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Comparison of transvaginal ultrasound and saline contrast sonohysterography in evaluation of cesarean scar defect. A prospective cohort study

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Conflicts of Interests statement

None of the authors have any relevant financial, personal, political, or religious interest linked to the subject of this article.

Abstract

Introduction

The aim of this study was to investigate the prevalence of post-cesarean isthmocele and to measure agreement between transvaginal ultrasonography and saline contrast sonohysterography in assessment of isthmocele.

Material and methods Prospective observational cohort study was carried out at Tampere University Hospital, Finland. Non-pregnant women delivered by cesarean section (n=371) were examined with TVUS and SHG six months after cesarean section. The main outcome measure was the prevalence of isthmocele using TVUS and SHG. Secondary outcome measures were characteristics of isthmocele.

Results Three hundred and seventy-one women were included. The prevalence of isthmocele was 22.4% based on TVUS and 45.6% based on SHG. Sensitivity and specificity for TVUS was 49.1 and 100% when compared to SHG. Therefore, half of the defects (50.9%) diagnosed with SHG remained undiagnosed with TVUS. Bland-Altman analysis showed an underestimation of 1.1 mm (range 0.00 to 7.90) for TVUS compared to SHG, with 95% limits of agreement from -1.9 to 4.1 mm.

Conclusions This methodological study provides confirmatory data that TVUS and SHG are not in good agreement in the isthmocele diagnostics and the use of only TVUS may lead to an underestimation of the prevalence of isthmocele. Thus, SHG should be considered as a method of choice in diagnostics of isthmocele.

Keywords Cesarean scar defect, isthmocele, niche, sonohysterography, cesarean section

Abbreviations

TVUS Transvaginal ultrasonography

SHG Sonohysterography

CS Cesarean section

US Ultrasonography

Key message

According to this large prospective study, sonohysterography is a method of choice in assessing cesarean scar defect in non-pregnant women.

Introduction

In the past decades, the cesarean section (CS) rate has increased worldwide. In 2014 over 1.2 million CS deliveries were performed in the USA, which was 32.2% of all deliveries (1). In China, the annual number of CS has been over 5 million for many years and between 2008-2014 the CS rate increased from 28.8 to 34.9%, which corresponds to a mean increase of 1.0 percentage point per year (2). According to WHO there are countries in which the CS rate has increased up to 56% (3).

Together with the growing CS rate, also the complications related to CS increase. One of the known complications is a defect of the uterine wall at the site of the CS scar called isthmocele or niche. It has been associated with adverse pregnancy outcome, higher risk of complications during gynecological procedures as well as clinical symptoms such as postmenstrual bleeding (4–7).

In previous studies the prevalence of isthmocele has ranged from 6.9% to 69% (8,9). The great variability may be caused by different definitions of isthmocele, various study designs and different diagnostic methods (5,10). Moreover, in most of the studies the patient material has been selected, i.e., only symptomatic patients have been enrolled (8,11–15). There are only few prospective studies addressing the prevalence of isthmocele. However, in these studies participants have been asked to participate several months after CS resulting in a possibility of selection bias (9,16). Various imaging methods have been utilized for assessing an isthmocele, which is often visualised in the uterine isthmus. Nowadays ultrasonography (US) has replaced other methods such as radiology based hysterography. Transvaginal ultrasonography (TVUS) has been considered as an accurate method for detecting isthmocele (9). However, contrast-enhanced sonohysterography (SHG) seems to facilitate its detection and measurement in non-pregnant woman (17). For this reason Vaate et al proposed that SHG should be the method of choice in the evaluation of isthmocele (5). Thus, the role and reliability of TVUS has remained controversial.

Using an unselected population of women who delivered by CS, we have performed a large prospective study to compare two different, widely accepted methods of imaging an isthmocele. Women were recruited at the time of CS and US examinations were performed six months later.

The aim of this study was to determine the prevalence of isthmocele and more specifically, to compare TVUS with SHG in the detection of isthmocele.

Methods

This prospective observational study was initially designed to assess the prevalence, risk factors and clinical outcome of cesarean scar defect. Here we report the results of comparison of TVUS and SHG in evaluation of CS scar, while the risk factors and clinical outcome are to be reported after follow-up of the participants. The study was carried out at Tampere University Hospital, Tampere, Finland. The study was registered in ClinicalTrials.gov (ClinicalTrials.gov Identifier: NCT02717312). All consecutive women who delivered by CS at Tampere University Hospital between January 2016 and February 2017 were asked to participate. Women were recruited either before the CS in the case of elective surgery or within three days of the operation in the case of emergency CS. Written informed consent was obtained from all participants. Exclusion criteria were a known anomaly of uterus, a lack of common language and age under 18. Participants were evaluated by TVUS followed by SHG six months after the CS. This time point was chosen due to previously reported healing time of six months of cesarean scar (18,19). US evaluations were performed at Tampere University Hospital. All US examinations were performed by the first author, who was blinded to the number of CSs and obstetric history of the women.

Transvaginal sonography

Women were examined in lithotomy position with empty bladder using Samsung WS80 Elite (Samsung Healthcare). The examination was performed in a random phase of the menstruation cycle but in the case of no contraception it was performed only in follicular phase to avoid an early pregnancy. The uterus was examined in a standardized way (10). Isthmocele was defined as an anechoic defect communicating with the endometrial cavity at the anterior wall of lower uterine segment. In longitudinal plane, the scar was identified and the depth and width of a possible isthmocele was measured. The length of the isthmocele was measured in transverse plane. If there was a visible isthmocele, the residual myometrial thickness (RMT) overlying the isthmocele and the adjacent myometrial thickness fundal to the isthmocele were measured. In case of more than one defect, the largest one was measured. As described in previous studies, the definition of isthmocele was a depth of the defect at least 2.0 mm in longitudinal plane (4,20). The US measurements are described in detail in Figure 1.

Sonohysterography

Right after the TVUS, sonohysterography was performed. A small catheter (Insemination cannula standard, Laboratoire CCD, Paris, France) was inserted into the uterus and sterile saline was flushed until the site of the caesarean scar was visualised. The used volume of saline solution was measured. In SHG analyses, equal measurements of the uterus were performed as described in the case of TVUS examinations (Figure 1) and the same definition of isthmocele was maintained.

Statistical analyses

This study is a part of our DICE-trial (**D**efect **i**n **Ce**sarean Scar), which was designed to investigate the prevalence, risk factors and clinical outcome of isthmocele. Here we report the results of US evaluation of CS scar by two different methods. The sample size of the whole study was calculated to investigate the clinical outcome (i.e. incidence of bleeding disorder) related to isthmocele. We wanted to detect a twofold increase of bleeding disorder in women diagnosed with isthmocele. Based on previous studies we assumed that the prevalence of bleeding disorder among patients without an isthmocele is approximately 15% (16).The prevalence of isthmocele in previous studies has been on average 50% (16). To achieve a 80% power with alpha of 0.05, and an anticipated dropout rate of 30%, we needed to include a total of 400 women. Risk factor analysis and clinical outcome of isthmocele will be reported in subsequent publications. Data was analysed using SPSS version 22.0 (IBM Corp, Armonk, NY). Chi-square test was used to compare the prevalence of isthmocele by TVUS and SHG in subgroups of elective and emergency CS. Cases of previous CS were categorized (no previous CS, one previous CS and ≥2 previous CS) and the prevalence of isthmocele by TVUS and SHG in each category of previous CS was also assessed. Bland-Altman plot was used to compare the two different methods of imaging in order to see whether they agree sufficiently (21,22).

Ethical approval

The study was approved by the Regional Ethical Committee of Tampere University Hospital, Tampere, Finland. Approval was granted on 2 September 2015 (ref. no. R15104).

Results

Altogether 401 women gave an informed consent. Three women were excluded because of pregnancy at the time of scheduled US examination; one was excluded because of severe vulvodynia, which made it impossible to perform SHG. Twenty-six women refused to continue the study. Three hundred seventy-one women were examined successfully by both TVUS and SHG. There were no complications during SHG, which was well tolerated by all women. Patient characteristics and sonographic results are shown in Table 1. Median age of participants was 32.4 (range 19–46) years. A total of 364 (98.1%) participants received a low transverse uterine incision. There were four (1.1%) J-shaped incisions, one vertical incision, one ruptured CS scar and one T-shaped incision in the study cohort. The uterine incision was sutured in double-layer in 370 out of 371 women.

The prevalence of isthmocele was 22.4% by TVUS and 45.6% by SHG. Sensitivity and specificity for TVUS was 49.1 and 100% when compared to SHG. Therefore, half of the isthmoceles (50.9%) diagnosed with SHG remained undiagnosed with TVUS. The prevalence of isthmocele in the subgroups of elective vs emergency CS diagnosed either with TVUS or SHG did not differ significantly (p=0.237 and p=0.898, respectively). The prevalence increased with the increasing number of previous CS diagnosed by either TVUS or SHG (OR 1.83 and OR 2.64, respectively), but the difference in the detection rate between TVUS and SHG remained. The prevalence of isthmocele diagnosed by TVUS and SHG was 18.9% and 35.4% in the subgroup of no previous CS; 22.6% and 63.1% in the subgroup of one previous CS; and 48.5% and 78.8% in the subgroup of ≥2 previous CS, respectively.

The median depth of isthmocele was 3.0 mm (±SD 1.1 mm) with TVUS compared to 3.3 mm (±SD 1.8 mm) with SHG. Most of the isthmoceles were triangular in shape (92%), while the rest were round or oval. Median volume of flushed saline was 7 ml (range 1-20). There was no difference in the saline volume between isthmocele and non-isthmocele groups (p=0.290).

Figure 2 shows an image of a small isthmocele with concordant results with both TVUS and SHG. In contrast, in figure 3 there is an isthmocele, which seems to be unimportant based on TVUS but appears more obvious with saline contrast SHG.

We used Bland-Altman plot to measure the agreement between TVUS and SHG. Figure 4 demonstrates the difference between the depth of an isthmocele measured by TVUS and SHG. It shows an underestimation of 1.1 mm (range 0.0 to 7.9) for TVUS compared to SHG, with 95% limits of agreement from -1.9 to 4.1 mm.

Residual myometrial thickness overlying the isthmocele was measured only when there was any visible indentation at the site of the cesarean scar. With TVUS an underestimation of RMT was 0.3 mm compared to SHG (range 0.00 to 15.55) with 95% limits of agreement from -3.8 to 3.2 mm. To determine a low RMT, we used a cut-off point of 3.0 mm. Thus, 59 (15.9%) and 73 (19.7%) of participants had RMT<3.0 mm with TVUS and SHG respectively. If SHG was considered as a reference method, sensitivity and specificity for TVUS were 50.7% and 92.6%, respectively.

Discussion

In this study, two different methods were compared in the diagnosis of cesarean scar defect. According to our results, TVUS leaves approximately half of the isthmoceles undiagnosed. These include even large isthmocele defects, which may be clinically relevant. Indeed, our results suggest that SHG is needed if the exclusion of isthmocele is truly warranted, because TVUS and SHG do not measure exactly the same phenomenon suggested by Bland-Altman analyses. Similarly, when measuring residual myometrium, almost half (49.3%) of the cases in which the RMT is <3.0 mm remain undiagnosed with TVUS compared to SHG. We used a cut-off level of 3.0 mm for RMT because it has been used in clinical practice to identify patients eligible for hysteroscopic resection of isthmocele (23). The type of CS (elective vs. emergency) or a history of previous CS did not influence the prevalence of isthmocele detected either with TVUS or SHG.

In the present study, women were prospectively recruited within three days of unplanned emergency CS or prior to elective CS, which can be regarded as strength of the present study. Vast majority of the previous studies assessing the prevalence of isthmocele have recruited the participants retrospectively. We think that this may have caused selection bias at least partly explaining the vast variation of previously reported prevalence numbers. Delayed recruitment can lead to enrichment of study population by for example symptomatic patients. Thus, our study can be regarded as a valuable amendment to the scarce previous data.

In this comparative study of two different methods, it can also be regarded as 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. Additionally, as far as we know, this is the largest prospective study carried out assessing cesarean scar prevalence by both TVUS and SHG with altogether 371 women included.

It is a limitation of the study that the same investigator performed both examinations. It can be argued that the SHG findings might have been affected by the previous TVUS findings leading to possible subjectivity of the data and ruling out the possibility to make inter-observer comparisons. This design was chosen due to practical reasons considering that performing US examinations of 371 women is quite laborious even for one researcher. However, the study design corresponds to the situation in everyday clinical practice where both examinations are performed one after the other. Therefore we do not think this could have caused a significant bias particularly when the prevalence of isthmocele was smaller by TVUS, which was performed first.

Another limitation of the study is the lack of an objective reference when comparing these two methods of imaging. In an ideal situation hysteroscopy could have provided a reference method to reveal the presence of isthmocele. However, hysteroscopy is also dependent on the surgeon who performs the procedure and is not totally objective. Here, our aim was to measure the agreement between two easily accessible and widely used non-invasive methods to diagnose the isthmocele. In order to evaluate the agreement between these two methods of clinical measurements, we used Bland-Altman analysis allowing analyses without a reference or golden standard.

The prevalence of isthmocele in our population was 22.4% with TVUS and 44.6% with SHG, which is comparable to a previous prospective study (16). Vaate et al. (16) reported the prevalence of 24.0% with TVUS and 56.0% with SHG when assessing a possible isthmocele 6-12 months after the CS. In their study, participants were recruited up to nine months after the operation.

Van der Voet et al. (4) found clearly higher prevalence in their population (49.6% and 64.5% with TVUS and SHG, respectively) but they performed ultrasound examination as early as 6-12 weeks after CS, which may have influenced the obtained result, since wound-healing process may still have been ongoing. We decided to perform the examinations six months after CS because it has been suggested that the cesarean wound healing process will take up to at least six months (18,19).

TVUS has been considered as a reliable method to detect an isthmocele by Osser et al (9). However, the same group stated later that the prevalence was nevertheless higher with SHG than with TVUS and isthmoceles appeared to be bigger with SHG (17). In that particular study only in 43% of cases TVUS and SHG were performed at the same visit and the participants were recruited several months after the CS. Our results show that the agreement between TVUS and SHG is not good. Half of the isthmoceles diagnosed with SHG remained undiagnosed with TVUS. When evaluating RMT, which is crucial when surgical treatment is considered, half of women (49.3%) with low RMT (< 3.0 mm) remain undiagnosed with TVUS. On the other hand, not even SHG is perfect as in some instances, low RMT values were detected with TVUS while SHG appeared as normal. However, the use of contrast-enhancement in transvaginal sonography seems to enable a better demarcation of isthmocele and both the defect and the RMT can be more exactly measured.

Conclusion

Several previous studies have attempted to evaluate isthmocele by using TVUS or SHG in non-pregnant women. To the best of our knowledge, our study is the first study, which compares the agreement of these two methods in a large prospectively collected unselected population examined at one visit. Our results suggest that the use of only TVUS may lead to an underestimation of the prevalence of isthmocele and that SHG should be considered as the method of choice in diagnostics of isthmocele. We also acknowledge that the clinical outcome and significance of isthmocele detected by SHG will be ascertained only in the course of follow-up of our prospective study cohort.

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Legends of Tables and Figures

Figure 1.

Following measurements were performed in longitudinal plane: a. Depth of isthmocele, b. Width of isthmocele, c.Thickness of adjacent myometrium, d. Thickness of residual myometrium. In transverse plane: e. Length of isthmocele.

Figure 2.

Legend: Both TVUS (A) and SHG (B) showing concordant results for a small isthmocele.

Footnote: D1 depth of isthmocele, D2 width of isthmocele, D3 thickness of residual myometrium, D4 thickness of adjacent myometrium.

Figure 3.

Legend: An isthmocele which with TVUS (A) seems to be unimportant but SHG (B) reveals more obvious defect.

Footnote: D1 depth of isthmocele, D2 width of isthmocele, D3 thickness of residual myometrium, D4 thickness of adjacent myometrium.

Figure 4.

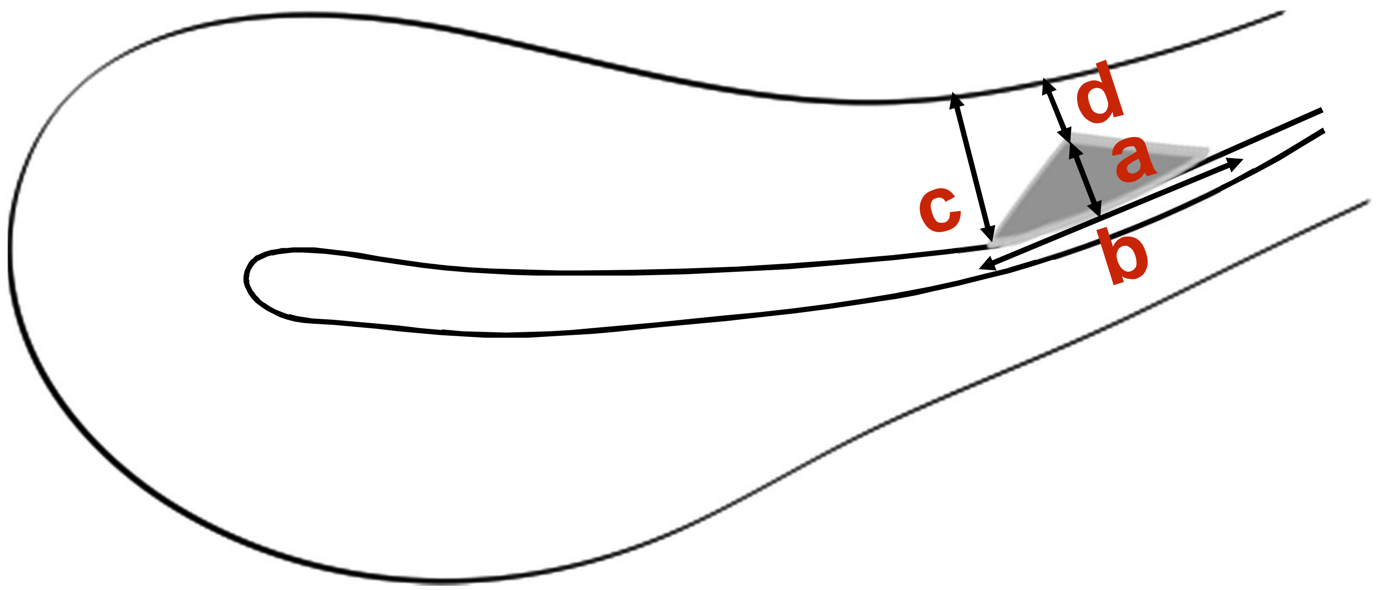
Bland-Altman plot for differences in depth of isthmocele measured by TVUS and SHG. Dashed lines represent the 95% limits of agreement for a depth of isthmocele.

Table 1.

Legend: Patient characteristics and ultrasonographic results.

Footnote: CS, Cesarean Section. US, ultrasonography. TVUS, transvaginal ultrasonography. SHG, sonohysterography. RMT, residual myometrial thickness. AMT, adjacent myometrial thickness.

[a] n=83, [b] n=169.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a
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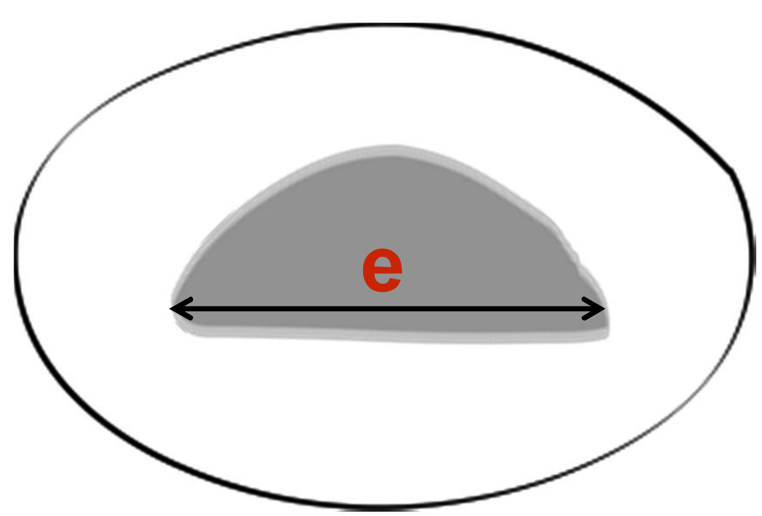
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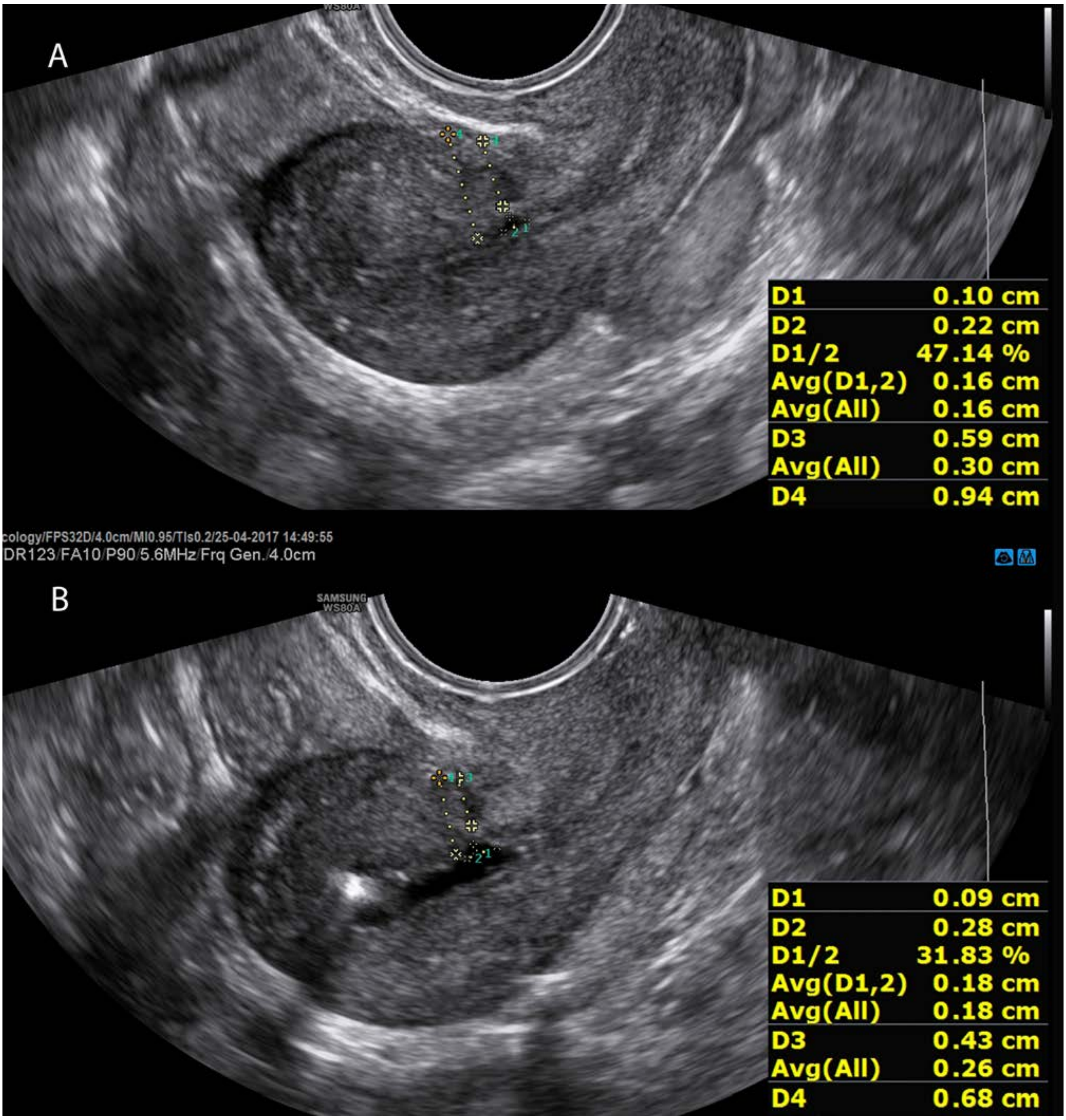
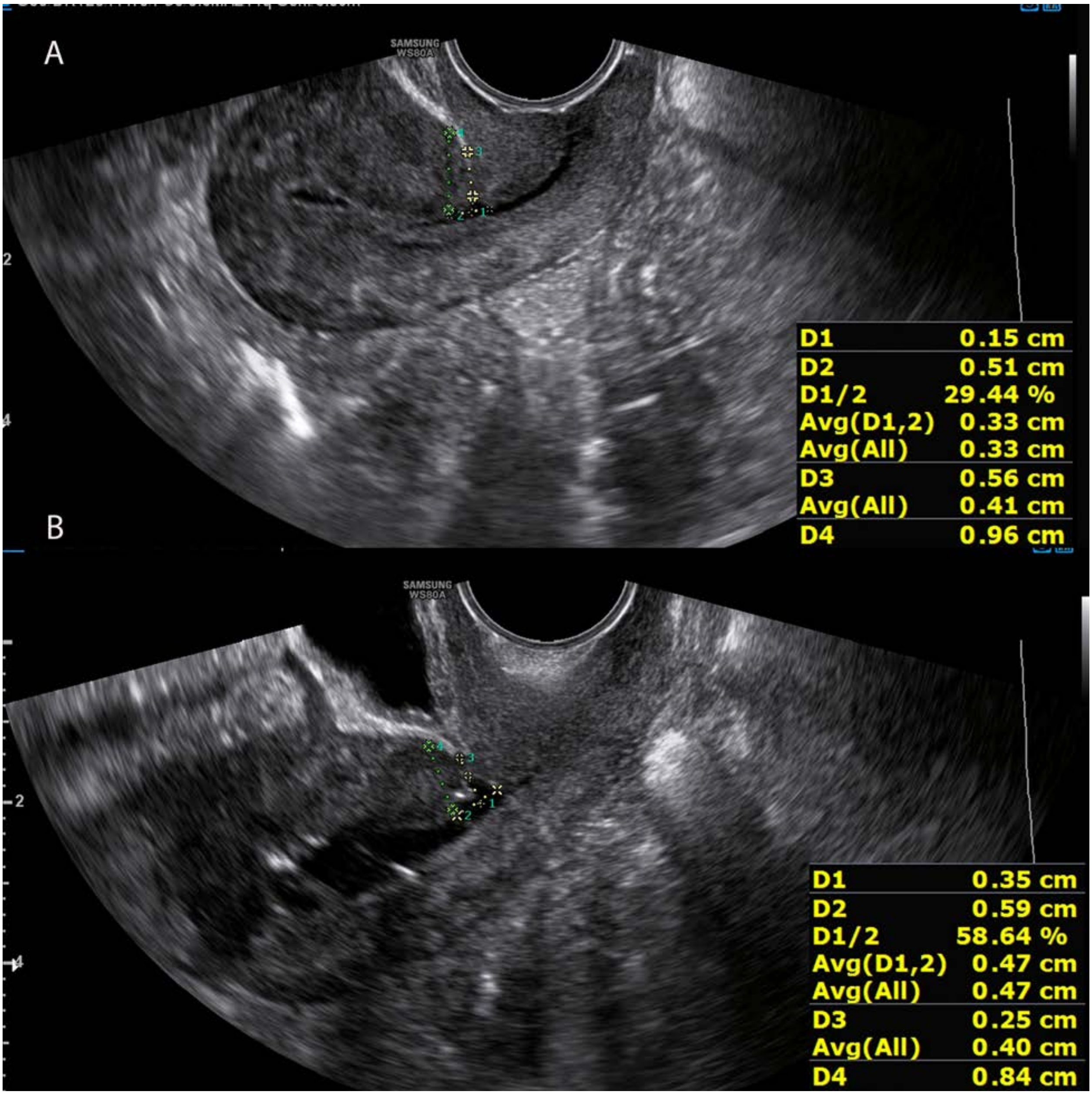
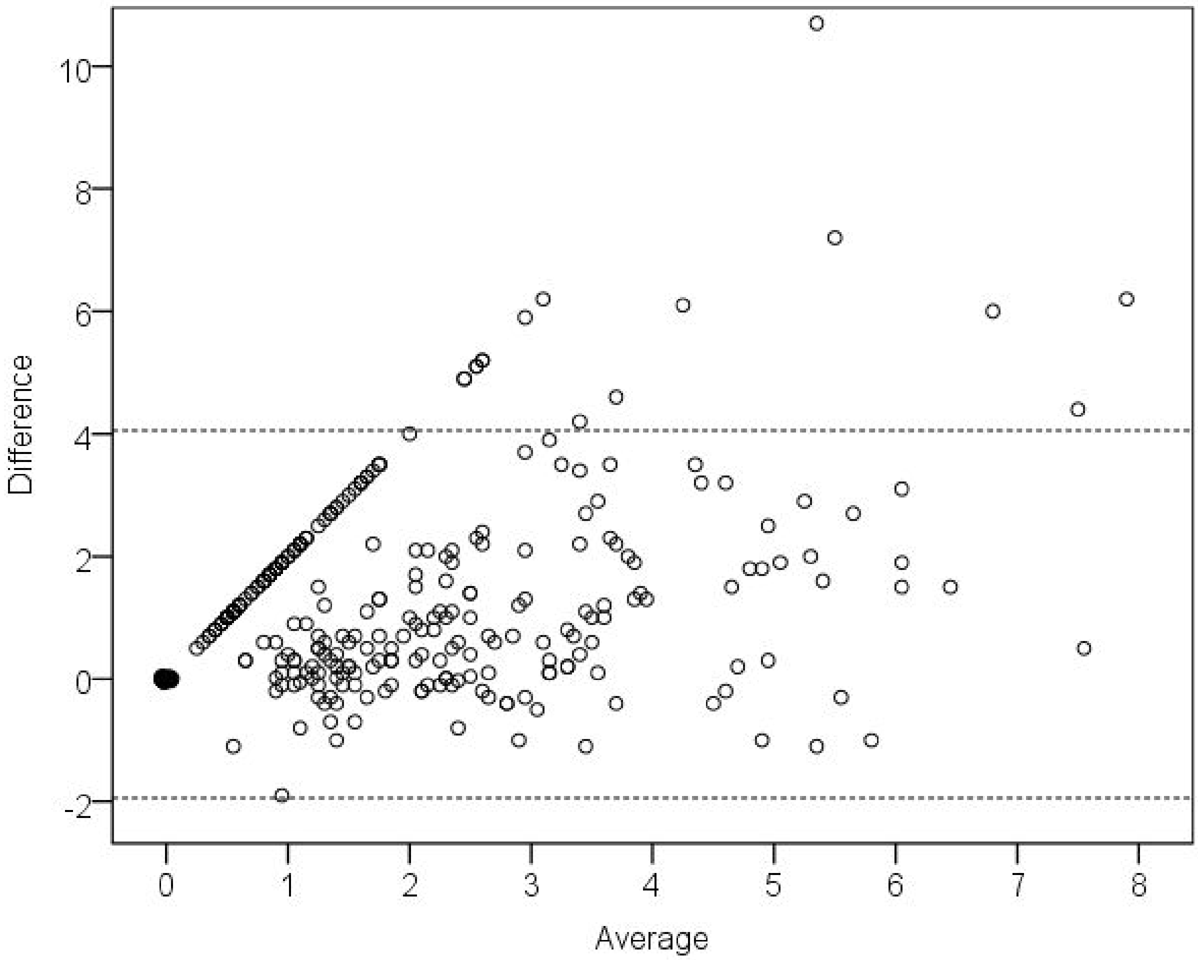

A
D1 0.10 cm
D2 0.22 cm
D1/2 47.14 %
Avg(D1,2) 0.16 cm
Avg(All) 0.16 cm
D3 0.59 cm
Avg(All) 0.30 cm
D4 0.94 cm
cology/FPS32D/4.0cm/MI0.95/TIs0.2/25-04-2017 14:49:55
DR123/FA10/P90/5.6MHz/Frq Gen./4.0cm
B
SAMSUNG WS80A
D1 0.09 cm
D2 0.28 cm
D1/2 31.83 %
Avg(D1,2) 0.18 cm
Avg(All) 0.18 cm
D3 0.43 cm
Avg(All) 0.26 cm
D4 0.68 cm


A
B
D1 0.15 cm
D2 0.51 cm
D1/2 29.44 %
Avg(D1,2) 0.33 cm
Avg(All) 0.33 cm
D3 0.56 cm
Avg(All) 0.41 cm
D4 0.96 cm
D1 0.35 cm
D2 0.59 cm
D1/2 58.64 %
Avg(D1,2) 0.47 cm
Avg(All) 0.47 cm
D3 0.25 cm
Avg(All) 0.40 cm
D4 0.84 cm


10
8
6
4
2
0
-2
Difference
0
1
2
3
4
5
6
7
8
Average

Patient characteristics	n=371
Maternal age (years), mean (SD)	32.5 (5.3)
Gestational age (weeks), mean (SD)	39+2 (2)
Parity, n (%)	
1	313 (84.4)
2	39 (10.5)
3	11 (3.0)
≥4	8 (2.1)
Number of previous CS, n (%)	
0	254 (68.5)
1	84 (22.6)
2	25 (6.7)
3	8 (2.2)
Type of CS, n (%)	
elective	155 (41.8)
emergency	216 (58.2)
Ultrasonographic results	
Time from CS to US (months), mean (SD)	6.7 (0.8)
Detected isthmocele, n (%)	
TVUS	83 (22.4)
SHG	169 (45.6)
Depth of isthmocele (mm), median (range)	
TVUS[a]	3.0 (2.0-7.3)
SHG[b]	3.3 (2.0-11.0)
Width of isthmocele (mm), median (range)	
TVUS[a]	3.5 (0.9-11.4)
SHG[b]	4.9 (1.0-14.3)
Length of isthmocele (mm), median (range)	
TVUS[a]	7.7 (2.3-16.4)
SHG[b]	8.2 (2.7-19.0)
RMT (mm), median (range)	
TVUS[a]	3.3 (0-9.9)
SHG[b]	3.7 (0-10.3)
RMT/AMT (mm), median (range)	
TVUS[a]	0.49 (0-0.99)
SHG[b]	0.60 (0-1.00)
Volume of flushed saline (ml), median (range)	7 (1-20)
Position of uterus	
anteversion	257 (69.5)
retroversion	113 (30.5)
Shape of an isthmocele, n (%)	
triangular	257 (91.8)
round	11 (3.9)
oval	7 (2.5)
total defect	5 (1.8)