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ORIGINAL ARTICLE

PREDICTION OF PRETERM DELIVERY BY ASSESSMENT OF CERVICAL LENGTH USING TRANSVAGINAL ULTRASOUND

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ABSTRACT: AIMS AND OBJECTIVES: To identify patients at risk of preterm deliveries before the onset of symptoms. Purpose of this study is to assess the diagnostic performance of transvaginal ultrasonographic evaluation of cervix in the prediction of preterm delivery. **MATERIAL AND METHODS:** Sonographic cervical length assessment in 200 antenatal women between 20 – 28 weeks gestation attending OPD was done. Study group was divided in group A (Those with cervical length more than 25mm) and group B (those with cervical length ≤25mm, again these women with short cervix divided in Group B1-Women with cervical length 21–25mm, Group B2-Women with cervical length ≤20mm). Cervical length was measured for all enrolled women using 6.5 MHz transvaginal probe. Cervical length on transvaginal sonography ≤25mm were considered as short cervix and remaining (>25 mm) were considered as normal cervical lengths. In present study, women with short cervix ≤25 mm and history of previous preterm delivery or second trimester abortions and evidence of cervical defect were treated with elective cervical cerclage by McDonald method. Women in group A and remaining women in group B (who had short cervix but os was closed and women without history of previous preterm delivery or second trimester abortions) were conservatively followed up. **RESULTS:** Out of 200 women 5(2.5%) women had cervical lengths ≤20 mm measured with TVS (Group B2); 11(5.5%) had cervical lengths ranging from 21-25mm (group B1). Out of 16 women (group B); 9(4.6%) women underwent elective cerclage and remaining 7(3.6%) women were managed conservatively. Incidence of preterm delivery in group A was 5.6% while in group B it was 75%. Relative risk of preterm delivery in group B was 13.35 (P=0.0000000 ←). Odds Ratio =50.4. Sensitivity of TVS 54.5%, Specificity of TVS 97.6% Positive predictive value 75%, Negative predictive value 94.3%. Incidence of preterm delivery was more in women with visible membranes at time of cerclage compared to women without visible membranes at time of cerclage (100% vs. 33.3%). Relative risk of preterm delivery in women who had previous history of 2nd trimester abortions and had cervical length ≤25mm on TVS was 4. Odds ratio =11.33 Chi-square value =3.91, P=0.047 and hence significant. In women with history of previous preterm deliveries; 6(75%) women had cervical length ≤25mm on TVS; out of which 3 (50%) women delivered preterm (<37weeks). Mean gestational age at birth in group A was 38.94±2.3 weeks while in group B; it was 35.3±3.2 weeks. Relative risk of preterm delivery (≤32 weeks) in women with cervical length ≤25mm on TVS was 5.56. Relative risk of preterm delivery (≤32 weeks) in women with ≤20 mm cervical length on TVS was 8.90. In group A; out of 10 preterm babies 50% required NICU care. Term babies were 168 and 2.4% required NICU care. In group B; 11(68.8%) babies were preterm out of which 36.4% babies required NICU care. Mean birth weight was lower in group B (2.3kg) compared to group A (2.8 kg). There were no neonatal deaths in group A. There was one (6.3%) neonatal death in group B. There was one (0.6%) still birth in group A and one (6.3%) still birth in group B. Mean birth weight in cerclage group=2.4±0.8kg. Mean birth weight in without cerclage (group B)=2.1±0.14kg.

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CONCLUSION: The use of transvaginal sonography of cervix has been found to be safe, acceptable, sensitive and cost effective screening test to assess risk of preterm delivery. This study has proved the positive relationship between cervical length and period of gestation at delivery. The likelihood of spontaneous preterm birth increases as cervical length decreases

KEYWORDS: Short Cervix, Trans vaginal sonography, Preterm labour.

INTRODUCTION: Preterm delivery remains one of the most important issues in Obstetrics, resisting solution and yielding its secrets slowly and reluctantly.

Transvaginal cervical assessment is useful tool to reduce the incidence of preterm delivery and reduce the incidence of perinatal mortality rate which varies from 40-150/1000 births in India.[1] This study is particularly aimed at identifying asymptomatic women in whom an ultrasonography guided evaluation of cervix would be done to assess short cervix and predict the risk for preterm delivery and to treat appropriately.

AIMS AND OBJECTIVES: Identify patients at risk of preterm deliveries before the onset of symptoms. Purpose of this study is to assess the diagnostic performance of transvaginal ultrasonography & evaluation of cervix in the prediction of preterm delivery.

MATERIAL AND METHODS: This study was done over a period of one (August 2013 to July 2014). Sonographic cervical length assessment in 200 antenatal women between 20–28 weeks attending OPD was done in the department of Obstetrics and Gynaecology, KIMS, Karad.

Cervical length was measured for all enrolled women using 6.5MHz transvaginal probe on Siemens Sonoline G50 machine.

Inclusion Criteria:

1. All primigravidare and multigravidae with gestational age 20–28 weeks.
2. Singleton pregnancy.
3. Women with regular cycles and sure of Last Menstrual Period (LMP).

Exclusion Criteria:

1. Multiple gestation.
2. Placenta previa/ bleeding per vaginum.
3. Developmental uterine anomalies.
4. Past history of surgical procedures on cervix.
5. Current vaginal infection.
6. Maternal medical conditions.
7. Women with irregular cycles and not sure of LMP.
8. Baby having congenital anomalies.

All the eligible women were explained the procedure and their consent were obtained.

Ultrasound guided cervical assessment was done on an empty bladder in dorsal position. 6.5 MHz transvaginal transducer covered with condom and jelly and inserted gently half the way between introitus and cervix. The vaginal probe was manipulated to obtain a sagittal view of entire cervix with echogenic endocervical canal. Calipers were used to measure distance between external

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os (Point at which anterior and posterior lips of cervix meet) and internal os (Point at which the cervical canal and amniotic sac or presenting part meet). The status of internal os and presence or absence of funneling recorded, the examination done over a period of 3-5 min.

Fig. 1

All the patients in study group were divided in two groups:

Group A: Women with cervical length > 25 mm on transvaginal sonography.

Group B: Women with cervical length ≤ 25 mm on transvaginal sonography.

In present study, women with short cervix ≤ 25 mm and history of previous preterm delivery, second trimester abortions and evidence of cervical defect were treated with elective cervical cerclage by McDonald method.

Women in group A and remaining women in group B (who had short cervix but os was closed and women without history of previous preterm delivery or second trimester abortions) were conservatively followed up.

In the present study, women who were admitted with the symptoms suggestive of preterm labour like:

1. Abdominal cramping (With or without diarrhea).
2. Menstrual like cramps.
3. Low dull backache.
4. Pressure (Feel like the baby is pushing down or feels heavy).
5. Increase or change in vaginal discharge.

Patients with above symptoms were hospitalized and treated on medical line of treatment:

1. Bed rest.
2. Hydration and sedation.
3. Tocolysis.
4. Corticosteroids when pregnancy was beyond 28 weeks.
5. Antibiotics.

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All the enrolled women were regularly followed up in antenatal clinic till delivery and fetal outcome was studied. Deliveries before 37 weeks considered as preterm delivery.

STATISTICS &RESULTS:

200 women included in present study divided in 2 groups:

Group A: Women with cervical length > 25 mm Measured with TVS.

Group B: Women with cervical length ≤ 25 mm measured with TVS.

Again group B divided in 2 groups:

Group B1: Women with cervical length 21 – 25 mm.

Group B2: Women with cervical length ≤ 20 mm.

In the present study, 16(8%) women had ≤25mm cervical lengths on TVS (Group B).

Cervical lengths measured with TVS	n = 200	
Group A (>25 mm)	184	92%
Group B1 (21 – 25 mm)	11	5.5%
Group B2 (≤ 20 mm)	5	2.5%

Table 1

Cerclage: 6 women from 200 study population were lost to follow up and so these 6 women were excluded from the study outcome and the remaining (194) women were followed till delivery.

	Group A		Group B	
Elective Cerclage	Nil	Nil	9	4.6%
No Cerclage	178	91.8%	7	3.6%

Table 2

DIAGNOSTIC PERFORMANCE OF TVS:

Gestational age at delivery	Group A (n =178)		Group B1 (n = 11)		Group B2 (n=5)	
Early preterm deliveries (≤34 weeks)	3	1.7%	2	18.2%	2	40%
Late preterm deliveries (>34 weeks)	7	3.9%	5	45.5.%	3	60%
Term Gestation	168	94.4%	4	36.4%	0	0

Table 3

N group A; 10(5.6%) women delivered preterm (<37 weeks) and 168 (94.4%) delivered at term gestation.

In group B; 12(75%) women delivered preterm (<37weeks) and 4(25%) women delivered at term gestation.

Relative risk of preterm delivery in women in group B was 13.35.

Odds ratio = 50.4

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Chi-square value = 63.56 P=0.0000000 ← highly significant statistical variation found.
Sensitivity of the TVS was 54.5%.
Specificity of the TVS was 97.6%.
Positive predictive values was 75%.
Negative predictive value was 94.3%.

In group B; 9(56.3%) women underwent elective cerclage at gestational age 20 – 22 weeks; remaining 7(43.8%) women managed conservatively. Among the cerclage women, 5(55.6%) had preterm deliveries (< 37 weeks) and 4(44.4%) women had term deliveries.

Women in group B, managed conservatively all (100%) were delivered preterm (< 37 weeks); [2(28.6%) women had early preterm deliveries (≤34weeks) and 5(71.4%) women had late preterm deliveries (>34 week)].

Gestational age at delivery	Group B with cerclage (n=9)		Group B without cerclage (n=7)	
Preterm	5	55.6%	7	100%
Term	4	44.4%	0	0

Table 4

Chi-square value = 2.12, P=0.1457 Mean gestational age at birth in cerclage and without cerclage group B women was 35.9±4 weeks and 34.4±1.7 weeks respectively.

In group B women with cerclage; 3 (33.3%) women had visible membranes at time of cerclage and 6 (66.7%) women had no visible membranes at time of cerclage.

In women with visible membranes at time of cerclage all (100%) delivered preterm (<37 weeks) ; out of which 2(66.7%) women delivered early preterm (≤34 weeks) & 1(33.3%) women delivered late preterm (>34 weeks).

In 6 women without visible membranes at time of cerclage, 2(33.3%) women delivered preterm [out of 2 women delivered preterm;1 (16.7%) was early preterm delivery (≤34 weeks) and 1(16.7%) was late preterm delivery (>34 weeks)] and 4 (66.7%) women delivered at term gestation.

Chi-square value = 1.41, P= 0.235, hence statistically not significant.

Gestational Age At Delivery: In the present study, women under age of 20 years were 64(32%), out of which 2 women were lost to follow up. 5(8.1%) women in this age group had cervical length ≤ 25 mm on TVS and all (100%) of them delivered preterm (<37 weeks). 57(91.9%) women had cervical length > 25 mm on TVS & one (1.8%) woman had preterm delivery (< 37 weeks)

Relative risk of preterm delivery in women ≤ 20 years was 57.

Chi-square value = 40.14, P=0.0000000 ← highly significant statistical variation found 136(68%) women were present in 21–35 years age group; 4 women were lost to follow up. Remaining 132 (68%) women were followed till delivery. 11(8.3%) women in this age group had cervical length ≤25 mm on TVS and out of these 7(63.6%) women had preterm deliveries (<37 weeks). 121(91.7%) women in this age group had cervical length >25mm on TVS; out of these 8(6.6%) women had preterm deliveries (<37weeks).

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Relative risk of preterm delivery in women of 21 – 35 years age group was 9.67. Chi-square value = 27.14, P = 0.0000002 ← hence statistically highly significant.

Odds ratio = 24.72.

In the present study, 100 women were primigravida, out of which 4 women were lost to follow up and remaining women (96) were followed till delivery. Mean cervical length for primigravida was 32.31±5.1 mm.

6(6.3%) primigravida had cervical length ≤25 mm on TVS, out of which 5(83.3%) women had preterm deliveries (< 37 weeks). 90(93.7%) primigravida women had cervical length >25mm on TVS, out of which 4(4.4%) women had preterm deliveries (< 37 weeks).

Relative risk of preterm delivery in primigravida women with cervical length ≤ 25 mm on TVS was 18.75

Odds ratio =107.50, Chi-square value 32.44, P =0.0000000 ← hence highly significant statistical variable found.

In the present study, 100 women were multigravida out of which 2 women were lost to follow up. Mean cervical length for multigravida was 32.91±6.03mm. In remaining 98 multigravida, 10 (10.2%) women had cervical length ≤25mm on TVS, out of which 7(70%) women had preterm deliveries (<37 weeks). 88(89.8%) multigravida had cervical length >25 mm on TVS; out of which 6(6.8%) women had preterm deliveries (<37 weeks)

Relative risk of preterm delivery in multi gravidae with cervical length ≤25mm on TVS; was 10.27. Odds ratio =31.89. Chi-square value =25.91,

P= 0.0000004 ← hence highly significant.

In the present study, 26(26.5%) women had a history of previous 2nd trimester abortions. In them 6(23.1%) women had cervical length ≤25mm on TVS; out of which 4 (66.7%) women had preterm deliveries (< 37weeks). Remaining 20(76.9%) women had cervical length >25 mm on TVS; out of which 3(15%) women had preterm deliveries (<37 weeks).

Relative risk of preterm delivery in women who had previous history of 2nd trimester abortions and had cervical length ≤ 25 mm on TVS was 4.44.

Odds ratio = 11.33.

Chi-square value = 3.91, P = 0.047 and hence significant.

In the present study, 8(8.2%) women had history of previous preterm deliveries (<37 weeks). In women with history of previous preterm deliveries; 6(75%) women had cervical length ≤ 25mm on TVS; out of which 3(50%) women delivered preterm (<37weeks).

2(25%) women had cervical length >25mm on TVS and both (100%) of them delivered at term gestation. Relative risk in these women wasα, Odd ratio undefined.

Chi-square value = 0.18, P =0.67. So not significant.

Mean gestational age at birth in group A was 38.94±2.3 weeks while in group B; it was 35.3±3.2 weeks.

Gestational age at delivery	Group A		Group B	
< 37 weeks	10	5.6%	12	75%
≥ 37 weeks	168	94.4%	4	25%

Table 5

Chi-square value 63.56, P=0.0000000 ← highly significant statistical variation found.

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n = 194			Preterm (≤ 32 weeks)		>32 weeks	
Cervical length ≤ 25mm	16	8.2%	1	6.3%	15	93.7%
Cervical length > 25mm	178	91.8%	2	1.1%	176	98.9%
Table 6						

Relative risk of preterm delivery (≤32 weeks) in women with cervical length ≤25mm on TVS was 5.56.

Odds ratio = 5.87, Chi-square value = 0.29, P = 0.59. Hence statistically not significant.

n = 194			Preterm ≤ 32 weeks		> 32 weeks	
Cervical length ≤ 20mm	5	2.6%	1	20 %	4	80%
Cervical length > 20mm	189	97.4%	2	1.1%	187	98.9%
Table 7						

Relative risk of preterm delivery (≤32 weeks) in women with ≤ 20 mm cervical length on TVS was 8.90.

Odds ratio = 10.88.

Chi-square value = 0.79, P=0.3733. Hence statistically not significant.

Fetal outcome: NICU care:

In the present study, 13(6.7%) babies required NICU care.

(Note: There was one stillborn preterm baby which was excluded from present chart)

Group A	NICU Admission		No NICU Admission	
Preterm	5	50%	4	40%
Term	4	2.4%	164	97.6%
Table 8				

Chi-square value = 39.64, P value = 0.0000000 ← which was statistically highly significant

(Note: Total preterm deliveries in group B were 12; as one baby was still born; hence excluded from present table. So in this table preterm deliveries considered were 11)

Group B	NICU Admission		No NICU admission	
Preterm (11)	4	36.4%	7	63.6%
Term (4)	0	0	4	100%
Table 9				

Chi-square value = 0.56, P value = 0.45 which was statistically not significant.

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FETAL MORTALITY:

	Fetal mortality		No. fetal mortality	
Group A	1	0.6%	177	99.4%
Group B	2	12.5%	14	87.5%

Table 10

Chi-square value = 7.02, P value = 0.0080617, which was statistically highly significant.

DISCUSSION: In the present study, the cut off cervical length measured on TVS was taken as ≤25 mm and over all incidence of preterm delivery was 11%; incidence of preterm delivery in women with short cervix was 75%.

These results were nearly correlated with the results of Kore SJ et al (2009) where cut off cervical length was <30mm and over all incidence of preterm delivery was 26% and incidence of preterm delivery was 89.5% in women with short cervix.[2]

In Caglar Gamze et al (2005) study, incidence of preterm delivery was 14.2% which was for cut off cervical length 28.5 mm.[3] this result was correlated with present study. Other study results were not coinciding with present study. In John Owen et al (2001) study, incidence of preterm delivery was 26% and cut off cervical length was 25 mm,[4] where as in V.C.F Heath et al (1998) study, incidence of preterm delivery (< 32 weeks) was 2% and cut off cervical length was 15 mm.[5]

In Jay D Iams et al (1996) incidence of preterm delivery was 4.3% for cut off cervical length 20 mm.[6] In Arjang Naim et al (2002) study, incidence of preterm delivery was 23% for cut off cervical length <30mm.[7]

Variation in results of present study and other studies might be due to racial and ethnic factors. In other studies cut off values of cervical lengths are different and incidence of preterm deliveries considered for ≤ 32 weeks, ≤35 weeks and ≤ 36 weeks.

The strength of present study inferences depends upon the rigor of study methodology and reliability of present study accuracy estimates.

In the present study, incidence of preterm delivery among women from group B without cerclage and women from group A was 9.1% where as in V C F Heath et al (1998) study incidence of preterm delivery was 5% among expectantly managed women.[5]

In the present study, incidence of preterm delivery was 100% in women of group B managed expectantly whereas incidence of preterm delivery was 55.6% in women of group B with cerclage. Relative risk of preterm delivery (for cervical length ≤25mm) in women < 20 years age and women 21–35 years ago were 57 and 9.67 respectively and both were statistically significant. Relative risk of preterm deliveries (for cervical length ≤ 25mm) was 4.44 among women with previous history of 2nd trimester abortions and was statistically significant.

Present study found statistically significant relation between primigravida and preterm delivery. Relative risk for primigravida (for cervical length≤25mm) was higher compared to multigravida (18.75 vs 10.27). Relative risk of preterm delivery ≤32 weeks (for cervical length ≤ 25mm) was 5.56 and not statistically significant. These findings were not correlating with V C F Heath (1998) et al study results.[5] this study found that teenage pregnancy and primigravida were asymptomatic and were at increased risk of preterm delivery.[8] Women with previous history of 2nd trimester miscarriage also had increased risk for preterm delivery.

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In the present study, mean cervical length in study population was 32.61±5.5mm which correlated to study results of Jay D Iams et al (1996) and almost correlated to results of Kore S J et al (2009).

Mean gestational age at birth in group A (cervical length >25 mm) was 38.94 ± 2.3 weeks and in group B (Cervical length ≤25mm) 35.3±3.2 weeks.

These results correlated with Kore SJ et al (2009) study results. [2]

In Caglar Gamze (2005) study mean gestational age was 38.33±1.85 weeks[3] and in John Owen (2001) mean gestational age at birth was 35.2±6.3 weeks. [4]

Cervical length > 25 mm rules out likelihood of spontaneous preterm delivery, hence in group A, mean gestational age (GA) at delivery was more than group B.

In the present study, mean gestational age at birth and birth weight in cerclage group (35.9±4 weeks; 2.4±0.8 Kg) were slightly greater than in women without cerclage (34.4±1.7 week; 2.1± 0.14 kg).

These results correlated well with results of Judith U Hibbard (2000) study. [9]

In the present study, incidence of preterm delivery was more in women with visible membranes at time of cerclage compared to women without visible membranes at time of cerclage (100% vs 33.3%). This study found that incidence of early preterm delivery (≤ 34 weeks) was more in women with visible membranes at time of cerclage compared to women without visible membranes at time of cerclage (66.7% vs 16.7%).

This indicates presence of visible membranes at time of cerclage acts as additive factor to incompetent cervix and finally adds to risk factors for preterm delivery.

Odds ratio measures the strength of association between risk factors and outcome. In the present study, Odds ratio for primigravidae was 107.50 which was not coinciding with Taipale P et al (1998) study (Odds ratio 3.6). [10] Difference in these two studies might be due to confounding factors like, age, race, ethnicity, socio-economic status of the patients.

Odds ratio for preterm delivery ≤ 32 weeks for cervical length ≤ 20 mm and ≤ 25 mm were 10.88 and 5.87 respectively. These findings did not correlated with Hassan et al (2000) study results (Odds ratio 18.3 & 13.4 respectively).[11]

Women with history of previous 2nd trimester abortions and women belonging to 21-35 age group were observed as risk factors for preterm delivery (Odds ratio 11.33, 24.72 respectively).

In the present study, patients with cut off value of ≤ 25 mm cervical length for screen positive at 20-28 weeks of gestation had sensitivity of 54.5%, specificity of 97.6%, positive predictive value 75% and negative predictive value 94.3%.

The present study results coincided with Kore S J et al (2009) which also showed 57.6% sensitivity, 97.6% specificity. [2] Negative predictive value of the present study correlated with results of Anderson et al (1990) study. [12] Specificity 97% in the present study correlated well with results of Iams et al (1996) study.[6]

Present study proved the positive relationship between cervical length and period of gestation at delivery.

CONCLUSIONS: The above results in the present study concluded that, primigravida, women ≤ 20 years age and women with previous history of 2nd trimester abortions are at increased risk of preterm delivery.

Transvaginal scan provides a better option to identify these asymptomatic women who are at risk of preterm delivery early enough, so that an optimum treatment (tocolysis or cerclage) can be given in time.

This study has proved the positive relationship between cervical length and period of gestation at delivery. The likelihood of spontaneous preterm birth increases as cervical length decreases.

In the present study, cervical cerclage failed to lengthen the pregnancy till term gestation, though it has reduced early preterm deliveries.

This study concluded that visible membranes at time of cerclage act as risk factor for preterm delivery and hence increases the incidence of preterm term delivery.

Cervical cerclage has reduced the neonatal morbidity and mortality.

Transvaginal sonography also provides objective and noninvasive method and also gives meaningful information regarding subtle changes at internal os.

This is a useful tool to diagnose increased risk of preterm delivery in asymptomatic women like primigravidae; before development of inevitable symptoms of preterm labour.

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