Comparison of outcomes of Foley’s induced labors with different sonographic floater densities in fore-water

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ABSTRACT

Background: Onset of spontaneous labor occurs on completion of fetal functional maturity at amniotic fluid optical density (AFOD) 0.98 ± 0.27 (mean ± SD). All three events occurring together at any time from 35 weeks to 42 weeks indicate the individualized term for each fetus. No failures of induction of labor were reported when labors induced at AFOD 0.98 ± 0.27. As AFOD estimation needs invasive amniocentesis, we tried to induce women with liquor with mature AFOD by observing the sonographic appearances of fore-water by transvaginal sonography.

Methods: In this comparative study, three groups of gestational age and parity matched uncomplicated singleton term pregnant women, underwent fore-water trans-vaginal sonography before induction of labor with Foley’s catheter. Sonographic images were divided into three grades based on floating particle densities. Each group consisted of 20 women with each grade of sonographic images. Uncentrifuged fresh AF samples collected at amniotomy were used for AFOD measurement with colorimeter at 650 nm in all groups. After Foley’s expulsion, labor was augmented with vaginal misoprostol. The mean AFOD values, Foley’s insertion expulsion intervals, Foley’s insertion delivery intervals (FIDI), T misoprostol required, and neonatal respiratory distress were recorded in each group and compared.

Results: In groups 1, 2, and 3, the mean AFOD was found to be 0.29 ± 0.09, 0.68 ± 0.14, and 1.15 ± 0.20, respectively. Mean Foley’s insertion expulsion intervals were 10.57 ± 3.76 h, 5.83 ± 2.24 h, and 4.08 ± 0.86 h, respectively. Mean FIDI were 20.00 ± 6.20 h, 11.22 ± 4.20 h, and 8.95 ± 2.98 h, respectively. The mean numbers of T misoprostol required in each group was 3 ± 1, 2 ± 1, and 2 ± 1, respectively. Significant differences were observed in all outcomes between groups (P < 0.05) favouring inductions with Grade 3 sonographic images.

Conclusion: Labor induction with Grade 3 sonographic images of fore-water was successful in all women with shorter FIDI, and with better perinatal outcomes.

Key words: Amniotic fluid optical density; Foley’s induction of labor; fore-water scanning; transvaginal ultrasonography.

Introduction

Samartharam et al. reported the concept of the individualized term for each fetus based on amniotic fluid optical density (AFOD). Babies attain completion of functional maturity at different gestational ages ranging from 35 weeks to 43 weeks. The AFOD value at completion of fetal functional maturity was found to be 0.98 ± 0.27 (mean ± SD), and
at this AFOD value the spontaneous labor occurs. Babies born with AFOD value ≤ 0.40 are functionally premature and develop varying degrees of respiratory distress, irrespective of gestational age, and birth weight.\textsuperscript{[2,6]} Raising levels of amniotic fluid lecithin during the third trimester induces progressive and rapid detachment of vernix from the fetal skin surface. The detached vernix clumps get mixed with amniotic fluid, resulting in a rapid surge like a change of color in liquor before the onset of spontaneous labor.\textsuperscript{[2,4]} The color of amniotic fluid, to start with looks watery, then changes to milky, buttermilk like, and then become curd-like.\textsuperscript{[11]} The color and turbidity of AF can be measured in terms of optical density (AFOD) at 650 nm by a laboratory colorimeter.\textsuperscript{[11]} It was reported, labors induced at mature AFOD values (0.98 ± 0.27, mean ± SD) result in optimally mature babies, shorter induction delivery intervals, no induction failures, less labor pain, and no neonatal respiratory distress (NRD).\textsuperscript{[8]}

Deciding the day of delivery at term is an unsolved dilemma in obstetrics. The ideal objective of any obstetrician is to deliver the baby at optimal functional maturity, i.e. the baby should be neither premature nor postmature. This can be achieved by AFOD-guided induction of labors,\textsuperscript{[8]} AFOD estimation before induction of labor needs invasive amniocentesis which is not acceptable.

In the first part of this study, we tried to find a correlation between the density of floating vernix clumps in fore water by transvaginal sonography and the AFOD. In the second part of this study, we attempted to compare the outcomes of Foley’s induced labors between 3 different grades of sonographic image groups of fore-water.

### Methods

In this comparative study, gestational age and parity matched uncomplicated singleton term pregnant women, underwent fore water transvaginal sonography, before induction of labor with Foley’s catheter insertion. Sonographic images were divided into 3 grades based on the floating vernix clump density. Three groups were made with 20 women in each group with each grade of sonographic images of fore-water. Uncentrifuged fresh AF samples collected at amniotomy were used for AFOD measurement with colorimeter at 650 nm in all women of three groups. After Foley’s Cather expulsion, labor was augmented with vaginal T. Misoprostol 25 mcg at an interval of four hours. The AFOD values, Bishop scores at induction, Foley’s insertion expulsion intervals (FIEI), Foley’s insertion delivery intervals (FIDI), and requirement of T. misoprostrol were recorded in each woman of all three groups. Babies that developed neonatal respiratory distress (NRD), and the babies that required NICU admission, were also recorded in each group. The outcomes of these variables were statistically compared between groups.

### Exclusion criteria

Women who underwent cesarean sections were excluded from the study.

#### Fore-water scanning by transvaginal sonography

After emptying the bladder, the woman lie-down on a foot end elevated table (around 30°) in the lithotomy position. The woman was advised to relax for 5 min. Presenting part was gently pushed above with fingers to create a better fore-water pocket. Fore-water scanning was done with transvaginal sonography. While scanning, the position of the presenting part can be adjusted by pushing the presenting part above with fingers per abdominally. Very gentle manipulation of the presenting part with TV probe can also be done to get better images [Figures 1–3].

#### Grading of sonographic images

- **Grade 1:** Hypoechoic fore-water with very few or no echogenic floating vernix clumps [Figure 1 and Video 1]. https://youtu.be/Zh5oZynGx-o
- **Grade 2:** Fore-water with moderate echogenic floating vernix clumps [Figure 2 and Video 2]. https://youtu.be/ SdwtqihbFP8
- **Grade 3:** Fore-water with heavy echogenic floating vernix clumps, irregular shaped cloud-like big vernix clumps [Figure 3 and Video 3], and also swarming fish like movement of vernix clumps (Swarming fish sign) can be seen. https://youtu.be/_jWs5zOEZZY

#### Method of Foley’s catheter induction

Foley’s catheter of 22 F size was inserted through cervix under strict aseptic precautions, and the bulb was inflated up to 60–70 mL with distilled water.

#### AF sample collection at amniotomy

When Foley’s catheters got expelled, cervices had more than 4 cm dilatation. Woman in the lithotomy position, under the good source of light, Sims speculum was applied and membrane visualized. AF sample was drawn using 2.5 cm long 23 G needle fitted with 2 mL disposable syringe. The membrane was pierced when the uterus was not acting to avoid splashing of liquor.

#### Method of measuring AFOD

The colorimeter was set at 650 nm wavelength. The test tube containing distilled water (control solution) was inserted into the cuvette holder of the machine and the “0” reading was adjusted. Later, this control test tube was removed.
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**Neonatal respiratory distress (NRD) defined**
Respiratory grunting, labored breathing, intercostal recession, and transient tachypnea within 1 h after birth was considered as NRD

Informed and written consent was obtained from all subjects who participated in this study. This study confined to the standards of Declarations of Helsinki.

**Statistical analysis**
Statistical software, MS Excel, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyze the data. Categorical data were represented in the form of frequencies and proportions. Chi-square test or Fischer’s exact test (for 2 × 2 tables only) was used as a test of significance for qualitative data [Table 1]. Continuous data were represented as mean and standard deviation. ANOVA was used as a test of significance to identify the mean difference between more than two quantitative variables [Table 1]. P value (the probability that the result is true) of < 0.05 was considered as statistically significant after assuming all the rules of statistical tests.

**Results**
In groups 1, 2, and 3, the mean ± SD values of AFOD was found to be 0.29 ± 0.09, 0.68 ± 0.14, and 1.15 ± 0.20, respectively (P < 0.001).

In groups 1, 2 and 3, the mean ± SD values of B. Score at induction were 5 ± 1, 7 ± 1, and 7 ± 1, respectively (P < 0.001).

The mean ± SD values of Foley’s insertion expulsion intervals were 10.57 ± 3.76 h, 5.83 ± 2.24 h, and 4.08 ± 0.867.0 h, respectively (P < 0.001).

The mean ± SD values of FIDI were 20.00 ± 6.20 h, 11.22 ± 4.21 h, and 8.95 ± 2.98 h, respectively (P < 0.001).

The mean ± SD values of T misoprostol required in each group were 3 ± 1, 2 ± 1, and 2 ± 1 (P < 0.001), respectively [Table 2].

The percentage of babies that developed NRD in group 1, 2, and 3 were 45%, 15%, and 0%, respectively (P < 0.001). The percentage of babies that were admitted to NICU in

Enter button, the AFOD value can be read directly from the display screen of the machine.

(AFOD Estimation with Colorimeter https://youtu.be/vfQhzRKeCI0)
Table 1 (Original): Comparison of neonatal outcome measures between groups

| Variable       | Yes/ No | Group 1 AFOD <0.45 | Group 2 AFOD 0.45 to 0.85 | Group 3 AFOD >0.86 | Sig P |
|----------------|---------|-------------------|--------------------------|-------------------|-------|
| NRD Absent     | 11      | 55                | 17                       | 20                | <0.012|
|                | Present | 9                 | 45                       | 3                 | 0     |
| NICU Admission | No      | 16                | 80                       | 18                | <0.001|
|                | Yes     | 4                 | 20                       | 2                 | 10    |

Table 2 (Original): Comparison of labor outcome measures between groups

| Variable                        | Group 1 n: 20 (Mean±SD) | Group 2 n: 20 AFOD 0.45 to 0.85 (Mean±SD) | Group 3 n: 20 AFOD >0.86 (Mean±SD) | Sig P |
|---------------------------------|--------------------------|-------------------------------------------|-----------------------------------|-------|
| GA (age at induction)           | 38.51±0.82               | 38.66±1.44                                 | 39.4±1.04                         | 0.035 |
| Para                            | 2±1                      | 2±1                                        | 2±1                               | 0.914 |
| B. Score at induction           | 5±1                      | 7±1                                        | 7±1                               | <0.001|
| Foley’s insertion- expulsion intervals | 10.57±3.76               | 5.83±2.24                                 | 4.08±0.86                         | <0.001|
| Foley’s insertion- Delivery intervals | 20.00±6.20               | 11.22±4.20                                | 8.95±2.98                         | <0.001|
| AFOD at ARM                     | 0.29±0.09                | 0.68±0.14                                 | 1.15±0.20                         | <0.001|
| No of T. miso used              | 3±1                      | 2±1                                        | 2±1                               | <0.001|

A baby destined to mature by 42 weeks, if delivered at 40 weeks, this baby will be functionally premature and develop NRD, and also suffer the problems of adaptation. On the other hand, a baby who attained completion of maturity by 35 weeks, and for some reason if the labor does not start, and if delivered at 39 weeks, this baby will be functionally posted mature, dysmature, and sometimes IUFD may also occur.[2] This could be one of the reasons for unexplained IUFDs.

Shorter induction delivery intervals and optimally mature babies with best perinatal outcomes were reported when labors were induced at AFOD value of 0.98 ± 0.27 (mean ± SD).[8] We need invasive amniocentesis to pick up the women at these mature AFOD values.

In the first part of this study, to avoid invasive amniocentesis for AFOD estimation, we tried to quantify the density of vernix floaters in amniotic fluid by scanning the bag of fore-waters by TV sonography. We divided these sonography images into three grades. The range of AFOD values for each grade of images was found [Figures 1-3]. In the second part of this study, we evaluated the outcomes of Foley’s induced labors with three different grades of sonographic images.

Very favorable Bishop Scores at induction, lowest Foley’s insertion expulsion intervals, lowest Foley insertion delivery intervals, and very less T misoprostol required, were observed in grade 3 sonography image group when compared to Grade 1 and 2 groups [Table 2]. Moreover, the number of babies that developed NRD, and the NICU admissions needed were the least in the grade 3 sonographic image group 1, 2, and 3 were 50%, 20%, and 10% (P < 0.001), respectively [Table 1].

Significant differences were observed in all outcomes between groups favouring inductions with Grade 3 sonographic images.

Discussion

Skin is the last organ to mature, and the completion of skin maturation is denoted by shedding of vernix from the fetal skin surface into the amniotic fluid.[7,9] This adding of vernix clumps into AF is responsible for the color of AF. This process of vernix shedding and color change in liquor starts occurring 8 to 10 days before the onset of spontaneous labor.[2] Human amniotic fluid cells (vernix cells) produce prolabor cytokines like IL6, IL8, IL1beta, and EGF which can trigger the expression and production of uterine activation proteins (UAPs) and prostaglandins.[10,11] These are the events that occur before the onset of spontaneous labor. The color and turbidity of AF can be measured in terms of optical density (AFOD) at 650 nm by a laboratory colorimeter.[1]

The onset of spontaneous labor occurs on completion of fetal functional maturity at AFOD value 0.98 ± 0.27 (mean ± SD). All these three events occurring together at any time from 35 weeks to 42 weeks indicate the individualized term for each fetus. There are early maturing fetuses that attain completion of functional maturity as early as 35–36 weeks, and there are late maturing fetuses that attain completion of maturity as late as 41–42 weeks.[2-5]

This concept of “individualized term for each fetus” is having a very significant impact on clinical obstetrics.
group [Table 1]. These results show, that the preparations for the onset of spontaneous labor were in a well-advanced stage in grade 3 sonographic image group when compared to grade 1 and 2 groups. This study showed the best perinatal outcomes by triggering labors with Grade 3 sonographic images.

Fore-water scanning by TV sonography, before induction of labor, helps to assess the functional maturity status of the fetus. With lower sonography grades, inductions can be postponed. In the case of obstetric need, antenatal steroids can be given to hasten the fetal functional maturity.

**Conclusion**

Elective Foley induction of labor with grade 3 sonographic images of fore-water helps to program labor at a convenient hour, helps to deliver babies at optimal maturity, avoids induction failures, and also helps to prevent iatrogenic prematurity and its related complications. As this is a non-invasive method, this can be readily accepted and practiced by all obstetricians. Further studies are needed to confirm our observations with a larger sample size.

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**Declaration of patient consent**

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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**Conflicts of interest**

There are no conflicts of interest.

**References**

1. Samartha Ram H, Sandhya Ram S, Shankar Ram HS. Amniotic fluid optical density at spontaneous onset of labour and it’s correlation with gestational age, birth weight, functional maturity and vernix caseosa of new born. Calicut Med J 2009;7:2009. Available from: https://drive.google.com/file/d/1_KiQAJ2_2-leDAMd6-JWTjJeLWbQLDXp/view?usp=sharing.youtu.be/75Aak7CiN6A youtu.be/wwBSiQL2RR8.

2. Samartha Ram H, Sandhya Ram D. Individualized term for each foetus: From surge in amniotic fluid optical density (AFOD). Available from: http://ispub.com/IJGO/18/1/14784. [Last accessed on 2018 Jun 11]. youtu.be/6SPfR9VbbCc.

3. Samartha Ram H, Shankar Ram HS, Sandhya Ram S, Hanuman RK. Correlation between amniotic fluid optical density (AFOD) and functional maturity status of the new-born at caesarean delivery in GDM. IOSR J Dent Med Sci 2014;13:1-5.

4. Klimek R. ‘The use in obstetrics of quantum theory as well as modern technology to decrease the morbidity and mortality of new-borns and mothers during iatrogenic induced delivery’. Neuroendocrinol Lett 2001;22:5-8.

5. Klimek M. Prediction of the birth term and course of the labour. Ob/Gyn Department, Jagiellonian University, Kopernika, Cracow, Poland, 23, 31-501. Available from: http://www.cyfronet.krakow.pl/~mmklimek/marek_re.html. [Last accessed on 2018 Jun 12].

6. Narendran V, Randall WR, William LP, Steven BH. Interaction between pulmonary surfactant and vernix: A potential mechanism for induction of amniotic fluid turbidity. J Pediatric Res 2000;48:120-4.

7. Zabkar JH. Evaluation of foetal maturity by amnioscopy. J Perinat Med 1975;3:145-53.

8. Samartha Ram H, Samyuktha IS, Nagasree V. Outcomes of induction of labour with mature and premature amniotic fluid optical density (AFOD): A preliminary case control study. Trop J Obstet Gynaecol 2019;36:206-11.

9. Agorastos T, Vlassis G, Zournatzi B, Papaloukas A. Foetal lung maturity and skin maturity: 2 distinct concepts and the clinical significance of their differences. Z Geburtshilfe Perinatol 1983;187:146-50.

10. Mazzucchelli I, Avanzini MA, Ciardelli L, Pagani S, Greco R, Belloni C, et al. Human amniotic fluid cells are able to produce IL -6 and IL- 8. Am J Reprod Immunol 2004;5:198-203.

11. Christaens I, Zaragoza DB, Guilbert L., Robertson SA, Mitchell BF, Olson DM. Inflammatory processes in preterm and term parturition. J Reprod Immunol 2008;79:50-7.