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Elastography of the cervix for prediction of induction of labour.

Dr. Sanjivani Wanjari*,

Professor, Department of Obstetrics & Gynaecology; MGIMS Sewagram, Wardha, Maharashtra, India

Dr. Suresh Phatak,

Professor, Department of Radio-diagnosis, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Sawangi (Meghe) Wardha, Maharashtra, India

Dr. Deepti Shrivastava,

Professor, Department of Obstetrics & Gynaecology, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Sawangi (Meghe) Wardha, Maharashtra, India

Abstract: Background –Labour can be induced for various indications. This is done when it appears that benefits of induction outweigh its risk. Bishop score is the gold standard that is used to determine whether labour can be induced. However, the assessment of the cervix with digital examination is subjective and less reproducible. Elastography is an upcoming modality which is an ultrasound-based imaging technique used for assessing elasticity of tissues. It is based on the premise that softer tissues get more compressed than harder tissues when pressure is applied with ultrasound probe. Thereafter colour mapping is done depending on the gradient values of strain.

Aim - to assess whether elastography findings of uterine cervix can be used to predict successful induction of labour.

Objectives -

1) To examine the cervix by digital examination.

2) To determine the length of the cervix with the help of trans-vaginal ultrasound.

3) To perform strain elastography of the cervix.

4) To observe within how many hours labour starts after induction.

Materials & methods –

A prospective observational study will be done at AVBRH over a three years period from October 2018 to October 2021. Inclusion criteria - Pregnant women with gestation of 36-41 weeks, having no contraindication for labour induction, will be included in the study. Sampling procedure –Simple Random Sampling. Sample size – estimated sample size for study is 80 cases. Strain Elastography of the cervix will be performed before labour induction in the sample population and the outcome will be assessed. A score will be devised based on the colour mapping of elastography.

Results-

Up till now we have had encouraging results. A colour map showing various colours from blue/purple through green/ yellow and then orange/red were noted. The colour red

depicted a soft cervix that was easily inducible. On the other hand, purple colour denoted an unfavourable cervix. The colour score will soon be formulated and shared.

Conclusion –

Elastography may emerge as a new and upcoming method for determining favourability of the uterine cervix for labour induction based on a colour scoring system.

Keywords: Elastography, uterine cervix, cervical assessment, induction of labour

Introduction -

Induction of labour means the practice of initiation of uterine contractions artificially by medical methods or surgical methods or by combined techniques. This is done before the onset of normal labour pains. Incidence of induction of labour is 15-20% in UK, 30-38% in USA and about 10% in India (1).

Labour induction is done when it appears that benefits of induction outweigh its risk. Induction can be done for maternal indications like diabetes mellitus, hypertensive diseases of pregnancy, antepartum haemorrhage or premature spontaneous rupture of membranes PROM and foetal indications like post maturity, foetal growth restriction, oligohydramnios or intrauterine foetal demise (2)

Today the understanding of the process of labour is better and newer advanced techniques are available that can replicate the natural process. Hence the chances of achieving successful induction of the labour are greater. The condition of the cervix is one of the main predictive factors for labour induction. The cervical changes are taking place throughout the pregnancy and also during labour. The changes that occur in the later weeks of pregnancy and during labour lead to a normal delivery. A uterine cervix contains less smooth muscle and mainly consists of connective tissue and collagen. It undergoes the process of cervical ripening, which means that the cervix softens. This allows the cervix to undergo changes in shape, from initial state of being long and tubular (closed) to becoming short and soft (effaced) & later becoming opened up (dilated). At the same time the uterus which mainly consists of smooth muscle fibres may respond to the stimuli of induction and begin contracting in waves that are characterise of labour pains.

In 1964, Bishop introduced a method to ascertain the status of the cervix before labour induction. This came to be known as the 'Bishop's score' or the 'pelvic score'. This score helps to determine the patient's suitability for labour induction. The score consists of five components: 1) cervical dilation, 2) cervical length, 3) cervical position, 4) cervical consistency and 5) station of foetal head. Score of less than 5 means that the cervix is not favourable and labour may not begin without induction. Score of more than 9 means that the cervix is favourable and labour will most likely begin spontaneously. Scores between 5 and 9 are intermediate and require thorough reassessment and evaluation.

However, the digital examination of the cervix has been found to be subjective and less reproducible. Hence the Bishop's score has been modified several times (3), (4), (5), (6), (7). But despite the several modifications, the Bishop's score is still the most widely accepted means of assessing the inducibility of the cervix (8).

Ultrasonographic measurement of the cervical length is another factor that has been evaluated. And the numerous studies show diverging results (9), (10), (11).

Elastography is a new method for assessment of the cervix. It assesses the cervical stiffness or compressibility and can be used either independently or combined with Bishop's scoring system and the sonographically measured cervical length, to plan induction of labour.

Elastography is a technique based on ultrasound imaging & colour mapping and is used for assessing the elasticity or stiffness of the tissues. This method depends on the presumption that soft tissues are compressed more than hard tissues when pressure is applied with the probe. The gradient values of strain then are visualized on a colour map. The introduction of elastography in Obstetrics and Gynaecology is new and it is used for assessment of degree of cervical firmness. The softness of the cervix can help identify women at risk of preterm labour and also those likely to have successful induction of labour. For semi-quantitative assessment of the consistency of the cervix during pregnancy, there are two different methods of cervical elastography: 1) static or strain elastography - which uses manual compression caused by movement of the probe and 2) shear wave elastography - which determines the propagation speed of the shear wave generated by the ultrasound probe. The speed of shear wave generated cannot be influenced by the operator, hence shear wave elastography is more reliable for giving objective results. Feasibility studies have confirmed the reliability of cervical elastography for successful labour induction (12), (13), (14), (15).

Rationale - With this background we decided to study elastography as a new modality for assessment of the pregnant cervix. Aim of our study is to assess elastographic findings of the cervix and to see if they can be used to predict the success of induction of labour. In this study we will use strain elastography for assessment of the cervix in a pregnant uterus.

Objectives -

1) To assess the cervix by digital examination.

2) To determine the length of cervix with the help of trans-vaginal ultrasound.

3) To perform strain elastography of the cervix.

4) To observe within how many hours labour starts after induction.

Research question –Can elastography of uterine cervix be used to predict successful induction of labour?

P- Pregnant women with 36-41 weeks of gestation, having no contraindications for induction of labour.

I – Eastography of cervix will be performed of the cervix using strain elastrography. This will be done with a Colour Doppler trans-vaginal probe of 5-11MHz.

C – Comparison between Bishop’s score and the ultrasound assessed cervical length and elastography of the cervix

O- Predicting the outcome of labour induction.

Materials & methods –

Study setting - The study will be conducted at AVBRH, Sawangi (Meghe) Wardha. Study duration will be conducted over three years. Approval from IEC (institutional ethics committee) has been obtained for the study.

Study design –Observational cross sectional study – prospective

Study population - Eighty pregnant women with gestational age of 36-41 weeks, having no contraindication for labour induction will be included in the study.

Inclusion criteria -

Pregnant women with gestational age of 36-41 weeks, having no contraindication for labour induction and vaginal delivery will be included in the study.

Exclusion criteria -

Women not fit for induction of labour.

Sampling procedure –Simple Random Sampling

Sample size – estimated sample size for study is 80 cases.

The sample size formulae used are as follows:

$$n_1 = \frac{(\sigma_1^2 + \sigma_2^2 / \kappa)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

$$n_2 = \frac{(\kappa * \sigma_1^2 + \sigma_2^2)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

The notation for the formulae are:

n_1 = sample size of Group 1

n_2 = sample size of Group 2

σ_1 = standard deviation of Group 1

σ_2 = standard deviation of Group 2

Δ = difference in group means

κ = ratio = n_2/n_1

$Z_{1-\alpha/2}$ = two-sided Z value (eg. Z=1.96 for 95% confidence interval).

$Z_{1-\beta}$ = power

Mean cervical length in failure =26.9

Mean cervical length in success=23.8

σ1=SD of failure=6.4

σ2=SD of success=7.6

For detecting mean difference of 3.1% i.e Δ=26.9-23.8=3.1

N1= (6.4*6.4+7.6*7.6)(1.96+0.84)2/(3.1*3.1)

=80.53 =80 patients required in study period of three years

Reference study for calculation of sample size - Elastography of the uterine cervix: implications for success of induction of labor, M. Swiatkowska-Freund and K. Preis, Ultrasound Obstet Gynecol 2011; 38: 52–56

STATISTICAL ANALYSIS -

Statistical methods: Descriptive statistics and inferential statistics will be obtained using chi-square test, student's unpaired t test, sensitivity, specificity, PPV, NPV and diagnostic accuracy. The data will be presented as mean standard deviations and percentage/proportions.

METHODOLOGY –

Initial vaginal examination will be performed for assessing cervical dilatation and effacement, position and consistency of the cervix and station of the foetal head. Bishop Score will be accordingly calculated.

Strain Elastography of the cervix will be done before induction of labour. The complete uterine cervix including the internal os, length of the cervix and external os will be examined. The cervical length will be noted. Elastography will be done on Hitachi Aloka Medical Ultrasound machine using color doppelr Arietta 700 Model with a trans-vaginal probe 5-11MHZ. A colour mapping will be done from blue/purple to orange/red. Colour map will be plotted with the hardest tissues displayed as blue and purple and progressively softer tissues displayed as yellow, orange and red. A colour scoring system will be designed which will help define the favourability of the cervix. This will help selecting the appropriate cases for labour induction and will decrease chances of failed induction.

The elastography findings of tissues at the internal os, the cervical canal, and at the external os will be correlated with the success of induction of labour.

Women will then be induced with the help of medical methods using oxytocin or prostaglandins like misoprostol or cerviprime gel. Initiation of uterine contractions and cervical dilatation and effacement will be noted after a few hours. The induction delivery interval will be noted. Percentage of women having failure of induction and women requiring caesarean section will be calculated. Maternal and perinatal outcome will be analysed.

Expected results-

We propose to formulate an elastography scoring system for assessment of the cervix based on colour mapping. This score can be applied to patients who require induction of labour for various indications. The score when it is found to be favourable will help clinicians make a decision regarding induction of labour. The score will help indicate the patients who will have a favourable delivery outcome.

Discussion –

The Bishop's score which was described in 1964, is even today considered the gold standard for predicting labour inducibility. However, the digital examination of the cervix remains highly subjective. The reliability and reproducibility is also low.

The Bishop's score has been modified several times in an attempt to improve the score. One such modification is the Calder score which was introduced in 1979. Calder modified the Bishop's score replacing cervical effacement with cervical length. The Calder score is popular worldwide and especially in the UK.

Women having certain characteristics have more chances of successful induction of labour are 1) women who are less than 35 years of age, 2) are multiparous 3) have favourable Bishop's Score 4) estimated fetal weight of less than 3.5 Kg at birth, 5) and adequate liquor amni. Parity becomes the most important variable needed for successful induction of labour (16). The variables like gestational age and AFI can also affect outcome of induction of labour. It is usually recognised that AFI of less than 5 cm is associated with more foetal risk and increased chances of caesarean section.

The Bishop's Score is highly subjective and less reproducible and hence its predictability was studied by in a meta-analysis (17). The conclusion was that the Bishop's score is not a strong predictor for deciding about labour inducibility.

In 1986 a semi-quantitative ultrasound scoring method was proposed in order to predict successful induction of labour (18). The scoring method used trans-abdominal ultrasound to evaluate the cervical length & dilation, the thickness and shape of the LUS lower uterine segment, and station of the presenting part. This ultrasound scoring method showed no added advantage of ultrasound over digital examination (Bishop's score).

In 1991 transvaginal sonography for assessment of the cervix was used (19). Transvaginal ultrasonography improved the accuracy of assessment of the cervix and had better diagnostic value. This is an invaluable tool in predicting the cases that will respond well to cervical ripening agents or labour inducing agents.

However some of the studies found conflicting results when they compared trans-vaginal length of cervix and the Bishop's score before labour induction (20). Their study included 122 subjects where both ultrasound assessment of the cervix and digital assessment of the cervix were done before labour induction. It was noted that ultrasound measurement did not show any significant relation with successful induction of labour.

Researchers have used measurement of fetal fibronectin as a predictor for successful labour induction. Fetal fibronectin is found in high concentrations in amniotic fluid and the choriodecidual tissues, and in vaginal secretions before onset of labour. Neither TVS cervical length nor fetal fibronectin have been found to be better than the Bishop's score (21), (22).

With this background we decided to investigate a new method of evaluation of the cervix in the form of ultrasound elastography. Elastography for evaluation of the uterine cervix was first used by (23), but this was in non-pregnant uterus. Imaging of the cervix with the use of elastography during pregnancy was first described (24). They expressed the cervical stiffness assessment done after manual compression using a colour scale.

In 2010 an elastography index EI was proposed for assessment of the cervix. In EI points were given to each colour component expressed on elastographic images where 0 was assigned for the harder tissue to 4 for the softer regions. Each part of the cervix was designated numbers according to the colours (25). Elastography measures the degree of displacement of tissues after pressure is applied to the tissues using ultrasound probe. This is noted in a special type of software. Soft tissues deform more easily than hard ones and the difference is noted as alteration in ultrasound images that are represented on a colour map. Colour mapping was done from purple to red with the hardest tissues displayed as purple and

assigned a score of 0 points and progressively softer tissues given higher points from 1 to 4. (12). Various studies related to induction of labour were reported. Acharya et al reported on mechanical cervical ripening with foley catheter balloon(26). Agrawal et al assessed effectiveness of isosorbide mononitrate in cervical ripening before induction of labour in full-term antenatal patients (27). Deshmukh et al studied use of Pg-e 2 Gel for cervical ripening in labour induction (28). ElShanti, A,et al The Prevalence and Severity of Gingivitis in High School Students in Gaza Strip – Palestine(29). Sharma and Tiwari reported about comparison of intravaginal misoprostol and intramuscular Carboprost for cervical priming(30). Singh et al reported on study of mifepristone vs misoprostol as pre-induction cervical ripening agent in term pregnancy(31).

We are in the process of developing our own score which may help clinicians make decisions regarding induction of labour based on this new method of investigation, namely elastography of the uterine cervix.

Conclusion –

Elastography can emerge as a promising method for determining favourability of the cervix for labour induction based on a colour scoring system.

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Figures –

Figure 1 – Bishop's score

Cervix	Score			
	0	1	2	3
Position	Posterior	Midposition	Anterior	--
Consistency	Firm	Medium	Soft	--
Effacement	0-30%	40-50%	60-70%	>80%
Dilation	Closed	1-2 cm	3-4 cm	>5 cm
Baby's Station	-3	-2	-1	+1, +2

Figure 2 – Modified Bishop's score

Cervical feature	Score: 0	1	2	3
Cervical dilatation	< 1cm	1-2 cm	2-4 cm	> 4 cm
Cervical length	4 cm	2-4 cm	1- 2 cm	< 1 cm
Station of presenting part	-3 cm	-2 cm	-1/0 cm	+1/+2 cm
Consistency of cervix	Firm	Average	Soft	
Position of cervix	posterior	Mid position/ anterior		

Ian Donald's practical obstetric problems, 7th edition, chapter 26, page 498, table 26.1.