CS is essential in order to define the real prevalence of niches and determine their size and RMT. This study can be a departure point for establishing the normal distribution of these variables. Recognizing a correlation between deviations outside the normal distribution and adverse outcomes, such as pelvic pain or spotting, would be instrumental for counseling women with these complaints and eventually for planning their management. Absolute measurements of niches and RMT are not expected to be beneficial for predicting outcomes, rather relative measurements because women have different sized uteri and uterine walls. This is the reason why our study protocol includes the predefined measurements in Figure 1 so that ratios can be assessed. Other studies similarly utilized ratios for calculating the degree of thinning at the scar level. A ratio of more than 50% was classified as severe deficiency.¹⁷

Previous work measured the CS scars longitudinally during the pregnancy and showed that the measurements are reproducible, but they utilized transvaginal ultrasound throughout second and third trimesters.⁸ Transabdominal ultrasound is more practical in the later stages of pregnancy; thus it should be the preferred method for evaluating the lower uterine segment. The measurement of the lower uterine segment at term with transvaginal ultrasound has been reported to be more accurate than with transabdominal transducer.¹⁸ Therefore, both transabdominal and transvaginal transducers will be utilized for measuring the lower uterine segment during pregnancy. A strong correlation between these

measurements can indicate equivalent accuracy, while weak correlation might invalidate our preference of transabdominal ultrasound. The published studies with proposed cut-off values for normal lower uterine segment, whether with transvaginal or transabdominal ultrasound, do not precisely show how the measurement was taken and leave several unanswered questions regarding standardization.¹⁹ This study describes and shows exactly how the lower uterine wall is measured over a 3 cm segment and takes into account the urinary bladder volume. The fullness of the bladder affects the evaluation of uterine wall; therefore, we document the bladder volume during the examination. The ultrasound examinations are performed by experienced sonographers with level 2 certification from the German Society for Ultrasound in Medicine.²⁰ Blinded cross evaluations of the performed scans will be crucial for testing the interobserver variability and the validity of the method.

It has been shown that the scar changes throughout pregnancy, and scars with the largest initial dimensions show bigger change and thinner RMT at third trimester.²¹ Moreover, it is believed that the appearance of the scar in a non-pregnant uterus can affect its performance in a subsequent pregnancy and effectively predict successful vaginal delivery after CS.²² This is the first study that demonstrates the changes of the scar longitudinally throughout pregnancy starting from a non-pregnant uterus. This is especially important after the guidelines for niche assessment were published by Jordans et al. in 2019.15 These measurements are standardized and might confirm the importance of the scar characteristics in predicting pregnancy outcome. This thinking is in line with inverting the prenatal care pyramid, and concrete findings from this study can lead to the integration of pregestational sonographic uterine assessment at the base of the pyramid for every woman with a history of CS.²³

The developing countries are faced with increasing CS rates that depict challenging consequences in the years to come. It is essential to construct evidencebased knowledge about CS scars in order to respond to the needs of our patients. Exploring the characteristics of these scars is fundamental for establishing norms, upon which future research can be found, and this study is a step in that direction.

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Disclosure

All authors confirm that there is no conflict of interest to be declared.

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