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Study the effectiveness of transvaginal sonography versus digital assessment of cervix in predicting preterm labour; among the pregnant women attending obstetric care unit, Siddipet, Telangana state

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Abstract
Introduction: New global estimates show that in 2014, approximately 10.6% of all live births globally were preterm. Preterm birth is the leading cause of perinatal mortality and morbidity. Preterm birth complicates 5-10% of pregnancies, but accounts for 85% of perinatal morbidity and mortality[1]. Cervix has a significant role in the aetiology, prevention and treatment of preterm labor1. Cervical factor is responsible for 17% of cases of preterm labor[2].
Methodology: Hospital based prospective study. Study included pregnant women attending the labor room or admitted in antenatal ward of RVM institute of medical sciences and Research Center, Siddipet district, Telangana state, conducted from March 2019 to January 2020. Sixty cases were included in this study by following inclusion and exclusion criteria.
Results: 53% of study group are in the age group of 21-25 years, Minimum age of the subject was16 years and maximum is 32 years. Most of them admitted were in between the gestation age of 34-36wk i.e. 39 (65%) pregnant women. Out of 60 pregnant women 21 (35%) had cervical length <2.5cm and 39 women (65%) had cervical length ≥2.5 cm measured by TVS. Out of 60 pregnant women 36 (60%) had cervical length <2.5 cm and 24 (40%) women had cervical length ≥2.5cm measured by digital examination.
Conclusion: Transvaginal ultrasonic measurement is considered to be the most accurate method of measuring the cervical length when compared to cervical length measurement by digital examination.

Keywords: Preterm, transvaginal sonography, digital examination, cervix

Introduction
The World Health Organization (WHO) has estimated that 9.6% of all births in 2005 were preterm-almost 13 million worldwide. Africa and Asia accounted for almost 11 million. New global estimates show that in 2014, approximately 10.6% of all live births globally were preterm [3]. Preterm births during 2014 ranged from 13·4% in North Africa to 8·7% in Europe, though data on preterm birth in North Africa is very limited. The authors state that "Asian and sub-Saharan African countries accounted for 78·9% of livebirths and 81·1% of preterm births globally in 2014." WHO defines preterm birth as babies born alive before 37 weeks of pregnancy are completed. It is the leading cause of death worldwide for children below 5 years of age [4]. Ultrasound assessment of the cervix has become an important part of obstetric evaluation, especially with the use of transvaginal probes during pregnancy. Transvaginal sonographic measurement of the cervix is a reliable alternative method for the assessment of cervical length as it allows better quality and more accurate visualization of the uterine cervix. Digital examination is also commonly used to diagnose premature labor, but Digital assessment of cervix is subjective and varies between examiners and underestimates the true anatomic cervical length. Cervix is a unique and complex structure, plays a vital role in maintaining the growth and developing embryo in the uterus until term. Its objective is achieved by remaining closed and non-compliant until the onset of labour at term. The cervix is therefore likely to play a significant role in the aetiology, prevention and treatment of preterm labor [5]. Cervical factor is responsible for 17% of cases of preterm labor [2]. This study aim to know the effectiveness of transvaginal ultrasound versus digital examination in assessment of cervical length in predicting spontaneous preterm labor in symptomatic women. Objectives are to compare cervical length, digitally and by transvaginal sonography at 28-36weeks of gestation and to estimate the risk of preterm labor based on cervical length.

Methodology

Hospital based prospective study. Study included pregnant women attending the labor room or admitted in antenatal ward of RVM institute of medical sciences and Research Center, Siddipet district, Telangana state, conducted from March 2019 to January 2020. Sixty cases were included in this study by following inclusion and exclusion criteria.

Inclusion criteria

1. Suspected preterm labor
2. Singleton pregnancy
3. 28-36 weeks of gestation
4. Primi gravida & multigravida
5. Intact membranes
6. Previous history preterm birth.

Exclusion criteria:

1. Established preterm labor
2. Obstetric complications like preeclampsia, gestational diabetes
3. Medical complications like diabetes, hypertension, severe anemia, local & systemic infections
4. Congenital fetal anomalies, IUD
5. PPROM
6. Not willing to participate and no consent women.

Prior to the study ethical clearance was obtained from RVM Institutional ethics Committee and then consent was taken from the pregnant women, a detailed history including obstetric history, menstrual history, past history, family history and personal history. General physical examination was done including routine obstetric examination and blood examination**.** Patient's cervical length was measured by digital assessment and ultrasonography and was compared.

Statistical analysis: Data entered in Excel and analyzed using SPSS Version 21. Results expressed as tables and graphs.

Results

Table 1: Age distribution among the study participants

Age in years	No. of pregnant women	Percentage (%)
16-20	16	27
21-25	32	53
26-30	10	17
> 31	2	3
Total	60	100

53% of study group are in the age group of 21-25 years, Minimum age of the subject was16 years and maximum is 32 years.

Table 2: Gestation age in weeks at the time of admission

Gestation age	No. of pregnant women	Percentage (%)
28-30 wk	8	13
31-33 wk	13	22
34-36 wk	39	65
Total	60	100

Most of them admitted were in between the gestation age of 34-36wk i.e. 39 (65%) pregnant women.

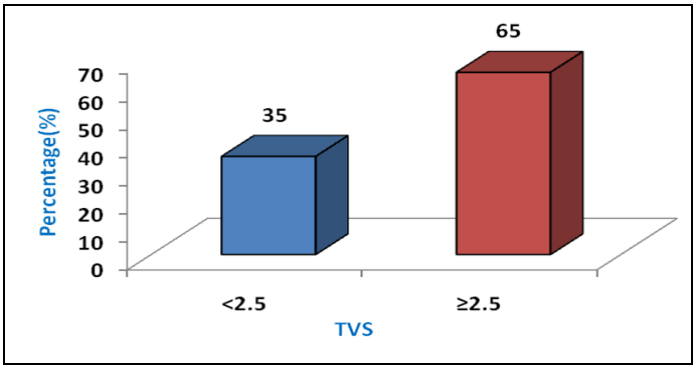

Fig 1: Distribution of cervical length by TVS among the study participants

Out of 60 pregnant women 21 (35%) had cervical length <2.5cm and 39 women (65%) had cervical length ≥2.5 cm measured by TVS.

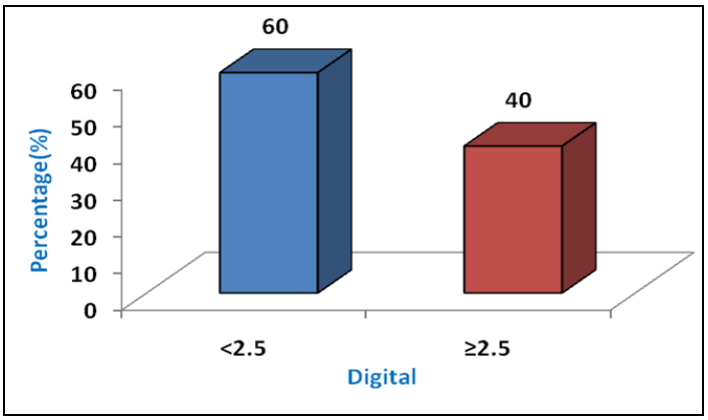

Fig 2: Distribution of cervical length by digital examination

Out of 60 pregnant women 36 (60%) had cervical length <2.5 cm and 24 (40%) women had cervical length ≥2.5cm measured by digital examination.

Table 3: Cervical length distribution by TVS among study participants

Cervical length in cms	No. of pregnant women	Percentage (%)
<2	12	20
2-2.4	7	12
2.5-3	18	30
3.1-4	23	38

Cervical length was < 2cm in 12 women, 2-2.4 cms in 7 women, 2.5-3 cms in 18 women and >3 cm in 23 women assessed by TVS

Table 4: Cervical length distribution by DIGITAL assessment

Cervical length in cms	No. of pregnant women	Percentage (%)
<2	17	28
2-2.4	11	18
2.5-3	30	50
3.1-4	2	3

Cervical length was < 2cm in 17 women, 2-2.4 cms in 11 women, 2.5-3 cms in 30 women and >3 cm in 2 women by DIGITAL Examination.

Table 5: Comparison of TVS versus Digital Assessment of cervical length

Indicators	TVS	Digital
Sensitivity	79%	98.20%
Specificity	95.46%	60.88%
PPV	94.80%	63.22%
NPV	88.22%	96.10%
Accuracy	91%	78%

TVS has sensitivity – 79%, specificity- 95.46% ,positive predictive value -94.80% and negative predictive value 88.22% , overall accuracy when compared with digital examination is 91% > 78%.TVS is more specific to predict preterm labour in women with cervical length <2.5 cms but Sensitivity and negative predictive value of digital examination is more compared to TVS assessment of cervical length

Table 6: Statistical significance between TVS and Digital examination

Variables	Area	SE	P-value	95% Confidence Interval	
				Lower Bound	Upper Bound
TVS	0.923	0.06	<0.001	0.804	0.962
Digital	0.716	0.042	<0.001	0.709	0.883

The p-value for transvaginal sonography and digital examination are <0.001, which suggests both are statistically significant in measuring the cervical length with certain limitations.

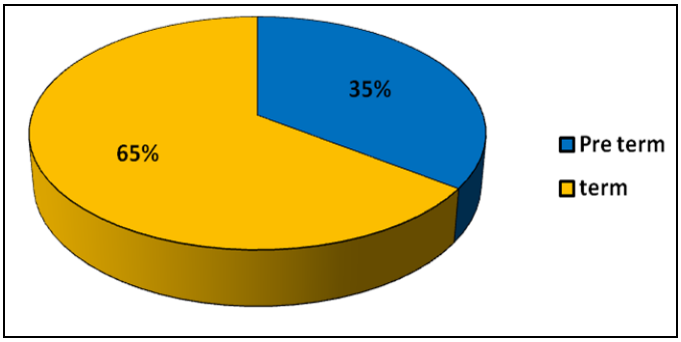

Fig 3: Distribution of preterm and term deliveries

Among 60 pregnant women term are 39 (65%) women and 21 (35%) women had preterm labour.

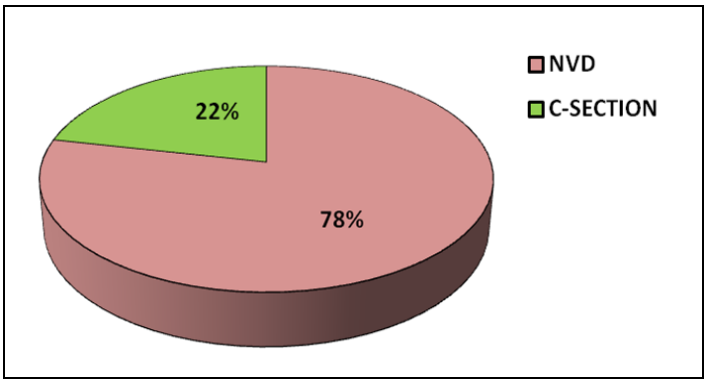

Fig 4: Pregnancy outcome among the study participants

47 women delivered by normal vaginal delivery were as 13 delivered by caesarean section.

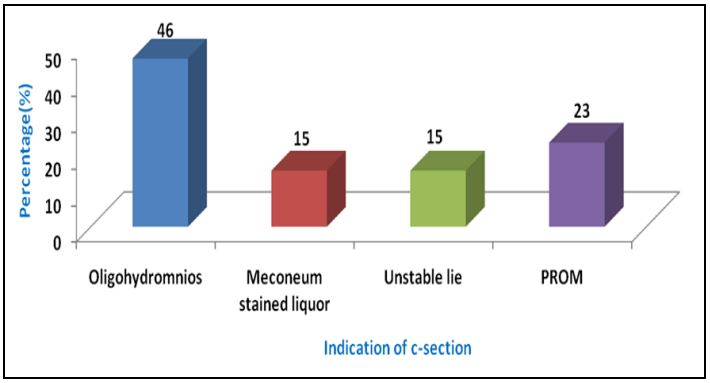

Fig 5: Indication of C-section among the study participants

46% of women underwent C-section for oligohydramnios, 23% for PROM and 15% for meconium stained liquor and 15% for unstable lie respectively.

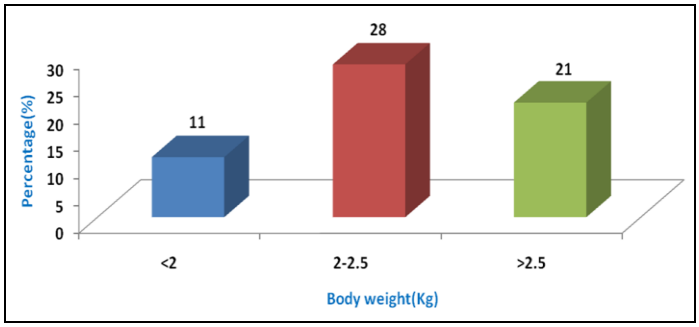

Fig 6: Birth weight distribution among the study participants

Out of 60 babies 11 were <2kg at birth, 28 babies were between 2-2.5 kg and 21 babies were >2.5 kg at birth.

Table 7: APGAR score distribution among the study participants

APGAR score	No. of babies (n=60)	Percentage
8-10	49	82
<7	11	18
Total	60	100

Of all 60 babies 49 babies had APGAR of 8-10 which means no distress and 11 babies had APGAR <8 in which mild distress was noticed.

Discussion

Treatment of preterm babies is very expensive and unaffordable in developing countries like India. It is a real challenge for both obstetrician and neonatologist in the management of preterm baby in spite of advanced and well established neonatal intensive care unit. Early prediction is important as it will ensure proper care to the pregnant mother and preterm neonate. The length of the cervix is correlated with the duration of pregnancy. The shorter the cervical length the greater risk of preterm delivery. Cervical length measurement is a major determinant of preterm delivery. A cervical length of less than 25mm between 16 and 24 weeks gestation is the most reliable threshold for an increased risk of preterm birth The current study was undertaken to assess cervical length by TVS and digital examination between 28-36 weeks of gestation in 60 pregnant women admitted in RVM Institute of Medical Sciences, fulfilling the inclusion criteria and were followed up for pregnancy outcomes. In the present study majority of the women belonged to age group of 21-25 years, i.e. 53% which is

similar to the study done by Kore SJ *et al.* [6], majority of the women were in the age group of 20-30 years. Mean age of the subjects studied was 21.28 years. The mean age of similar study done by Leslie A. Moroz *et al.* [7]. The median maternal age for the women involved in a similar study by M.H.B. Carvalho *et al.* [8] was 26.2 years. In the present study most of the women are in the age group of 21-25 years, as most of women were in the reproductive age group. In the present study 57% were prim gravidae and 27% were multigravidae, 53% were nulliparous and 47% were multiparous. In other study conducted by Cande V. Ananth [9] *et al.* preterm births are more common in prim gravida. In present study most of the women admitted at gestational age between 34- 36weeks of gestation are about 65%, gestational age between 31-33 weeks are about 22%, and the gestational age between 28-30weeks are about 13%. The incidence of preterm in a study conducted by Wathawan UT *et al.* [10] was 12%. According to Lancet study, the incidence of preterm birth rate was 13%, which is more in this study because the study was conducted on symptomatic women. In the present study cervical length measurement of 2.5cm was cut off for predicting preterm delivery. In similar studies, Iams *et al*. used cervical length measurement cut –off as <2 cm, Murakawa *et al.* used cervical length measurement cut-off as <3.0 cm, Kore SJ *et al.* [6] used cervical length measurement cut off as <3 cm, Crane JMG *et al.* used cervical length measurement cut off as 3.0 cm, Tanvir *et al*. [11] used cervical length measurement cut off as 2.5 cm. In the present study cervical length less than 2.5 cm, measured by transvaginal sonography are 35%, among those 85.7% of the women delivered less than 37 completed weeks of gestation and 14.3% of them delivered above 37 completed weeks of gestation (term). The cervical length ≥2.5 cm measured by transvaginal sonography are 65%, among these 10.3% were delivered less than 36 completed weeks of gestation(preterm), and 89.7% were delivered above 37 completed weeks of gestation (term). In the present study cervical length measurement of less than 2.5 cm, measured by digital examination are 60%, among those 55.6% were delivered before 37 completed weeks of gestation and 44.44% were delivered above 37 completed weeks of gestation .The cervical length ≥2.5 cm measured by digital examination are 40%, among those 8.3% were delivered less than 37 completed weeks of gestation (preterm) and 91.7% were delivered above 37 completed weeks of gestation.

In the present study mean cervical length measurement by transvaginal sonography was 2.8 cm. and by digital examination was 2.3 cm, a similar study conducted P. Arora [12] by transvaginal sonography, the mean cervical length measurement was 3.2 cm, and another study by Jay D. iams *et al*. and Hebbar [13] the mean cervical length measurement was 3.5cm.The present study was done in 60 women, with gestational age between 28-36 weeks of gestation with transvaginal sonography the sensitivity was 79%, specificity was 95.46%, positive predictive value was 94.80% and negative predictive value was 88.22b%,with overall accuracy of 91%. Kore SJ *et al.* [6] conducted a study in 2009 on 115 women of 22-24 weeks of gestation with cervical length measurement of <30mm taken as cut off, has sensitivity of 57.6%, specificity of 97.6%, positive predictive value of 89.5% and negative predictive value of 89.2%.In the present study transvaginal sonography has more specificity and accuracy comparable to the study done by Kore SJ *et al*. In the present study by digital examination of the cervix length, sensitivity was 98.20%, specificity was 60.88%, positive predictive value was 63.22% and negative predictive value was 96.10%. with overall accuracy of 78%. Newman RB *et al.* [14] 36%, specificity of 95%, positive predictive value of 20% and negative predictive value of 98%. Volumenie *et al.* [15] conducted a study in 2004, on 2916 women, has sensitivity of 74%, specificity of 61%, positive predictive value of 55% and negative predictive value of 79%. In the present study digital examination is more sensitive but less specific in predicting preterm labor. Present study was done in 60 women with gestational age between 28-36 weeks of gestation, 12% of the women has previous history of preterm labor. Guzman and coworkers [16] also found a strong relationship between previous obstetric history and cervical length in the subsequent pregnancy. Andrews and coworkers [17] found that women with a history of spontaneous second trimester miscarriage and preterm delivery due to cervical insufficiency had an increased risk of recurrence in a subsequent pregnancy. In the present study with gestational age between 28-36 weeks, 78% of the women have set into spontaneous labor, 22% of the women underwent caesarean section for varied indications. Most common indication for caesarean section was oligohydramnios 46%.In the present study majority of babies i.e. 47% had their birth weights between 2-2.5kgs, 82% of babies had APGAR score of 8-10 at 1 minute and 5 minutes, and about 18% of babies had APGAR score of less than 8 with mild to moderate distress admitted in neonatal intensive care unit due to low birth weight and prematurity.

Conclusion

Transvaginal ultrasonic measurement is considered to be the most accurate method of measuring the cervical length when compared to cervical length measurement by digital examination. Corticosteroids should be given to those found to have a short cervix by both transvaginal sonography and digital examination so as to improve the neonatal outcome.

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