



COMPARISON OF TVS CERVICAL LENGTH AND CERVICAL ELASTOGRAPHY IN PREDICTING SPONTANEOUS PRETERM LABOUR

Dr. Ayesha Master

Resident in department of obstetrics and Gynecology, Jawaharlal Nehru medical college, DMIMS Sawangi (M), Wardha

Dr. Chella Hariharan Iyer*

Professor Obstetrics, Dept of Obgy, JNMC, Sawangi, wardha, chella
*Corresponding Author

Dr. Deepti Shrivastava

MD (OBGY), PhD, HOD, Dept of Obgy, JNMC, Sawangi, Wardha

Dr. Sanjivani Wanjari M.D.

Obgyn, professor department of obgyn DMIMS, Sawangi (M), Wardha

ABSTRACT

Objectives : To determine whether there is an association between a "soft" cervix identified by cervical strain elastography between 18 to 22 weeks of gestation and spontaneous onset of preterm labour.

Materials and methods: This is a prospective observational study conducted on 246 randomly selected women. Cervical length and Elastographic strain was performed by TVS in a single sitting between 18-22 weeks of gestation. Spontaneous preterm delivery (sPTD < 37 weeks) in women with soft cervix was noted and compared to women with or without a short cervix.

Results: 16/20 women who had sPTD < 37 weeks had a "Soft cervix" (red + yellow) on elastography. 4/20 women who had sPTD < 37 weeks had a short cervix (≤ 2.5 cm). Sensitivity of elastography in predicting sPTD was 80% and specificity was 78.76%.

KEYWORDS :

INTRODUCTION :-

Preterm birth, defined as birth before 37 weeks of gestation⁽¹⁾, is the single most important factor in determining adverse infant outcomes by affecting the survival and quality of life of the newborn⁽²⁾. Prematurity is the number one cause of perinatal and neonatal mortality and morbidity all over the world and accounts for 75% of perinatal mortality and more than half of the long term morbidity⁽³⁾. It is also the leading cause of death in children under the age of 5 years. World Health Organisation recently estimated that 15 million babies are born prematurely every year i.e. more than 1 in 10 babies worldwide. Apart from being the direct major cause perinatal mortality, complications related to preterm birth (PTB) account for more newborn and infant deaths than any other cause⁽⁴⁾ i.e. approximately 1 million children die each year due to complications of preterm birth⁽⁵⁾, and those who manage to survive face a lifetime of disability, including visual and hearing problems and learning disabilities.⁽⁶⁾

Africa and South Asia account for more than 60% of global preterm births. There an average of 12% babies are born prematurely compared to 9% in higher-income countries. Despite the efforts to decrease the rate of preterm birth, in almost all countries preterm birth rates have seen a rising trend⁽⁴⁾.

A short mid-trimester cervical length (≤ 25 mm) has been one of the strongest risk factors for sPTB making cervical length (CL) measurement the gold standard for identifying high risk preterm labour group. Innumerable studies have consistently shown that the risk of spontaneous preterm birth (sPTB) is inversely proportional to the length of the cervix.^(7,8) However, a 2013 Cochrane review did not find sufficient evidence to recommend routine cervical length screening for all pregnant women as they found a non significant association between knowledge of transvaginal ultrasound cervical length results and a lower incidence of preterm birth.⁽⁹⁾

It goes without saying that cervical length and funneling are parameters that definitely belong in any model of cervical remodeling leading to preterm labour. However, the highly inconsistent outcomes (term vs. preterm delivery) associated with various cervical lengths and degrees of funneling suggest that additional parameter are required to diagnose premature cervical remodeling or to screen women for risk of spontaneous preterm labor. The gold standard for clinical assessment of cervical softness is the "cervical consistency" component of the Bishop score. Cervical

insufficiency or premature cervical ripening or effacement (which leads to preterm labour) can only be subjectively physically demonstrated as cervical "softness". Fortunately elastography can quantify cervical tissue softness and its relationship to the underlying collagen microstructure in pregnancy. It is a non-invasive, ultrasound-based method in which gentle pressure is applied by the operator via the ultrasound transducer, after which specialized software produces a color map (Elastogram) that describes deformation of the tissue relative to neighboring areas ("strain"). Several studies have suggested that higher cervical strain values seen in a soft cervix are associated with sPTB. Elastography has also been applied to evaluate tissue architecture of various other pathologies like malignancy of thyroid, breast, prostate and liver.⁽¹⁰⁻¹³⁾ Softening of the cervix usually preceded shortening. Hence Elastography might be able to identify high risk women before cervical length starts to decrease.

MATERIAL AND METHODS

This prospective observational study was conducted in Department of Obstetrics and Gynecology at Acharya Vinoba Bhave Rural Hospital, Sawangi (Meghe), Wardha from September 2016 to August 2018 on 246 pregnant women between 18¹⁷ to 22⁶⁷ weeks of gestation attending the antenatal clinic. The study was approved by the ethical committee of Datta Meghe University of Medical Sciences. Both TVS cervical length measurement and Cervical Elastography were performed on the same patient in the same sitting by a single radiologist who has received formal training in Elastography using the Hitachi Aloka Arietta 705 ultrasound machine. The transvaginal probe used was a 10-12 MHz transducer (FDA approved). The patients were subsequently followed up till delivery and fetal outcome was noted.

Pregnant women above 18 years of age, whose period of gestation was between 18¹⁷ to 22⁶⁷ weeks, determined either by date of last menstrual period or by first trimester scan; singleton pregnancy, no signs or symptoms of preterm labor or PPRM at the time of study, history of previous preterm delivery and history of spontaneous abortion in the past but not those who needed manual evacuation were included in the study.

Women with unknown dates, who have not consented to participate in the study, with signs and symptoms of preterm labour pain, PPRM or bacterial vaginosis were excluded. Women with pregnancy complicated by Placenta praevia, Polyhydramnios, Cervical incompetence, Multifetal gestation, Uterine anomalies,

history of cervical encirclage or cervical surgeries like amputation in previous pregnancy were also excluded. Their demographic data with detailed history was noted. Transvaginal cervical length measurement was carried out using the standards put forth by Burger et al 1997. ⁽¹⁴⁾Elastography technique was similarly to that put forth by Swiatkowska- Freund and Preis ⁽¹⁵⁾. During the examination no force was applied via the transducer and the patients were asked to breathe normally. The elastographic image of the cervix was generated by patient's breathing movements and arterial pulsation. Sagittal section of the cervical canal was visualised. Region of interest was set as the internal os, predominantly anterior lip of cervix. (most accurate results)⁽¹⁵⁻¹⁷⁾ Elasticity of the internal os was assessed using a colormap ⁽¹⁵⁾:Red-Soft, Yellow-Medium soft, Blue-Medium hard, Purple-Hard.

Statistical analysis was done by using Chi square test, Student's t-test, Receiver operating characteristic(ROC) curve, sensitivity, specificity, Positive predictive value, Negative predictive value and likelihood ratio. Cervical length findings were dichotomized as short (≤ 25 mm) and normal (>25 mm). Cervical internal os Elastography strain findings were dichotomized as soft (Red + Yellow) and Hard (Blue + Purple)⁽¹⁵⁻¹⁹⁾. Relative Risks were estimated using the Poisson regression model. Two-tailed Fisher's exact tests were used to compare simple differences between proportions and 2×2 marginal tables. The software used in the analysis were SPSS 24.0 and GraphPad Prism 6.0 version and values for statistics below the 5% significance level were accepted as statistically significant ($p < 0.05$).

OBSERVATION AND RESULTS

The demographic characteristics of the 246 women in our study are given below.

Table 1: Demographic characteristics of study group.

Demographic characteristic	Study population (n=246)
Age(years), mean \pm SD(Range)	24.59 \pm 3.68 (19-40)
Gestational age at enrolment(weeks), mean \pm SD(Range)	20.11 \pm 0.78 (18.0-22.6)
Parity, median(Range)	1(1-2)
Gravidity, median(Range)	2(1-4)
Cervical length(cm), mean(SD)	3.77 \pm 0.78
Elastography, median(Range)	2(1-4)
Primigravida(n)	49(19.91%)
Spontaneous miscarriages(n)	33(13.41%)
Multipara	164(66.66%)
No prior history of preterm delivery	120(48.78%)
Previous full term deliveries only (excluding abortions and previous preterm deliveries)	55(22.35%)
Previous term delivery + previous abortion (no h/o previous preterm delivery)	65(26.425%)
Prior history of preterm delivery (may or may not include previous term delivery and or abortion)	44(17.88%)
Previous term delivery + previous preterm delivery+ abortion	18(7.31%)
Previous term delivery + previous preterm delivery (no previous abortions)	26(10.56%)
Total short cervix (short \pm soft)	13(5.28%)
Exclusively short cervix (short-soft)	6(2.43%)
Total Soft cervix (soft \pm short)	64(26.01%)
Exclusively soft cervix (soft-short)	57(23.17%)
Short and soft cervix	7(2.84%)
Neither short nor soft cervix	176(71.54%)
Delivery ≥ 37 weeks	226(91.87%)
Delivery 34-36.6 weeks	13(5.28%)
Delivery < 34 weeks	7(2.84%)

Table2: Association cervical length and spontaneous preterm delivery.

Cervical length (cm)	OUTCOME			Chi2-value
	Preterm delivery	Term delivery	TOTAL	
≤ 2.5	4(30.8%)	9(61.2 %)	13	Chi2=9.4183 p = 0.002, HS
> 2.5	16(6.9%)	217(93.1%)	233	
TOTAL	20	226	246	

Sensitivity=20%, Specificity=96.02%, LR+=5.02, LR- =0.83 , PPV=30.77%, NPV=93.13%

30.8% women with $CL \leq 2.5$ cm had a sPTD < 37 weeks whereas only 6.9% women with $CL > 2.5$ cm had a sPTD < 37 . There is a significant association between incidence of sPTD and CL ($p = 0.002$). The Sensitivity , Specificity, PPV, NPV, Positive likelihood ratio and Negative likelihood ratio of CL for predicting sPTD are 20%, 96.02%, 30.77%, 93.13%, 5.02 and 0.83 respectively.

Table3: Association of preterm delivery with Elastography strain value.

Elastography	No. of Women	Total Preterm delivery	Early PTD (≤ 33.6 weeks)	Late PTD (34.0-36.6 weeks)
Red (Soft)	36	11(30.5)	2(5.5)	9(25.0)
Yellow (Medium soft)	28	5(17.8)	5(17.8)	0
Blue (Medium Hard)	70	1(1.4)	0	1(1.4)
Purple (Hard)	112	3(2.7)	0	3(2.7)
Total	246	20	7	13
p-value		$< 0.0001, HS$	$< 0.0001, HS$	$< 0.0001, HS$

(Figures in parenthesis indicates percentage within each group)

The majority of sPTD < 37 weeks women belonged to the Red group (4.47%) followed by yellow (2.04%), purple (1.21%) and blue (0.40%). sPTD at $\leq 33.6/7$ weeks of gestation in soft cervix (Red + Yellow) was 35% (7/20). No early sPTD were observed in women with a Hard (Blue + Purple) cervix. sPTD at 34.1/7-36.6/7 weeks of gestation in soft cervix (Red + Yellow) was 25%. 4% of women with a Hard (Blue + Purple) cervix had a late preterm delivery. There was significant association of sPTD between all three categories and cervical Elastography ($p < 0.0001$).

Table4: Association of Elastography strain colour and sPTD.

Cervical Elastography	OUTCOME			Chi2-value
	Preterm	Term	TOTAL	
Soft (Red + Yellow)	16(25%)	48(75%)	64	Chi2=32.9611 p $< 0.0001, HS$
Hard (Blue + Purple)	4(2.2%)	178(97.8%)	182	
TOTAL	20	226	246	

Sensitivity=80% , Specificity=78.76%, LR+=3.77, LR- =0.25 , PPV=25.0 % , NPV=97.80 % RR(3.76), 95% C.I.(3.69-5.25), $p < 0.0001, HS$

Percentage of sPTD in subjects with a Soft (Red + Yellow) cervix was 25% and in subjects with a hard (Blue + Purple) cervix was 2.2%. Having a Soft (Red + Yellow) cervix increased the risk of sPTD by 3.76 times compared to Hard (Blue + Purple) cervix. [RR 3.76, {95% CI (3.69-5.25)}]. There was a significant association between Elastography finding of a soft cervix and sPTD ($p < 0.0001, HS$)

Table5: Diagnostic accuracy of Elastography in predicting sPTD for various cut-offs: red , yellow and red, blue yellow and red

Cervical Elastography	Red	Yellow and Red	Blue, Yellow and Red
Sensitivity(95% CI)	55	80	85

Specificity(95% CI)	89.95	78.56	48.23
PPV(95% CI)	30.56	25	12.69
NPV(95% CI)	95.71	97.80	97.32
LR +ve	4.97	3.77	1.64
LR -ve	0.50	0.24	0.31

As the cut-off for the colours moves from only soft colour i.e. Red towards the category where medium hard colour i.e. blue is also included, the sensitivity of the test increases but at the same time its specificity decreases. The PPV goes on decreasing as medium-soft and medium-hard colors i.e. yellow and blue are included in the cut-off. The difference between the positive predictive values of the red group vs. the yellow and red group is less compared to the difference between the yellow and red vs. the blue yellow and red group.

Comparison between preterm deliveries in all four color groups:-

1. The number of preterm deliveries was not significantly different between the Purple and Blue colors [p=0.576]. (Hard vs. Medium hard)
2. Similarly the number of preterm deliveries was not significantly different between Red and Yellow colors [p=0.244]. (Soft vs. Medium soft)
3. The number of preterm deliveries in the Red group was significantly higher than in Blue and Purple group [p<0.0001]. (Soft vs. Medium hard + Hard)
4. The number of preterm deliveries in the Yellow group was also significantly higher than in Blue and Purple group [p=0.008]. (Medium soft vs. Medium hard + Hard)

Table6: Diagnostic accuracy of combination of cervical length and Cervical Elastography as a predictor of sPTD.

Cervical Length and Elastography	OUTCOME			Chi ² -value
	Pre Term	Term	TOTAL	
Yes	20	50	70	Chi²=60.5528 p<0.0001, HS
No	0	146	146	
TOTAL	20	196	246	

Sensitivity=100% , Specificity=79.67%, LR+=4.92, LR- =0 , PPV=28.57%, NPV=100%

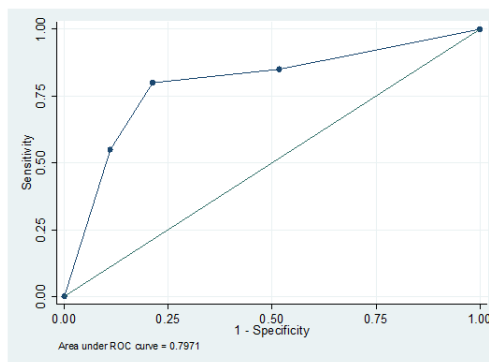
All the women who had a sPTD had either a short or a soft cervix or a combination of the two. Hence combining the two tests could identify all the subjects in this study group who had a sPTD. The sensitivity of the two tests combined was 100%, Specificity 79.67%, LR+ 4.92, LR- 0, PPV 28.57% and NPV was 100%. The statistical correlation between the combination of the two tests and prediction of spontaneous preterm delivery was highly significant [Chi²=60.5528;p <0.0001,HS]

Table7: Comparison of diagnostic accuracy of Cervical length, Elastography and a combination of the two in predicting sPTD.

Diagnostic test	Sn	Sp	PPV	NPV	LR+	LR-
Cervical length	20%	96.02%	30.77%	93.13%	5.02	0.83
Elastography	80%	78.76%	25%	97.80%	3.77	0.25
Combination	100%	79.67%	28.57%	100%	4.92	0

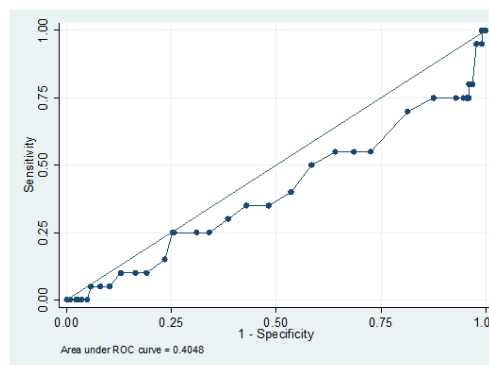
The sensitivity of CL measurement is the least in predicting sPTD (20%), however its specificity is highest (96.02%). Sensitivity of Elastography in predicting spontaneous preterm delivery was 80% which is much more as compared to CL. The combination yielded a sensitivity of 100%, specificity of 79.67%, PPV of 28.57%, NPV of 100%, positive likelihood ratio of 4.92 and negative likelihood ratio was 0. The difference in the specificity of the two tests however wasn't significantly large i.e. 96.02% vs. 78.76%. The PPV, NPV, LR+ and LR- for both the tests and a combination of the two were almost similar.

Graph1. Receiver operating characteristic curve of Cervical Elastography



*Color coding: 1-Purple, 2-Blue, 3-Yellow, 4-Red.

Graph2. ROC curve of cervical length



Graph3. ROC curve for combination of cervical length and Elastography

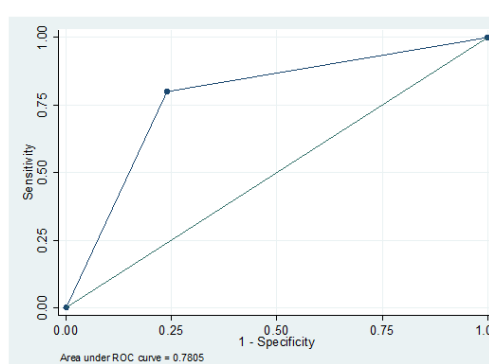


Table8: ROC of Cervical length and cervical Elastography for predicting spontaneous pre term delivery.

Diagnostic criterion	Area under Curve	95 % C.I.	Sensitivity	Specificity	Best cut off
Cervical length	0.4048	0.26-0.54	50.0%	41.59%	<3.6
Cervical Elastography	0.7971	0.68-0.91	80.0%	78.76%	Yellow (≥3*)
Combination of Cervical length and cervical Elastography	0.7805	0.68-0.87	80.0%	76.11%	-

*Colour coding: 1-Purple, 2-Blue, 3-Yellow, 4-Red.

The optimal cutoff for our study was ≥3 i.e. yellow with a sensitivity of 80% and specificity was 78.76%. A yellow cut-off would mean that red and yellow colors must be included for optimum diagnostic accuracy. The optimum cut-off for CL in our study was

<3.6cm with a sensitivity of 50% and a specificity of 41.59%. Combining CL and elastography yielded a sensitivity of 80% and specificity of 76.11%.

DISCUSSION

Our study included pregnant women above 18 years of age of which 60.2% were between 21 to 25 years of age. sPTD is the leading cause of perinatal mortality and India is a major contributor of this global problem. This study shows that cervical strain elastography can identify a cervix to be either soft or hard and that a soft cervix is a risk factor for sPTD independent of CL.

Elastography for the evaluation of cervix in pregnancy is a relatively new modality that is in its formative years and hence there is a deficit of well established standards and protocols for its use. One of the obstacles faced was the determination of an optimum gestational age at which this test should be carried out. The gestational age had to be such that it was early enough to give us adequate time in hand to provide the woman at risk with appropriate measures to ameliorate the risk of onset of spontaneous preterm labour and not so late that it is detected after the process of labour has started. The latter is one of the shortcomings of CL measurement and detection of funneling. Both these processes especially funneling is usually seen after the cervix has begun to ripen. Our understanding of the process of cervical ripening suggests that softening of the cervix at the internal os takes place before it begins to dilate or shorten. Since cervical Elastography measures the softness of the internal os it may be applied to pick up changes of cervical ripening before transvaginal CL can. CL is usually measured between 16-24 weeks gestation to identify women with a short cervix. The current recommendation for management of high-risk women with short cervix is either medical or surgical management in the form of progesterone and cervical encirclage in "women in whom a transvaginal ultrasound scan has been carried out between 16+0 and 24+0 weeks of pregnancy that reveals a CL of less than 25 mm" (NICE).⁽²⁰⁾ The ideal gestational age for cervical elastography in a pregnant woman to predict spontaneous preterm labour was thus fixed at 18-22 weeks of gestation as was also done by Hernandez-Andrade et.al.(2013)⁽¹⁸⁾, Wozniak et.al.(2014)⁽²¹⁾ and Wozniak et.al.(2015)⁽¹⁶⁾.

As per the RCOG guidelines a "short" cervix was taken as ≤ 2.5 cm and was measured transvaginally.⁽²⁰⁾ The mean CL of Preterm and Term delivery groups in our study were 3.45 ± 0.94 cm and 3.79 ± 0.76 cm respectively. The two values were compared using Student-t-test ($p=0.049$). Though there was a statistically significant difference between the mean CL of the two outcome groups, it was marginal.

Dichomatisation suggested by Swiatkowska-Freund et.al.(2011)⁽¹⁵⁾ and Wozniak et.al.(2015)⁽¹⁶⁾ was adopted by us since Red and Yellow combined showed highest diagnostic potential with maximum sensitivity without compromising specificity or positive predictive values of the test. In our study 64 women (26.01%) had a soft cervix and the remaining 182 women (73.98%) had a hard cervix. 16 out of the 20 women who had a sPTD<37 weeks had a Soft (Red or Yellow) cervix. The Hard (Purple or Blue) cervix category had 4 out of 20 women who had sPTD<37 weeks. Chi sq test for statistical significance between sPTD<37 weeks and Elastography showed a highly significant correlation between the two [$p<0.0001$].

As mentioned earlier, the internal os strain cutoff value in our study has been kept at Yellow hence when we analyzed outcome based on this categorization, we found that out of 64 women with a soft cervix, 16(25%) had a sPTD and out of 178 women with a hard cervix, 4(2.2%) women had a sPTD. Chi square test correlating the softness of cervix with outcome of sPTD yielded a highly significant result [$X^2=32.9611$; $p<0.0001$]. Cervical elastography had a Sensitivity of 80%, Specificity of 78.76%, PPV of 25%, NPV of 97.80%, LR+ 3.77 and LR- 0.25 also a woman with a soft cervix had a 3.76 fold increase in chance of having a sPTD<37 weeks compared to a woman with a Hard cervix [RR-3.76, 95% CI (3.69-5.25); $p<0.0001$, HS]. On comparing the diagnostic accuracy amongst the four internal os

strain colors we found that there wasn't a significant difference amongst the two hard colors (Purple vs. Blue) and soft colors (Red vs. Yellow). When we compared the hard group (Purple or Blue) with either one of the colors in the soft group i.e. Red or Yellow, there was a significant difference in the number of preterm deliveries (Purple vs. Red or Yellow/ Blue vs. Red or Yellow). Keeping the above findings in mind we have compared the diagnostic accuracy of three possible cut-offs. The first category included only red colors, the second included red and yellow colors and the third included red yellow and blue colors. On comparing the number of spontaneous preterm deliveries in all three categories we found that the sensitivity increased significantly when yellow and red colors of internal cervical os were combined as the cut off compared to red alone (80% vs 55% respectively). The sensitivity further increased when Blue color of internal cervical os was added to the cutoff, however this increase was not significantly large (85%) and it simultaneously led to a three time increase in false positive rate. The specificity is seen to decline with a significant difference between all three groups i.e. Red, Red-Yellow and Red-Yellow-Blue (89.95%, 78.56% and 48.23% respectively). There is a three times increase in false positive rate in the Red-Yellow-Blue group when compared to Red group alone. The positive predictive values in the Red and Red-Yellow groups are nearly the same (30.56% vs. 25%) however that of the Red-Yellow-Blue group is significantly less (12.69%). Thus the cutoff for "soft" colors was set as Red + Yellow thereby dichomatising the four colors into "Hard" and "Soft" groups with Blue and Purple colors signifying a Hard cervix and Red and Yellow colors signifying a Soft cervix. Combining both CL measurement and Elastography in predicting preterm delivery in our study population led to a sensitivity of 100%, specificity of 79.67%, PPV of 28.5%, NPV of 100%, LR+ =4.92 and LR= 0. The statistical correlation between the combinations of the two tests and sPTD<37 weeks was highly significant [$X^2=60.5528$; $p<0.0001$, HS]. The positive predictive value was highest in case of CL measurement but all three groups had almost similar results. Same was the case for negative predictive value however combination of the two tests had the highest NPV (100%). The purpose of doing so was that although identification of a woman with a short cervix has an established role in predicting sPTD, its sensitivity is low. By combining elastography with CL measurement we will be able to identify more women at risk of spontaneous preterm delivery due to increase in sensitivity. We compared the diagnostic indices of all three and found the following. The capacity of a Short cervix to predict sPTD <37 weeks compared to a soft cervix was significantly less. The sensitivity of a soft cervix to predict spontaneous preterm delivery was 80% in comparison to 20% as seen for a short cervix. The greatest sensitivity was that of combination of the two tests i.e. 100%.

The specificity however was greatest in case of short cervix (96.2%). A combination cervix and a soft cervix, both had comparable specificity i.e. 79.67% and 78.76% respectively. A similar finding was seen in the study done by Weichert et.al.(2016)⁽²²⁾ where on combining elastography with cervical length measurement yielded a sensitivity of 90% and a specificity of 80%.

In our study ROC for cervical Elastography produced significant data to assess the risk of preterm birth but not CL. This could be attributed to the fact that the number of women who had a short cervix was far less as compared to women who had a soft cervix (13 vs. 64). Cervical Elastography cut-off value for our study was 3 i.e. Yellow which had the highest area under curve (AUC=0.7971), Sensitivity (80%) and Specificity (78.6%). Cervical length however did not show significant AUC (0.4048). At Sensitivity and specificity values of 50% and 41.59% respectively, CL cutoff was found to be ≤ 3.6 cm. When both of these methods were combined, the sensitivity was found to be 80% and specificity 76.11% with a significant AUC (0.7805).

The cutoff for CL to be able to identify high risk women in our study was found to be ≤ 3.5 cm as suggested by ROC. As we have discussed earlier various authors suggest that the cut-off used to screen for a short cervix must vary based on the prevalence of a short cervix in

that population(23), this added to the fact that the percentage of women who had a short cervix in our study was only 5.28% could explain the low sensitivity and high cutoff for a short cervix in our study group.

The above findings coupled with the fact that the Cochrane review of "Cervical assessment by ultrasound for preventing preterm delivery of 2009⁽⁹¹⁾, found non-significant association between knowledge of CL results and a lower incidence of preterm births before 34 and 37 weeks in symptomatic women", beckons the need for a modality that can identify women who aren't currently classified as "at-risk" of having a preterm delivery but do land up having a preterm delivery irrespective of their CL.

The independent impact of CL and softness as risk factors for sPTD was done using logistic regression analysis in which all patients were included (women with a short cervix). When only patients with normal cervical length were included in the regression model, a soft cervix, following adjustment for previous PTD was still a risk factor for sPTD<37 weeks [OR 10.16]. Thus from the above analysis we can infer that cervical softness identified by internal os strain Elastography is a risk factor for preterm delivery independent of cervical length and history of previous preterm delivery.

CONCLUSION

Preterm birth has seen a gradual rise the world over and its sequelae are a burden to the families of those who are affected as well as society as a whole.

Cervical length measurement though the gold standard for predicting preterm delivery has shown varying results in different populations mainly due to the low incidence of a short cervix in most populations. Elastography though lacking standardization of technique at present is showing promising results in predicting spontaneous preterm delivery in low risk asymptomatic women in various studies including ours. It can not only identify those women that are missed by cervical length measurement but it can do so independent of whether the woman has a short cervix or history or preterm delivery. We thus recommend supplementing cervical tissue evaluation using internal os strain Elastography along with cervical length measurement in midtrimester (18^{1/7} to 22^{6/7} weeks) to detect women at risk of having a spontaneous preterm delivery.

RECOMMENDATIONS

- A longer duration of study with a larger sample size is required for proper analysis of confounding factors that influence spontaneous preterm delivery. Eg. Previous preterm delivery.
- We hope that this study urges obstetricians to apply cervical elastography in their routine clinical practise so that we can analyse and substantiate its use in predicting spontaneous preterm labo

REFERENCES

1. F. Gary Cunningham Kenneth J. Leveno Steven L. Bloom Catherine Y. Spong Jodi S. Dashe Barbara L. Hoffman Brian M. Casey Jeanne S. Sheffield. Williams Obstetrics 25th Ed.-Reduced.pdf. 25th ed. Copyright © 2014 by McGraw-Hill Education. All rights reserved; 1358 p.
2. McCormick MC. The Contribution of Low Birth Weight to Infant Mortality and Childhood Morbidity. *N Engl J Med*. 1985 Jan 10;312(2):82–90.
3. Kinney MV, Lawn JE, Howson CP, Belizan J. 15 million preterm births annually: what has changed this year? *Reprod Health [Internet]*. 2012 Dec [cited 2018 Sep 25];9(1). Available from: <http://reproductive-health-journal.biomedcentral.com/articles/10.1186/1742-4755-9-28>
4. WHO. Preterm birth [Internet]. World Health Organization. 2018 [cited 2018 Sep 25]. Available from: <http://www.who.int/news-room/fact-sheets/detail/preterm-birth>
5. Black RE, Cousens S, Johnson HL, Lawn JE, Rudan I, Bassani DG, et al. Global, regional, and national causes of child mortality in 2008: a systematic analysis. *The Lancet*. 2010 Jun;375(9730):1969–87.
6. The Lancet. The global burden of preterm birth. *The Lancet*. 2009 Oct;374(9697):1214.
7. Miller ES, Tita AT, Grobman WA. Second-Trimester Cervical Length Screening Among Asymptomatic Women: An Evaluation of Risk-Based Strategies. *Obstet Gynecol*. 2015 Jul;126(1):61–6.
8. Owen J, Yost N, Berghella V, Thom E, Swain M, Dildy GA, et al. Mid-trimester endovaginal sonography in women at high risk for spontaneous preterm birth. *JAMA*. 2001 Sep 19;286(11):1340–8.
9. Berghella V, Baxter JK, Hendrix NW. Cervical assessment by ultrasound for preventing preterm delivery [Internet]. Chichester, UK: John Wiley & Sons, Ltd; 2009 Jul [cited

- 2018 Oct 9]. Available from: <http://doi.wiley.com/10.1002/14651858.CD007235.pub2>
10. Kumm TR, Szabunio MM. Elastography for the Characterization of Breast Lesions: Initial Clinical Experience. *Cancer Control*. 2010 Jul;17(3):156–61.
11. Thomas A, Degenhardt F, Farrokh A, Wojcinski S, Slowinski T, Fischer T. Significant differentiation of focal breast lesions: calculation of strain ratio in breast sonoelastography. *Acad Radiol*. 2010 May;17(5):558–63.
12. Rago T, Santini F, Scutari M, Pinchera A, Vitti P. Elastography: New Developments in Ultrasound for Predicting Malignancy in Thyroid Nodules. *J Clin Endocrinol Metab*. 2007 Aug;92(8):2917–22.
13. Kato K, Sugimoto H, Kanazumi N, Nomoto S, Takeda S, Nakao A. Intra-operative application of real-time tissue elastography for the diagnosis of liver tumours: Real-time elastography for liver tumour. *Liver Int*. 2008 Mar 6;28(9):1264–71.
14. Andersen HF, Nugent CE, Wanty SD, Hayashi RH. Prediction of risk for preterm delivery by ultrasonographic measurement of cervical length. *Am J Obstet Gynecol*. 1990 Sep;163(3):859–67.
15. Swiatkowska-Freund M, Preis K. Elastography of the uterine cervix: implications for success of induction of labor. *Ultrasound Obstet Gynecol*. 2011 Jul;38(1):52–6.
16. Wozniak S, Czuczwar P, Szkodziak P, Milart P, Wozniakowska E, Paszkowski T. Elastography in predicting preterm delivery in asymptomatic, low-risk women: a prospective observational study. *BMC Pregnancy Childbirth*. 2014 Jul 21;14:238.
17. Preis K, Świątkowska-Freund M, Pankrac Z. Elastography in the examination of the uterine cervix before labor induction. *Ginekol Pol [Internet]*. 2010 [cited 2018 Oct 16];81(10). Available from: https://journals.viamedica.pl/ginekologia_polska/article/view/46418
18. Hernandez-Andrade E, Romero R, Korzeniewski SJ, Ahn H, Auroles-Garibay A, Garcia M, et al. Cervical strain determined by ultrasound elastography and its association with spontaneous preterm delivery. *J Perinat Med [Internet]*. 2014 Jan 1 [cited 2018 Oct 8];42(2). Available from: <https://www.degruyter.com/view/j/jpme.2014.42.issue-2/jpm-2013-0277/jpm-2013-0277.xml>
19. Hernandez-Andrade E, Garcia M, Ahn H, Korzeniewski SJ, Saker H, Yeo L, et al. Strain at the internal cervical os assessed with quasi-static elastography is associated with the risk of spontaneous preterm delivery at ≤34 weeks of gestation. *J Perinat Med [Internet]*. 2015 Jan 1 [cited 2018 Sep 25];43(6). Available from: <https://www.degruyter.com/view/j/jpme.2015.43.issue-6/jpm-2014-0382/jpm-2014-0382.xml>
20. Preterm labour and birth NICE guideline NG(25) [Internet]. www.nice.org.uk. 2015 [cited 2018 Oct 8]. Available from: <https://www.nice.org.uk/guidance/ng25/resources/preterm-labour-and-birth-pdf-1837333576645>
21. Woźniak S, Czuczwar P, Szkodziak P, Wrona W, Paszkowski T. Elastography for predicting preterm delivery in patients with short cervical length at 18-22 weeks of gestation: a prospective observational study. *Pol Gynaecol*. 2015;86(6):442–7.
22. Weichert A, von Schöning D, Fischer T, Thomas A. Cervical Sonoelastography and Cervical Length Measurement but not Cervicovaginal Interleukin-6 Are Predictors for Preterm Birth. *Ultrasound Int Open*. 2016 Aug 24;02(03):E77–82.
23. Pedretti MK, Kazemier BM, Dickinson JE, Mol BWJ. Implementing universal cervical length screening in asymptomatic women with singleton pregnancies: challenges and opportunities. *Aust N Z J Obstet Gynaecol*. 2017 Apr;57(2):221–7.