A comparison of ultrasonic measurement techniques for the maternal cervix in the second trimester

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Abstract

Introduction: The appropriate ultrasound technique to assess the maternal cervical length in women at low risk of preterm birth is yet to be established. This study aimed to determine the accuracy of different ultrasound approaches for measuring the maternal cervix in patients between 17 and 22 weeks gestation.

Methods: The prospective study recruited 50 patients who were at a low risk of preterm birth. All measurements were acquired by one operator who was blind to the measurements being acquired in all approaches. The cervical length was registered using the transabdominal approach with a full and empty bladder, the transperineal approach and the transvaginal. The transvaginal approach was used as the reference measurement.

Results: The transabdominal full bladder, post void, transperineal and transvaginal measurements were obtainable in 50, 49, 45 and 50 participants respectively. The transabdominal post void measurements showed a bias of -0.06 mm from perfect agreement with transvaginal. The transperineal measurements showed a bias of -0.16 mm. The transabdominal full bladder measurements were positively biased by 14.05 mm ($p < 0.05$). All transabdominal post void cervical lengths of 30 mm or greater registered a transvaginal cervical length greater than 25 mm in this study.

Conclusion: The cervix should not be assessed in the transabdominal approach with a full maternal bladder due to overestimation of cervical length. Transvaginal cervical length can be reproduced accurately by post void transabdominal cervical length in most cases. Transperineal cervical length should be considered if transvaginal cervical length is contraindicated.

Keywords: cervix, maternal, preterm birth, transvaginal, transperineal, transabdominal, ultrasound.

Introduction

Over the last decade, little progress has been made in understanding and preventing preterm birth (PTB), and the incidence of spontaneous PTB has continued to rise, even in low risk women.[1] It has been shown that a sonographically shortened cervix is a powerful indicator of PTB in women with singleton and twin gestations - the shorter the cervical length (CL), the higher the risk of spontaneous PTB.[2]

A review of three trials performed over the last decade found that screening of CL and treatment with daily progesterone in cases of a shortened CL resulted in a reduction in PTB rates and neonatal morbidity and mortality. It was found that 400 to 600 ultrasound examinations would be required to prevent one early PTB of < 34 weeks gestation, and that universal screening and daily progesterone will reduce overall spontaneous delivery before 34 weeks from 2.11 to 1.85%. These studies included women with a previous PTB.[3]

A further recent meta-analysis found that seven patients were required to have vaginal progesterone treatment (as opposed to placebo) to prevent one case of PTB or perinatal morbidity/mortality at less than 32 weeks gestation. The corresponding numbers needed for treatment with cerclage were 10 for PTB and 11 for perinatal morbidity/mortality.[4] The cervical pessary has been shown to have a significant reduction in spontaneous delivery before 34 weeks in single and multiple gestations.[5]

A recent study of 2998 women between 22 and 24 weeks gestation assessed the use of transvaginal cervical length screening in a high and low risk population. Utilising a cervical length of 20 mm, to prevent one case of prior to 34 weeks spontaneous PTB in high risk, nulliparous and low risk patients (at least one prior full term delivery), they concluded we would need to perform 97, 221 and 802 ultrasound examinations respectively.[6]

The transvaginal (TV) ultrasound (US) approach is considered the 'gold standard' for measurement of CL. It has been established that

women who are at a clinically increased risk of PTB should have cervical length assessment performed with the transvaginal approach.[7] The appropriate method for screening the maternal cervix in low risk women is debatable.[8] It has been recommended that further investigation of transabdominal (TA) CL screening and determination of a threshold TA CL above which no women would have a short TV CL was needed.[3,9,10]

There have been prior studies comparing the TA to the TV approach and also the transperineal (TP) to the TV approach. These studies have had varying methodology and outcomes. This research was developed to compare the performance of the TA approach using a full and empty maternal bladder, and also the TP US approach to the TV approach, for the measurement of CL during the second trimester. This research utilised one operator to collect all data and was unique in that the operator was blind to all registered measurements in all ultrasound approaches.

Research methods

Participant recruitment

The study was approved by the Institutional Review Board (IRB) and the informed consent was obtained from all patients.

Over a period of 11 months from February 2013 to January 2014, 167 women were asked to participate in this study. Of these women 12 (7.2%) were excluded from the study, 9 women (5.4%) were unable to consent due to an inability to understand the participant information and 96 (57.5%) did not consent to participate.

The 50 women (29.9%) who consented had an average age of 29 years (range 19–41). Of these 50 women 38% were in their first pregnancy, 32% in their second, 12% in their third, with the remaining ranging from their fourth to seventh pregnancy.

This was a cross-sectional study with participants from all age groups, ethnicities and socioeconomic status included in the study group. Participants of varying parities were also included in the study, with all participants at a historically low risk of PTB. The participants were between the gestations of 17 and 22 weeks of pregnancy and attending the department for their routine screening anatomy scan. Patients were excluded from the study due to the following reasons: unable to give informed consent, < 18 years of age, past medical history (PMH) of preterm deliveries, PMH of cervical cerclage, PMH of cone biopsy or Large Loop Excision of the Transformation Zone (LLETZ) procedure on cervix, any cervix with suspicion of premature rupture of membranes (PROM) on the TA approach, vaginal bleeding, vaginal fluid loss, multiple gestations.

Scanning and measurement protocols

All images were acquired using the Toshiba Aplio 500 (Japan) ultrasound machine.

The cervix was measured initially using the TA approach with a full maternal bladder (TAF). The cervix was then measured post void using the TA approach (TAE), TP and then TV approaches. The TA approach was imaged using the 6C1 curvilinear transducer set at a transducer frequency of T4mHz. The TP approach was imaged using the same 6C1 transducer as the TA approach, set at a transducer frequency of T3mHz. The TV approach was imaged using the 6PV1 VT, TV transducer with a frequency of 7.3 mHz.

The TA full bladder and post void measurements were obtained with the patient in a supine position. The full bladder approach uses the maternal bladder as an acoustic window. The TA post void approach utilises the amniotic fluid as the acoustic window. The transducer placement was slightly cephalic with a caudal tilt to visualise the cervix. The transducer was manipulated with oblique and parasagittal movements to delineate the length of the cervical canal and internal and external os.

The TP CL was obtained with the patient's hips elevated on a supportive lithotomy sponge. Placing the patient in an elevated lithotomy position helps alleviate rectal gas overlying the external os. The transducer was placed in a sterile latex free cover and sterile gel is used as a coupling agent. The transducer was placed on the labia majora or perineum. Oblique or parasagittal movements were used to delineate the full length of the cervical canal.

The TV approach used a high frequency endovaginal transducer. The transducer was placed in a probe cover and sterile gel was used as a coupling agent. The patient was placed in the elevated lithotomy position for this approach also. The transducer was placed into the vagina on the anterior fornix of the cervix and advanced far enough to visualise the cervical canal. Oblique or parasagittal movements were used to delineate the full cervical canal. The transducer was then withdrawn till the image became out of focus and then advanced again just enough to bring the cervix back into focus. This technique was used to alleviate pressure on the cervix from the transducer that can cause artifactual lengthening of the cervical canal.

The cervix and uterus are dynamic organs that will both change in appearance throughout the ultrasound examination. The post void measurements inclusive of the TA, TP and TV approaches of the cervix were obtained in a consecutive fashion to help avoid variability in the appearance of the cervical canal due to uterine and cervical contractions. All measurements were acquired twice in each ultrasound approach. The principal operator was blind to the measurements registered in all ultrasound approaches, as seen in Figure 1 the registered length was not visible on the acquired ultrasound image. The registered measurements were input into a calculation package and collated by the principal operator at the conclusion of the examination. The images were reviewed by the primary operator and a second sonographer with more than 15 years of experience.

All of the measurements were performed by an experienced sonographer with more than 20 years of experience in ultrasound imaging. The protocols were specified to achieve consistency with cervical measurements.

Measurement of cervical length

All CL measurements used a single straight line technique with caliper placement at the internal and external os for all approaches. For all ultrasound approaches the hyperechoic cervical mucosa should be seen in its full length. The adjacent hypoechoic cervical glandular tissue may also be visible. The caliper placement for the internal os should be adjacent to the cervical mucosa at the point where the opposing sides of the cervix come together and form a flattened T-shape appearance. The caliper placement for the external os should be adjacent to the cervical mucosa at the point where the cervix meets the vagina. This often appears as a very slight indentation, the posterior wall of the cervix should also be used as a guide for

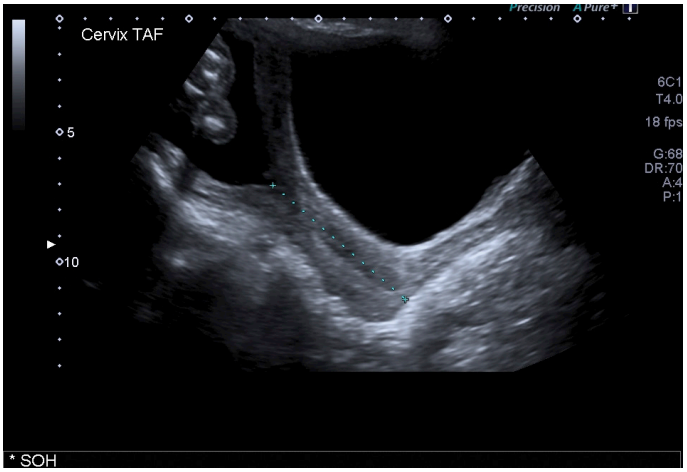

Figure 1: TA measurement of cervical length with a full bladder.

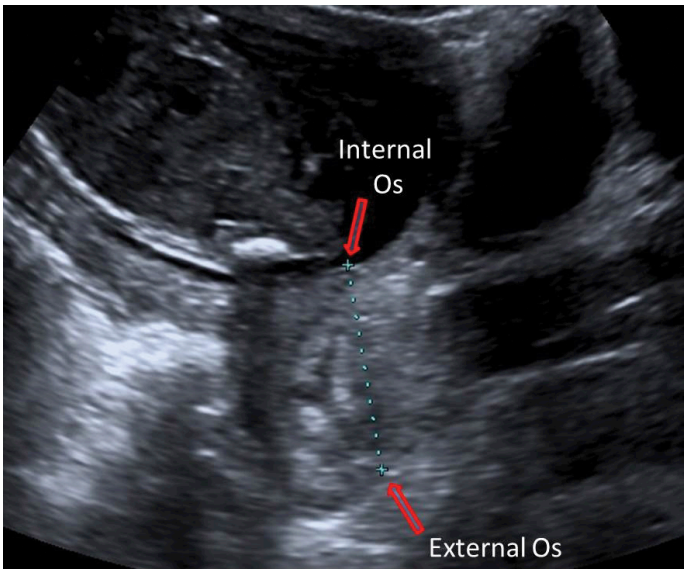

Figure 2: TA cervical length measurement post void.

caliper placement of the external os.[11–13] For this study in all likelihood the over-distended bladder in the TAF approach will cause the myometrium to be 'pushed' together to mimic the internal os, and this is where the caliper defining the internal os is placed. In the TP approach the external os may be seen as a small hypoechoic 'notch' on some patients.[10,13–15] In the TV approach the internal os may appear as a typical V-shaped notch. It may also appear as the flattened T-shape appearance. The external os is often seen with a triangular notch.[11,14,16]

Figures 1 to 4 are examples of caliper placement for the measurement of cervical length in the different ultrasound approaches used for this study.

Statistical analysis

Data analysis was performed using SPSS version 21.0 (SPSS V21.0, Chicago, USA). Descriptive data were presented as mean ± standard deviation (SD). All variables input to t-test procedures were first examined for normality with the Kolmogorov-Smirnov Test. None was found to deviate significantly ($p < 0.05$) from normality.

The TV method was used as the reference measurement for cervical length. The other ultrasound methods were assessed for

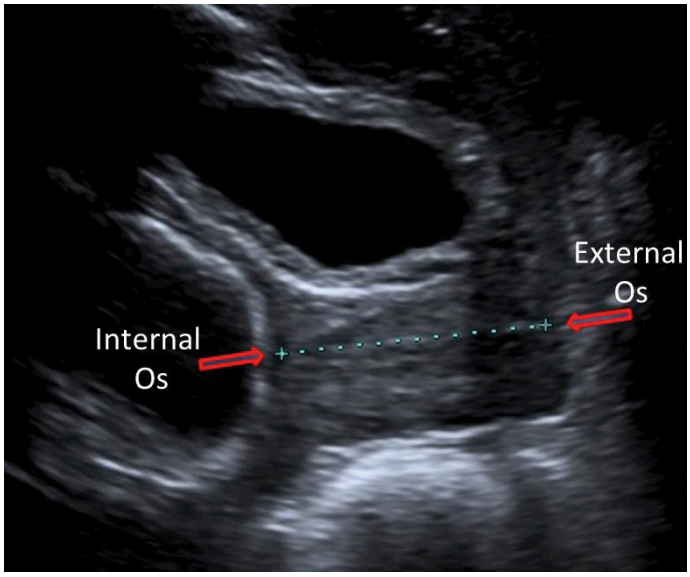

Figure 3: Measurement of cervical length using the TP approach.

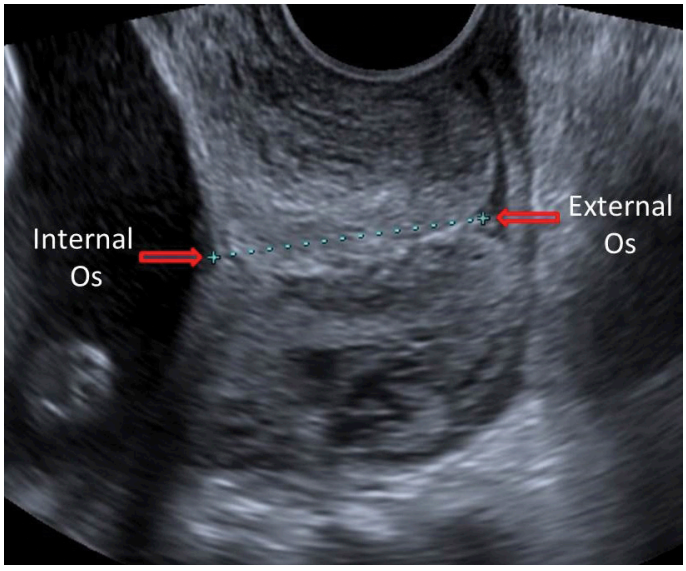

Figure 4: Measurement of cervical length using the TV approach.

difference from the reference length. We defined any observed difference between the two measurements as measurement bias. Thus, for example (TAF-TV) represents the measurement bias attributable to the TAF method, relative to the TV standard method. Each of the test methods was assessed for bias in this way.

Bias was assessed in two ways: 1) The mean of the array of 50 differences, one difference from each participant, was compared to an ideal value of zero using a 1-sample t-test. The null hypothesis, H_0: mean bias = 0, was tested against a two-sided alternative, at the 5% level of statistical significance, ($p < 0.05$). 2) Additionally, the bias values were plotted against the averages of the pairs of measured lengths using Bland-Altman plots.[16,17] This provides a visual indication of how the measurement bias varies, if at all, with a range of input cervical lengths in respect of both magnitude and trend.

Results

The TAF CL, TAE CL, TP CL, and TV CL measurement was obtained in 50 (100%), 49 (98%), 45 (90%), and 50 (100%) of participants, respectively.

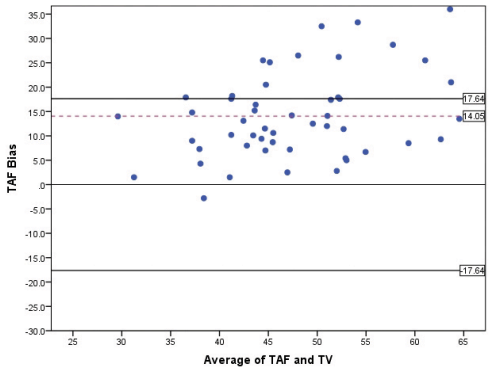

Figure 5: Bland-Altman plot of TAF vs TV bias, showing line of mean bias (14.05mm) and 95% tolerance limits about zero bias.

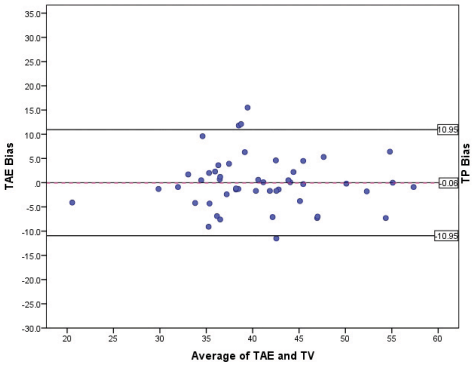

Figure 7: Bland-Altman plot of TAE vs TV bias, showing line of mean bias (-0.06mm) and 95% tolerance limits about zero bias.

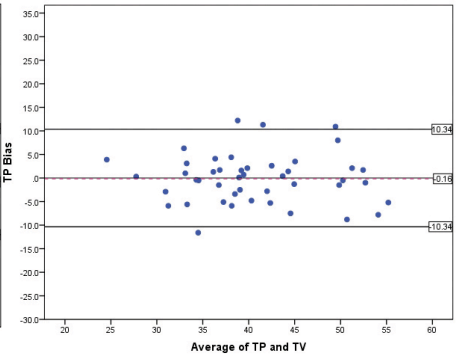

Figure 9: Bland-Altman plot of TP vs TV bias, showing line of mean bias (-0.16mm) and 95% tolerance limits about zero bias.

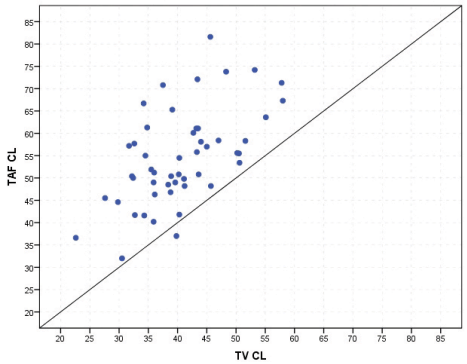

Figure 6: Scatterplot of TAF vs TV CL showing line of equal length.

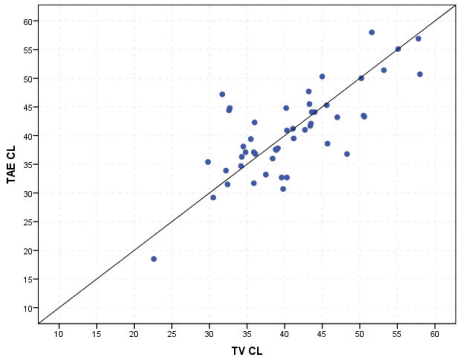

Figure 8: Scatterplot of TAE vs TV CL showing line of equal length.

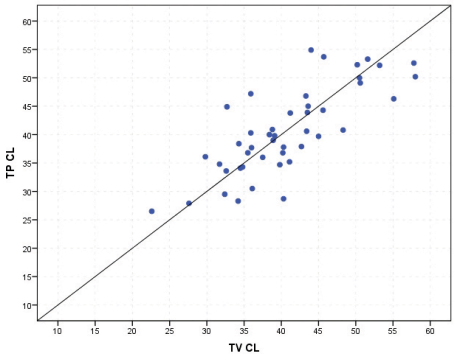

Figure 10: Scatterplot of TP vs TV CL showing line of equal length.

The mean TAF CL obtained for the 50 cases was 54.58 mm (SD 10.63). The mean TV CL obtained was 40.53 mm (SD 7.76). The mean difference of TAF and TV CL was significantly different from zero with a mean difference of 14.05 mm (SE 1.25); $t_{(49)}$=11.26, p <0.001. The Bland Altman plot seen at Figure 5 shows a significant positive bias of 14.05 mm for the TAF measurements away from the zero bias line in comparison to the TV measurements; this generally increases with increasing cervical length. The registered TAF and TV CL obtained for each of the 50 cases is also presented in Figure 6 in the format of a scatterplot which also displays the line of equal length.

The mean TV CL and TAE CL obtained for the 49 comparable cases were 40.80 mm (SD 7.60) and 40.74 mm (SD 7.49) respectively. The mean difference of TAE and TV CL was not statistically different from zero with a mean difference of -0.06 mm (SE 0.78); $t_{(48)}$= -0.08, p = 0.94. The Bland Altman plot seen at Figure 7 shows a large amount of values near the zero bias line and a very slight negative bias of -0.06. The registered TAE and TV CL obtained for each of the 49 cases is also presented at Figure 8 in the format of a scatterplot which also displays the line of equal length.

The mean TV CL and TP CL obtained for the 45 comparable cases were 40.76 mm (SD 7.87) and 40.60 mm (SD 7.69) respectively. The mean difference of TP and TV CL was not statistically different from zero with a mean difference of -0.16 mm (SE 0.77); $t_{(44)}$=-0.21, p = 0.84. The Bland-Altman plot seen at Figure 9 shows a large amount of values near the zero bias line and a very small negative bias of values of -0.16. The registered TP and TV CL obtained for each of the 45 cases is also presented at Figure 10 in the format of a scatterplot which also displays the line of equal length.

Discussion

This study has three important findings. Firstly, the TAF CL overestimates cervical length by a statistically and clinically significant amount. A second finding was that the TAE CL and TP CL showed quite close correlation with the TV CL, but the TP CL was not obtainable in a number of cases. A third significant finding was that all TAE CL's registered at 30 mm or greater registered a TV CL of greater than 25 mm.

This study reports a statistically and clinically significant difference between the mean TAF CL and TV CL of 14.05 mm for the 50 cases. Our findings are consistent with those reported in the literature, with a full bladder found to overestimate CL in other studies. Hernandez-Andrade, *et al.*[18] and Marren, *et al.*[19] found that a cervical length obtained with a full bladder overestimated the length compared to TV CL by 8 mm and 6.1 mm respectively. The TAF CL can also be problematic as the cervical canal may be compressed by the bladder and 'mask' the appearance of funnelling of the cervical canal due to premature rupture of membranes.[11]

There was a small difference between the mean TV CL and TAE CL of -0.06 mm for this study. Other studies also found that the mean TAE CL was shorter than TV CL, these studies reported the mean TAE CL -2.5 and -0.4 mm different respectively.[13,20]

Marren, *et al.*[19] found a mean difference of 0.6 mm between TAE and TV CL. The TAE CL was registered in 98% of cases in this research; Saul, *et al.*[13] were able to measure the TAE CL in 100% of cases. Studies by Marren, *et al.*[19] and Friedman, *et al.*[9] were able to register measurements for TAE CL in 82.8% and 82.1% of patients respectively.

There have been recommendations made by other researchers that there is a need for an established 'cut off' point where we can be confident that if the TA CL obtained is above a certain length that we can be confident that the TV CL would be greater than 25 mm. Freidman, *et al.*[9] concluded that a TA CL of 35 mm or greater would need to be obtained to be confident that the TV CL would be greater than 25 mm, if acquired with a full bladder. Marren, *et al.*[19] concluded that a policy of routinely performing the TA CL and proceeding to TV with a TAE CL < 25 mm would miss 67% of cases with a shortened CL. Saul, *et al.*[13] found that a post void TA cervical length cut off of 30 mm or less showed 100% sensitivity for identifying cervices with lengths of 25 mm or less on TV sonography.

This study only yielded two TV CL measurements less than 30 mm, the shortest TV CL obtained was 22.6 mm, and for this case the registered TAE CL was 18.5 mm. The one case in this study that could not be measured using the TAE approach was the second shortest measurement obtained with a TV CL of 27.6 mm. This resulted in 48 of the 49 comparable cases registering a TV CL greater than 25 mm, and of these 47 registered a TAE CL equal to or greater than 30 mm, with the remaining case having a TAE CL of 29.8 mm.

This study reports a difference of -0.16 mm between the mean TV and TP CL, but TP CL was only obtainable in 90% of cases. These results are similar to Cicero, *et al.*[20] who also looked at the cervix using the TP approach in the mid trimester (22-24 weeks). They showed a mean difference in CL of 0.2 mm between TV and TP CL, though were only successful in 80% of patients. Yazici, *et al.*[21] showed a mean CL difference of 1 mm between TP and TV approaches and were successful in measuring the TP CL in 89% of patients. The shortest TV CL obtained at 22.6 mm had a registered TP CL of 26.5 mm with the second shortest TV CL of 27.6 mm registering a TP CL of 27.9 mm. There were three further cases that registered a TP CL of less than 30 mm and all registered greater than 30 mm on TV CL.

Sonographer training and experience is a key factor in obtaining diagnostic images in all ultrasound approaches. The TA approach performed post void appears to be more successful in obtaining a CL than the TP approach. The TAE CL showed a slightly better correlation to TV CL than the TP approach.

The TV approach is technically easier to obtain in most patients, but experience is also required to utilise the correct technique and recognise key landmarks.

This study has some limitations that should be acknowledged. Firstly, the sample size is quite small, as the acceptance rate to participate in the study is relatively low. Excluding the women who were unable to consent for this study only 34% of women agreed to participate. Furthermore, it is based on a single centre experience with experienced operators.

Conclusion

In conclusion, the cervix should not be assessed using the transabdominal approach with a full maternal bladder due to overestimation of length. Transvaginal cervical length can be reproduced accurately by post void transabdominal cervical length. The transperineal approach is unsuccessful even with an experienced sonographer, and hence it only should be utilised if the transvaginal approach is contraindicated. The poor acceptance rate of women to undertake the transperineal and transvaginal approaches, and the close correlation of transabdominal post void cervical length to transvaginal cervical length warrants further investigation into the use of transabdominal empty bladder cervical length as a screening tool for preterm birth in low risk women. There is a need for standardisation of accepted landmarks and establishment of a standard transabdominal cervical length above which all transvaginal cervical lengths will be in the normal range. For this study all registered transabdominal post void cervical lengths of 30 mm or greater registered a transvaginal cervical length greater than 25 mm.

Acknowledgements

We would like to thank Ms Karen Rocke and Ms Emmeline Lee for their assistance in this study. Our great appreciation is given to Mr Gil Stevenson for his kind help with statistical analysis.

There was no source of funding for this article. There are no potential conflicts of interest for this article.

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