Journal of Cardiovascular Disease Research

ISSN: 0975-3583, 0976-2833 VOL15, ISSUE1, 2024

"A study to predict success of induction of labour in primigravida beyond 40 weeks of pregnancy by ultrasonographic measurement of fetal adrenal gland size."

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ABSTRACT

Objective

To establish Ultrasonographic measurements of fetal adrenal gland size as a predictive marker of successful outcome of induction of labour.

Study Design

This prospective observational study was conducted at Department of Obstetrics and Gynaecology, MGM Medical college and M. Y. Hospital & associated hospital Indore, over a period of one year, approved by the institutional ethics and scientific committee .The study involves 200 study participants .The inclusion criteria were all primigravida pregnant women with 40 weeks or beyond 40 weeks gestation, single intrauterine pregnancy, Patient willing to labour induction and adequate pelvis. After detailed history and clinical examination, participants were subjected to 2 D ultrasonographic measurements of foetal adrenal gland volume and fetal adrenal zone parameters .The induction of labour was performed by any of the following methods, Mechanical, Mechanical Plus Dinoprostone gel, Dinoprostone gel or tablet Misoprostol. Outcome was measured based on mode of delivery; vaginal or LSCS.

Results

On analysis of data by Mann-Whitney U test, there was a significant association between. Fetal Adrenal Gland Volume and mean corrected fetal adrenal gland volume (p <0.001) with vaginal delivery, indicating that the chances of successful induction of labor increases with increased adrenal size. ROC curve was plotted for corrected fetal adrenal

gland volume in order to determine the cut off values, the efficacy of the cut off had the sensitivity of 93.8%, specificity of 77%, positive predictive value 50.1%, negative predictive value 96.3%

Conclusion

The ultrasonographic measurement of fetal adrenal gland size helps predict success of labor induction. The cFAGV appears to be an efficacious parameter and can be used independently to predict possibility of the success of induction of labor**.**

KEYWORDS- Fetal Adrenal gland volume. Induction of labor, Vaginal delivery, Primigravida

INTRODUCTION

Labor is initiated when there is cessation of uterine quiescence and the Placental clock plays a crucial role in this event.[1,2] Fetal adrenal gland regulates this process. Biochemical activation causes increased dehydro-epi-androstenedione sulfate production in central zone of fetal adrenal gland. Hence fetal adrenal zone and gland increases in size. Timing of parturition is associated with increased expression of corticotrophin -releasing hormone from placenta. This placental corticotrophin releasing hormone further stimulates maternal and fetal pituitary glands to produce adreno-corticotrophin hormone, which results in fetal adrenal gland enlargement due to increased stimulation to release cortisol.[2]

Labor induction is an artificial process to promote cervical ripening and enhance uterine contractions before spontaneous onset of labor. It has become the most common intervention performed during pregnancy, with 24.5-35.5% of pregnancies undergoing induction of labour.[3] In India, the incidence of induction of labor ranges from 5% to 22%.[4]

Common indications for the induction of labor are Maternal indications like abruptio placentae, chorioamnionitis, intrauterine fetal demise, gestational hypertension, preeclampsia and eclampsia, PROM, post term pregnancy and Fetal indications like fetal growth restriction, isoimmunization and oligohydramnios. Various methods such as pharmacological and mechanical, are used to induce labor.[3]

There needs to be a consensus in defining the success and failure of labor induction. The success of the labor

ISSN: 0975-3583, 0976-2833 VOL15, ISSUE1, 2024

induction is defined as vaginal delivery within 24 hours from the beginning of induction, but the timing is subject to other factors; for instance, Ellis JA et al. reported that obese women are said to have a more extended period than normal weight.[3,5]

According to American Maternal-Fetal Medicine Units Network, Specifically, among women undergoing labor induction, when maternal and fetal maternal and fetal conditions permit, cesarean delivery should not be undertaken in the latent phase prior to at least 15 hours after rupture of membranes has occurred and oxytocin has been started. The decision to continue labor beyond this point should be individualized, and may take into account factors such as other evidence of labor progress.[6]

Failed induction leads to unnecessary increased maternal-fetal exhaustion. Therefore, to predict the outcome of labor induction would improve the fetal-maternal well- being, Bishop's score was one of the traditional methods used to predict outcome of labor induction based on the assessment of the "cervix favorability," but it is subjective and has little reproducibility.

Zhang J et al. and Alcantara-Alonso V et al. reported that the cascade of events initiating the onset of labor is due to the "placental clock" mechanism. Mclean et al. suggested Corticotropin-releasing hormone (CRH) as a marker for the placental clock, which causes activation of the fetal adrenal gland and leads to enlargement. It has been found that quantitative measurement of the fetal adrenal gland is used as a non-invasive marker to predict preterm labour.[7,8,9]

Similarly, this concept can be used to predict the success of labor induction at term. But there is insufficient data to predict induction of labor (IOL) by measuring the fetal adrenal gland.

This study aims to study the relation of fetal adrenal gland size with the outcome of labor induction in primigravida beyond 40 weeks.

MATERIALS AND METHODS:

This prospective observational study was conducted at Department of Obstetrics and Gynecology, MGM Medical college and M. Y. Hospital & associated hospital Indore, over a period of one year, approved by the institutional ethics and scientific committee, IEC NO.-EC/MGM/APRIL -22/01. The study involves 200 primigravida with gestational age 40 weeks or beyond. All the participants in the study cohort gave written consent to participate in the study.

The inclusion criteria were all primigravida pregnant women with 40 weeks or beyond 40 weeks of gestation, Single intrauterine pregnancy, patients willing to consent for labor induction, and no cephalopelvic disproportion.
Exclusion criteria were: Pregnant women who are in active labor, who are not willing to consent for induction of labor, malpresentation, Cephalo-pelvic disproportion (CPD) and absolute contraindications for induction of labor like Placenta previa, Active herpes infection, Umbilical cord prolapse, History of prior cesarean section, previous myomectomy breaching the endometrial cavity.

The gestational dating was based on last menstrual period if it corelated with first trimester ultrasound. If not, first trimester ultrasound was used. The Subjects will undergo detailed clinical examination, assessed using modified bishop score. If the score was less than or equal to 5, they were recruited in the study for induction of labor.

All the study participants were subjected to 2D ultrasonography to measure fetal adrenal gland dimensions. Philips HD 11 XE, 2 D Ultrasound Machine (manufactured in the USA), model number 989605325131. To avoid bias, all patients were imaged by a single sonographer.

The right fetal adrenal gland was imaged to obtain measurements, as it is better visualized than the left adrenal gland, which is usually obscured by the rib shadow. The fetal adrenal gland is visualized as a hypoechoic, inverted 'V'-shaped structure/cap-like structure above the kidney. Both transverse and sagittal planes were obtained. The length of the gland was measured in the sagittal plane, whereas the width and depth of the adrenal gland were measured in the transverse plane.

The fetal adrenal gland volume was calculated using the ellipsoid formula (0.523 × lengths × width × depth). Corrected fetal adrenal gland volume (cFAGV) was obtained by dividing fetal adrenal gland volume by the estimated fetal weight to make it a gestational-age- independent factor.[10]

ISSN: 0975-3583, 0976-2833 VOL15, ISSUE1, 2024

Then IOL was performed by any of the following methods,
1.Mechanical 2. Mechanical Plus Dinoprostone gel (Prostaglandin E2) 3. Dinoprostone gel 4. Misoprostol tablet
Mechanical method of induction done by 16-F-Foley catheter inserted into the endocervical canal, once the catheter was past the internal os of the cervix, the balloon was inflated with 80 ml sterile saline solution. Dinoprostone, PG E2 gel is available in 2.5 ml syringe for intracervical application of 0.5 mg of Dinoprostone, Dose repeated after 6 hours if cervical dilatation of at least 3-4 cm is not achieved. Tablet misoprostol 25 microgram, kept vaginally in Posterior fornix 4 hours apart, maximum 4 doses. Outcome was measured based on the mode of delivery; vaginal or Cesarean section. Data was recorded in master sheet.

Figure. No: 1 Ultrasonographic image while measuring the foetal adrenal gland length

Figure. No:2 Ultrasonographic image while measuring the fetal adrenal gland depth

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Figure. No:3 Ultrasonographic image while measuring the fetal adrenal gland width

Data analysis:

The Microsoft Excel and SPSS (SPSS Inc, ver. 27 Chicago) software packages were used for data entry and analysis. The results were averaged (mean + standard deviation) for each parameter for continuous data and numbers and percentages for categorical data presented in Table and Figure.

Demographic details were expressed as means. cFAGV estimated fetal weight, and the amniotic fluid index was expressed as mean and standard deviation (S.D).

Mann–Whitney U test was used to compare the mean. Significance was assumed at a p-value of less than 0.05.

Proportions were compared using the Chi-Square and Fisher's Exact test of significance. Significance was assumed at a p-value of less than 0.05.

Receiver operated curve (ROC) was plotted to determine the cut-off values, and the sensitivity and specificity were noted, and the area under the curve,

0.9–1: excellent predictor,

0.8–0.9: good predictor,

0.7–0.8: fair predictor,

0.6–0.7: poor predictor,

0.5–0.6 fails to predict, were assumed.

Results

We recruited a total of 200 primigravida singleton women meeting the inclusion criteria. The mean age of the study participants was 23.87 ± 3.51 years.

The mean modified bishop score was 3.42 ± 1.04. On ultrasonogram, the mean estimated fetal weight was 2.78 ± 0.35, the mean Fetal Adrenal Gland Volume was 785.19 ± 265.47, the mean corrected fetal adrenal gland volume was 282.99 ± 92.70, and the mean Amniotic fluid index was 7.82 ± 3.07.

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In the study majority, (98/200, 49%) of the patients were induced by Mechanical plus Dinoprostone Gel, followed by Dinoprostone Gel (89/200, 44.5%) and (13/200) 6.5% underwent induction by Misoprostol.
The average birth weight of the babies born to the study subjects were 2.77 kgs ± 0.36. The average interval duration between induction to normal vaginal delivery was 7.35 ± 4.28 hrs. Majority 158 (79%) of the patients in the study delivered vaginally and 42 (21%) delivered by cesarean section.

Association of maternal characteristics in relation to the mode of delivery (Table 1).

Maternal Characteristics	**Normal Vaginal delivery (Mean ± SD)**	**LSCS (Mean ± SD)**	**P-value**
Mean Age (Years.)	23.66 ± 3.48	24.64 ± 3.56	0.107*
Mean Modified Bishops score	3.51 ± 1.02	3.07 ± 1.02	0.820*
Mean Gestational age at the time of diagnosis (Weeks)	35.98 ± 1.42	36.08 ± 1.51	0.075*

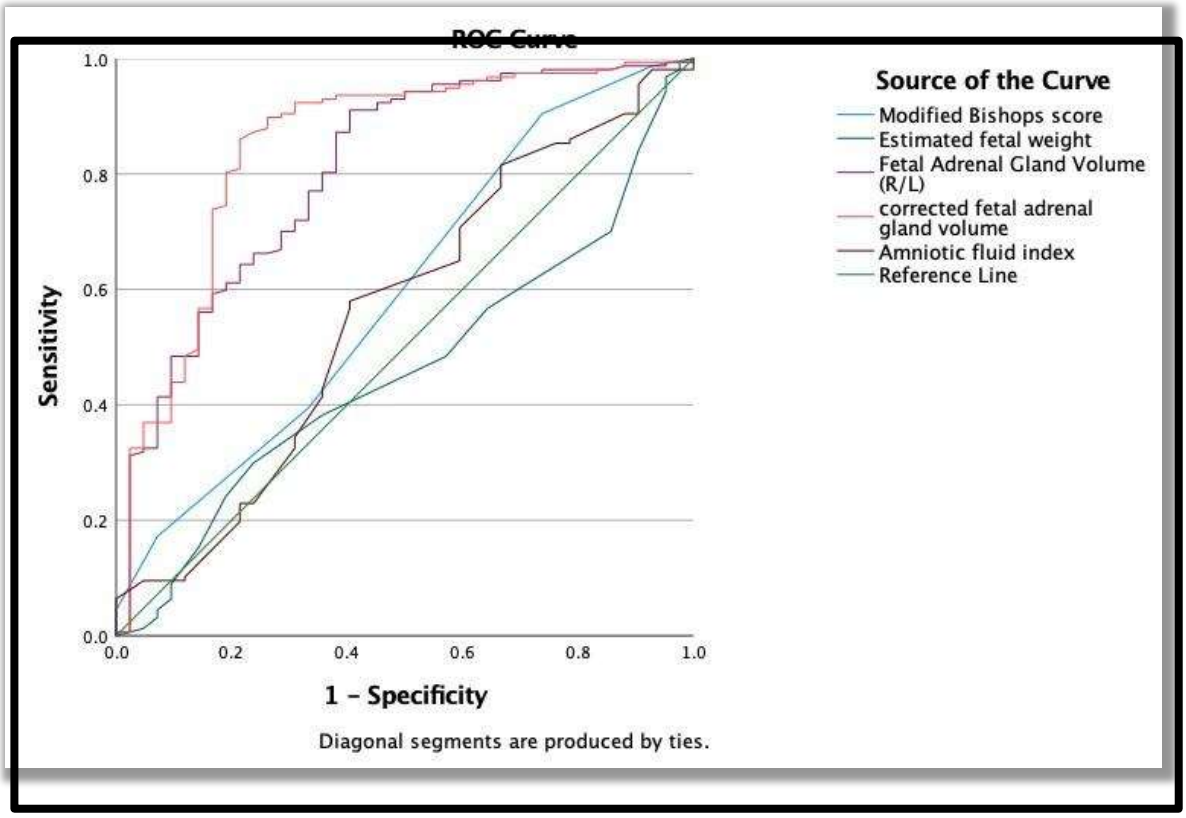
**** Mann–Whitney U test***

Comparison of ultrasonographic characteristics in relation to the mode of delivery:
The average Fetal Adrenal Gland Volume for subjects who underwent vaginal delivery was 835.85 mm3/kg (SD 251.12) and for subjects who underwent cesarean section, volume was 594.60 mm3/kg (SD 231.28). The average corrected fetal adrenal gland volume was 302.14 mm3/kg (SD 86.46) for participants who underwent vaginal delivery and 210.96 mm3/kg (SD 79.76) among patients who underwent LSCS.
On analysis by Mann-Whitney U test, there was a significant association between patients who underwent normal vaginal delivery to the mean Fetal Adrenal Gland Volume and mean corrected fetal adrenal gland ($p < 0.001$), indicating that the chances of successful induction of labor increases with increased adrenal size.
On comparing the fetal adrenal gland volume with the birth weight, the birth weight of <2kg had the smallest mean fetal adrenal gland size, 257.74 mm3/kg, and the birth weight of > 3.1kg had the highest of 299.11 mm3/kg, indicating that the larger the adrenal gland size, larger the birth weight of the baby.

A Receiver-operating characteristic (ROC) Curve analysis was used to determine the different parameters to predict the outcome of the induction of labor. It was found that corrected foetal adrenal gland volume had the highest area under the curve value of 0.846 (good predictor), followed by Fetal Adrenal Gland Volume with AUC of 0.804 (good predictor).
Receiver-operating curve was plotted for Corrected fetal adrenal gland volume in order to determine the cut-off values (Cut-off 244 mm3/kg body weight), the efficacy of the cut-off

ISSN: 0975-3583, 0976-2833 VOL15, ISSUE1, 2024

had the sensitivity of 93.8%, specificity 77%, positive predictive value 50.1%, negative predictive value 96.3%.



Discussion:

The time between the induction of labor and the vaginal delivery is crucial. Predicting the success of labor induction is challenging for obstetricians because of the unavailability of reliable techniques. Several attempts have been made to predict the success of labor induction, but the studies have shown poor results.

A reliable predicting technique would help minimize the waiting period, exhaustion of the mother and fetus, and other medical-related problems.

The definition of successful induction is divergent, Pandis et al.and Rane et al. considered the success of labor induction as vaginal delivery within 24 hours.[11,12] Due to the unavailability of a standard definition, it is difficult to compare it with different studies published on prediction of labor induction.

Few studies have used fetal adrenal gland measurements to predict preterm delivery.[13,14] Still, there is insufficient knowledge using the fetal adrenal gland in predicting the success of labor induction.

Among the various factors influencing the success of labor induction, parity is one of the significant factors. It has been found in many studies that labor induction is easier and has a shorter interval as the parity increases.[15] Therefore, in this study, we have opted to determine the relation of fetal adrenal gland size with the outcome of labor induction in primigravida beyond 40 weeks and to establish ultrasonographic measurements of fetal adrenal gland size as a predictive marker of the successful outcome of induction of labor.

Chandana s. Bhat reported that the chances of spontaneous delivery increase in study participants with increased adrenal gland size. The smaller the size, the greater chance that the pregnancy will be prolonged and needs to be induced.[10]

In our study, successful induction was done in 79%, which was in concurrence with the other studies , with a successful vaginal delivery rate of 75% to 86%.[15,16]

The induction to delivery interval can be affected by various factors, such as gestational age, parity, and birth weight. In our study, the mean induction to vaginal delivery time was 7.35 ± 4.28 hours, which was shorter as compared to the study by Tan et al., where it was 19.1 ± 1.1 hour, can be because of, in our study, all the women recruited are at the gestational age of 40 and above. The duration of induction to delivery has been reported to

ISSN: 0975-3583, 0976-2833 VOL15, ISSUE1, 2024

be shorter with increasing gestation.[16]

The status of the cervix plays a vital role in predicting successful induction of labor; the best tool measures the cervical condition is the modified bishops score which is based on the histological changes; it is defined as a score <6 is an unfavorable cervix, and it has a high rate of failed induction of labour.[18]

in our study, the mean modified bishop score for vaginal delivery was 3.51, ± 1.02, and for LSCS
3.07 ± 1.02 It was found that comparing the bishop score between successful induction and failed induction, there was no significant association.
3.08
The birth weight significantly predicted successful labor induction, with a direct correlation between lower birth weight and delivery within 24 hours.[19]In our study, the estimated fetal weight among the patients with successful induction was slightly less than those with failed induction. There was no significant association (p>0.05), which was in discord with the studies conducted by Teixeira C et al., Tolcher MC et al., Batinelli L et al., where it was found that the lower birth weight was associated with successful induction[20,21,22].

A study by Bhat CS et al, found that the chances of spontaneous delivery increase in patients with increased adrenal gland size. The smaller the size, the greater chance that the pregnancy will continue and needs to be induced. Also, they found that the patients who had undergone spontaneous labor had increased cFAGV than those who were induced. On taking the cFAGV cut-off as 271.16 mm3/kg body weight. It had a sensitivity of 90% and 81.9% specificity to predicting women at preterm delivery, indicating that a patient above this cut-off has an increased chance of delivery.[10]

A study conducted by Turan et al. concluded that cFAGV of greater than 422 mm3/kg was best in predicting preterm birth within five days, with a sensitivity and specificity of 92% and 99%.[13,14]

In our study comparing the cFAGV between patients delivered by vaginal delivery and LSCS, the patients who delivered vaginally had a greater volume, which was statistically significant (<0.001).

We found that the Corrected fetal adrenal gland volume cut-off values to predict the success of induction (Cut-off 244 mm3/kg body weight), the efficacy of the cut-off had a sensitivity of 93.8%, specificity of 77%, positive predictive value of 50.1%, negative predictive value 96.3%. Our study found that with the increase in the FAG size, there is an increased chance of vaginal delivery, indicating the success of induction.

A study conducted by Bhat CS et al,[10] calculated the cFAGV cut-off as 271.16 mm3/kg body weight. On analysis, it had a sensitivity of 90% and 81.9% specificity to predicting women at preterm delivery.
Similarly, a study conducted by Garrett Fitzgerald et al. predicted the success of labor induction by measuring Fetal zone enlargement (FZE). FZR was significantly higher (42±8%) in successful IOL versus failed IOL (29%±7, p=0.002). By ROC curve analysis, FZR >35% had a sensitivity of 86% and specificity of 100% (AUC 0.922, p=0.07) in predicting successful IOL; PPV=100%, NPV=50%. This was in concurrence with our study, where Receiver- operating characteristic (ROC) Curve analysis was performed on various predictive parameters. It was found that corrected fetal adrenal gland volume had the highest area under the curve value of 0.846 (which indicates a good predictor).[23]

Establishing day-wise predictable cut-offs will give fetal adrenal glands a new position in predicting labor in modern obstetrics. This kind of predictability will provide the obstetrician time to utilize resources optimally and give the parturient and her family a clear plan.

Conclusion:
The ultrasonographic measurement of fetal adrenal gland size can help to predict the success of labor induction. The cFAGV measurement has clinical potential because of its non-invasive diagnostic method. Compared with other predictive markers, cFAGV appears to be efficacious and can be used independently to predict the possibility of the success of IOL and reduce the fatigue and agony faced by pregnant women with failed induction.

Funding disclosure:
None

ISSN: 0975-3583, 0976-2833 VOL15, ISSUE1, 2024

Declaration of competing interest:
None declared

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ISSN: 0975-3583, 0976-2833 VOL15, ISSUE1, 2024

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