Comparison of Time to Delivery With and Without Cervical Ripening Balloon Catheter for Induction of Labor

A Retrospective Cohort Study Chart Review

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EMR Chart Review
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Introduction

Induction of labor is a common practice. Induction of labor refers to techniques for stimulating uterine contractions to accomplish delivery prior to the onset of spontaneous labor. There are multiple clinical indications for inducing labor in a gravid patient. In general, indications for induction of labor are in cases that the benefits of expediting labor outweigh the risks of remaining pregnant. Approximately 20% of pregnant women in the US are induced. Since as early as 1948, oxytocin has been used to stimulate uterine contractions. There are multiple methods for induction of labor including membrane stripping, artificial rupture of membranes, and prostaglandins. However, patients with an unfavorable cervix may benefit from cervical ripening prior to stimulating uterine contractions. Cervical ripening can be performed via mechanical methods or using prostaglandin analogues.

Advantages of mechanical cervical ripening include: lower cost and reduced risk of uterine tachysystole. Some studies have shown that mechanical methods of cervical ripening are associated with similar or decreased cesarean delivery rate when compared with oxytocin alone. However, there is insufficient and conflicting data on the effectiveness of mechanical cervical ripening compared with other methods of cervical ripening and induction of labor.

There is currently no consensus guideline or protocol to help providers navigate the choices for cervical ripening and induction of labor. Data is sparse and insufficient to indicate which methods are more effective at quickly and safely expediting the total time from induction to

delivery. This study aims to explore the use of cervical ripening balloons as a method to decrease total duration of labor. This is practical information that would be able to help guide obstetric providers choose an appropriate method of cervical ripening. The benefits could lead to decreased length of stay, cost of hospitalization, decrease antepartum complications, and guide the development of standardized induction protocols.

Background literature

As stated above, current literature has shown some consensus on the benefits of mechanical cervical ripening. A Cochrane System Review comparing mechanical ripening with other methods showed similar cesarean rates compared to prostaglandins and reduced cesarean rates compared with oxytocin. Overall, it was also noted that mechanical ripening had a lower risk of uterine hyperstimulation [4]. However, literature on the time to delivery has mixed outcomes. A study of 731 patients in 2016 comparing dinoprostone versus foley catheter showed that induction-to-delivery was shorting in the dinoprostone group (mean difference of 5.73 hours) [10]. Another study of 200 patients in 2008 compared foley catheter versus foley catheter with oxytocin and showed no significant difference in time to delivery [6]. A similar, but larger study in 2018 showed that the use of cervical ripening balloon alone was associated with a longer induction time compared to cervical ripening balloon and oxytocin [3]. In contrast, a small study in 2018 showed that the use of cervical ripening balloon used alone was associated with a shorter time to delivery (9.45 hours compared to 13.2 hours) to oxytocin alone [8]. As seen in these studies, there is no clear consensus on the effect of time to delivery when using cervical ripening balloons.

Methodology

This a retrospective review of the electronic medical records at UnityPoint Health Methodist. All investigators took part in reviewing records. Patient data was initially pulled from EPIC using a query that identified all gravid patients admitted for induction of labor over 24 months. Data also included the EPIC EMR query includes: MRN, patient age, gestational age, category of induction method, fetal presentation, delivery method, delivery date, delivery time. All data acquired from the EPIC query was recorded in a spreadsheet. This initial query yielded 1,385 patients that were induced. Preterm and labors that resulted in cesarean section deliveries were excluded. Due to limitations of the EPIC query, all investigators manually reviewing each chart to further identify the following data: cervical exam on admission (dilatation, effacement, station, position, consistency), starting time/date of induction. This data was entered into the spreadsheet. At this point, all inductions with a bishop score of > 8 were also excluded. The spreadsheet was then used to automatically calculate the patient's bishop score on admission, time from induction start to active labor, and total time of induction of labor. Personal Health Information is not necessary for data collection. No identifying information for any patient will be

published. No identifying information will be maintained in the spreadsheet after completion of the study. Besides the MRN, no identifiers will be used during the data collection.

Primary outcome: total duration from induction of labor to delivery

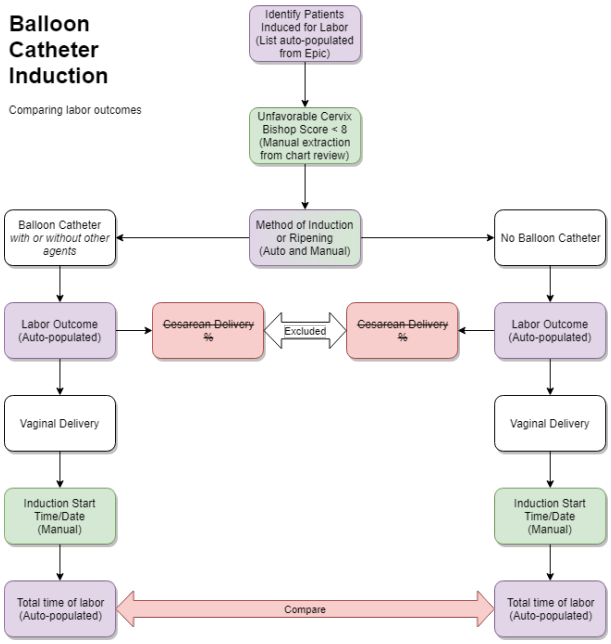
Patient inclusion criteria

- Gravid females
- Age >= 18 y/o
- Admitted for induction of labor at UPH Methodist
- Term pregnancy (gestational age ≥ 37w0d)
- Unfavorable cervical exam:
- Bishop score < 8
- In the absence of a complete bishop score: Cervical dilation < 4 cm

Exclusion

- Induction of labor stopped prior to complete dilation
- Cesarean section delivery outcome
- Inability to verify method of labor induction on chart review
- Spontaneous labor prior to initiation of induction

Of note, unfavorable cervix as defined per ACOG as a Bishop score of 6-8. A score of 6-8 or higher denotes a high chance of successful vaginal delivery. A lower score would be considered a candidate for cervical ripening prior to induction of labor. In this study, the research group has chosen to exclude any patient's with a Bishop score > 8 as these patients would not require cervical ripening.



Result

Cervical Ripening Balloon Induction

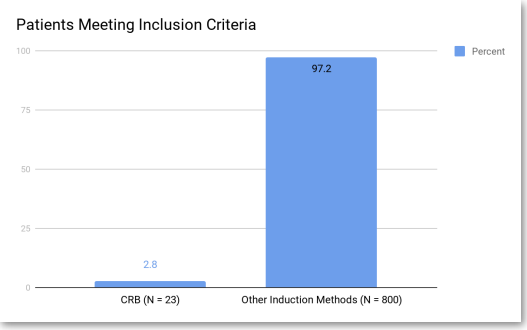
Variable	N	Minimum	Maximum	Mean	Std Dev	Median
Hours Induction to Delivery	800	1.2	82.6	15.8	10.8	12.9
Bishop Score	800	0	7	5.6	1.4	6
Gestational Age	800	37	42.7	39.5	1.1	39.3

Other Induction Methods

Variable	N	Minimum	Maximum	Mean	Std Dev	Median
Hours Induction to Delivery	800	1.2	82.6	15.8	10.8	12.9
Bishop Score	800	0	7	5.6	1.4	6
Gestational Age	800	37	42.7	39.5	1.1	39.3

Out of 823 inductions that met the inclusion criteria, only a small majority utilized cervical ripening balloon (N = 23). This is visualized in figure 2. Figure 3 and Figure 4 demonstrate the distribution of gestational age and the distribution of type or combination of induction.

Analysis was performed using a Wilcoxon analysis due to this imbalance. Wilcoxon test used to compare the difference in hours from induction to Delivery. P value=0.003, showed significant difference between cervical ripening balloon and other induction methods in terms of the hours from induction to delivery. The patients from cervical ripening balloon group showed longer hours from induction to delivery (figure 5). Wilcoxon test was used to compare the difference in Bishop scores. The P value=0.422 which showed No significant difference between CRB and other induction methods in terms of Bishop scores. Wilcoxon test was used to compare the difference in gestation age. P value=0.923 which showed No significant difference between CRB and other induction methods in terms of gestation age. Spearman correlation was used to check the accusations between hours from induction to delivery and Bishop score, hours from induction to delivery and gestational age, respectively. The results showed that Hours from induction to delivery was negatively correlated with Bishop score. The higher of bishop score, the shorter hours (p<.0001, spearman correlation coefficients= -0.34).



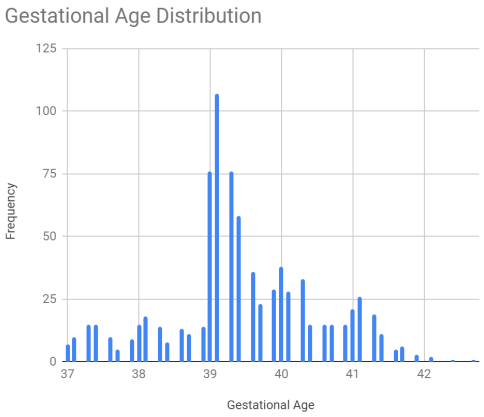


Figure 3

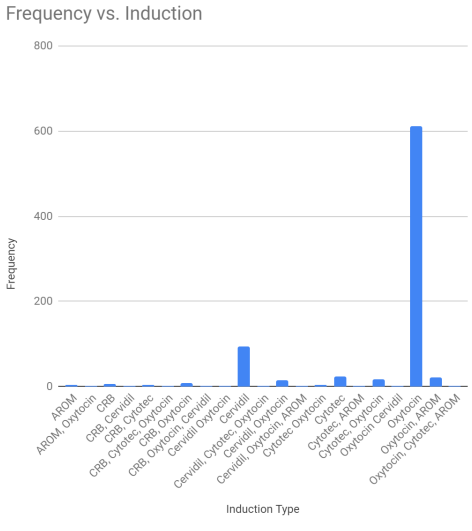
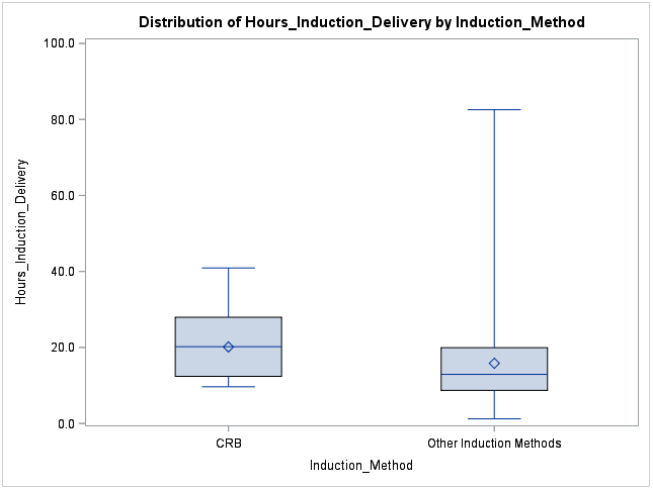


Figure 4



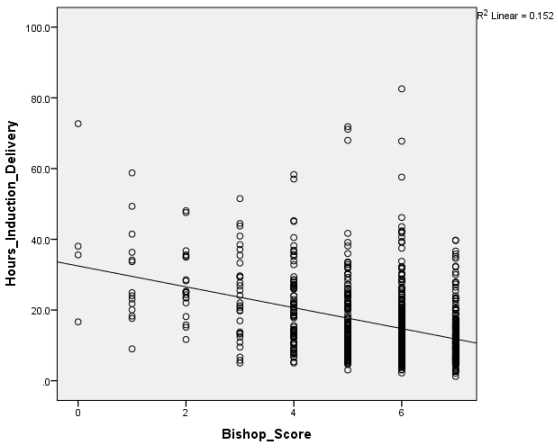


Figure 5

Conclusion

In conclusion, The patients in the cervical ripening balloon group had significantly longer time from induction of labor to time of delivery (p=0.003). The results indicated that there were no statistical association between hours from induction to delivery and gestational age(p=0.66, can correlation coefficient=0.02) See Figure 6. Robust regression was used to do check the difference between the 2 groups, after adjusted Bishop score. The result is consistent with the previous univariate result. P=0.0002. There was significant difference between the 2 groups. The patients from CRB group showed longer hours from induction to delivery.

Future recommendation

This study was hampered by multiple variables. Most importantly, the sample size was very unbalanced. While the population was large enough to show significant statistical difference. Further studies would benefit from a larger population especially in the cervical ripening group. Part of this is due to the limited use of the cervical ripening balloon at UnityPoint Methodist hospital. Numbers were also hampered due to several ripening balloons being placed prior to arrival at the hospital which led to no known time of induction and these patient automatically fell out of the inclusion into the study.

Parity was also not accounted for during this study and could potentially be a large source of data bias. Another study would benefit from parity being included in the data gathering and analysis. Furthermore, to make sure that all inductions could be included in this study. Combinations of different induction methods were not documented well enough for the researchers to effectively analyze. Even if manually combing through all the included patients, it may still be unclear which method was initiated and when. Thus the different methods were batched into 2 larger groups.

An optimal study would likely involve a randomized controlled trial with established labor induction and ripening protocols. EMR documentation could be optimized to allow quicker gathering and automatic calculation of bishop score which would significantly decrease the amount of time spent by the researchers in gathering this data. Parity could be included in this documentation and the combinations of different induction methods could be better differentiated and analyzed

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