



A Retrospective Chart Review

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Introduction



Terms and Definitions

Induction of Labor

- Techniques for stimulating uterine contractions to accomplish delivery prior to onset of spontaneous labor
- Benefits of expediting labor outweigh the risks of remaining pregnant
- ~22% of pregnancies in the US are induced
- Ex: membrane stripping, artificial rupture of membranes, oxytocin and prostaglandins

Oxytocin

- Stimulates uterine contraction
- Increases local prostaglandin production

Prostaglandins

- Promote biochemical/biophysical changes that lead to cervical ripening
- Prostaglandin E2 (dinoprostone)
- Prostaglandin E1 (misoprostol)
 - Risk of uterine tachysystole
 - Risk of uterine rupture (h/o uterine surgery)



Terms and Definitions

Unfavorable Cervix

- Bishop score < 6-8
- Predicts likelihood of successful vaginal delivery

Bishop scoring system:

Score	Dilation (cm)	Position of cervix	Effacement (%)	Station (-3 to +3)	Cervical Consistency
0	Closed	Posterior	0-30	-3	Firm
1	1-2	Mid position	40-50	-2	Medium
2	3-4	Anterior	60-70	-1, 0	Soft
3	5-6	--	80	+1, +2	--



Cervical Ripening

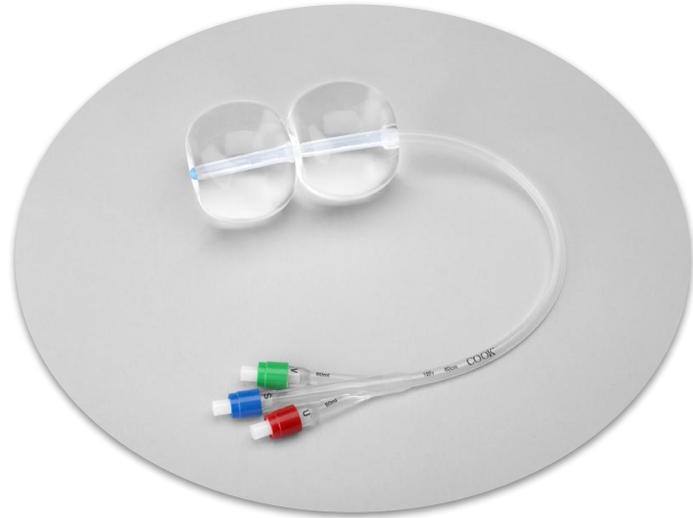
- Prior to stimulating contractions
 - Prostaglandin analogues
 - Mechanical methods

Advantages of Mechanical Cervical Ripening

- Lower cost
- Reduced risk of uterine tachysystole
- Similar vs decreased rate of cesarean when compared with oxytocin alone

Cervical Ripening Balloon

- Direct/physical pressure
- Causing the release of prostaglandins from the decidua, adjacent membranes, and/or cervix
- Cervical ripening and an increase in myometrial contractility



Unclear Consensus Guidelines



Current Data

- Sparse/Insufficient
- Conflicting results

Current Practice

- Varies greatly by institutional and provider



Clinical Implications

Better data for developing safe and efficient induction of labor protocols

Length of stay

Cost of hospitalization

Avoid antepartum complications caused by induction of labor

- Higher postpartum hemorrhage risk after oxytocin administration
- Fetal intolerance to induction - uterine tachysystole



Research Question

Does utilizing a balloon catheter with or without prostaglandins/oxytocin for cervical ripening in patients with an unfavorable cervical exam decrease the time to delivery compared to alternative methods of cervical ripening?

- Specific/Measurable Primary Outcome: “Time from Induction to Delivery”
- Giving providers information that matters to their current practice
 - Barriers: concern for time of induction, comfort/experience with placement of balloon



Background Literature



Mechanical methods for induction of labour. Cochrane Database System Review (2012)

Jozwiak, M., Bloemenkamp, K. W.,
Kelly, A. J., Mol, B. W., Irion, O., &
Boulvain, M

Compare mechanical vs placebo,
prostaglandin, oxytocin (meta-analysis)

Similar cesarean rates vs prostaglandins

Reduced cesarean rates vs oxytocin

Lower risk of hyperstimulation

9722 patients



Controlled-release dinoprostone insert versus Foley catheter for labor induction: a meta-analysis (2016)

Wang, H., Hong, S., Liu, Y., Duan, Y.,
& Yin, H

Dinoprostone vs foley cath; time to delivery
and safety

Induction-to-delivery shorter in
dinoprostone group (Mean difference 5.73)

Dinoprostone caused excessive uterine
contractions more frequently (RR 0.07)

731 patients



Transcervical Foley catheter with and without oxytocin for cervical ripening: a randomized controlled trial (2008)

Pettker CM, Pocock SB, Smok DP, Lee SM, Devine PC

Foley vs foley + oxytocin

No effect on time to delivery

200 patients



Cervical Ripening Using Foley Balloon with or without Oxytocin (2018)

Gallagher, L. T., Gardner, B.,
Rahman, M., Schoen, C., Connolly,
K. A., Hankins, G. D

CRB vs CRB + oxytocin

CRB alone for cervical ripening had a longer
induction to delivery time

1,133 patients



Double balloon catheters: a promising tool for induction of labor in multiparous women with unfavourable cervixes (2018)

Tulek, F., Gemici, A., & Soylemez, F

Compare efficacy and safety of oxytocin vs CRB

Median time to delivery CRB 9.45 hr vs oxytocin 13.2 hr ($p < 0.001$) multiparous

Median time to delivery CRB 11.48 hr vs oxytocin 13.46 hr ($p < 0.001$) primiparous

Rate of cesarean was similar

80 patients



Recap

Cervical ripening balloons have less adverse side effects

Cervical ripening balloons have reduced rate of cesarean section vs oxytocin

Time to delivery with cervical ripening balloon has conflicting data and no clear consensus in studies

Methodology



Retrospective Cohort Study

IRB Approved
EMR Chart Review
January 2016 - November 2018

Wilcoxon Analysis





Patient Population

Inclusion Criteria

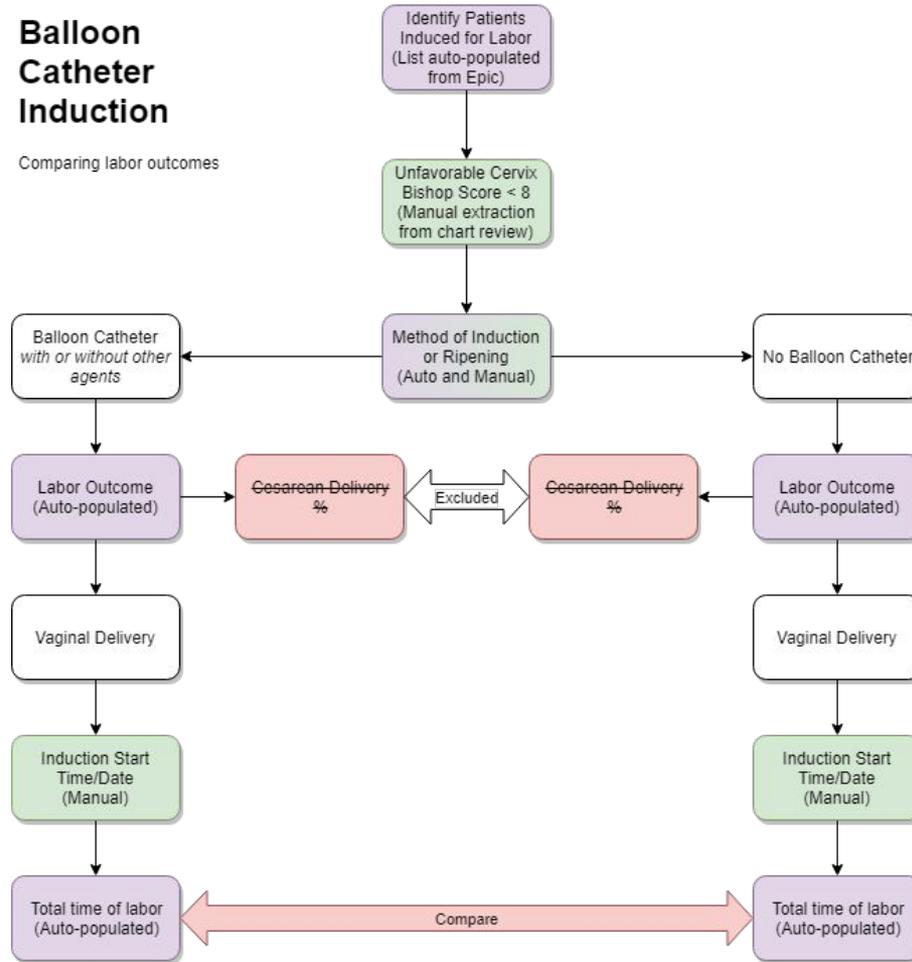
- Gravid females
- Age ≥ 18 y/o
- Admitted for induction of labor at UPH Methodist
- Term pregnancy (gestational age ≥ 37 w0d)
- Unfavorable cervical exam:
 - Bishop score < 8
 - In the absence of a complete bishop score:
Cervical dilation < 4 cm

Exclusion Criteria

- 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

Balloon Catheter Induction

Comparing labor outcomes

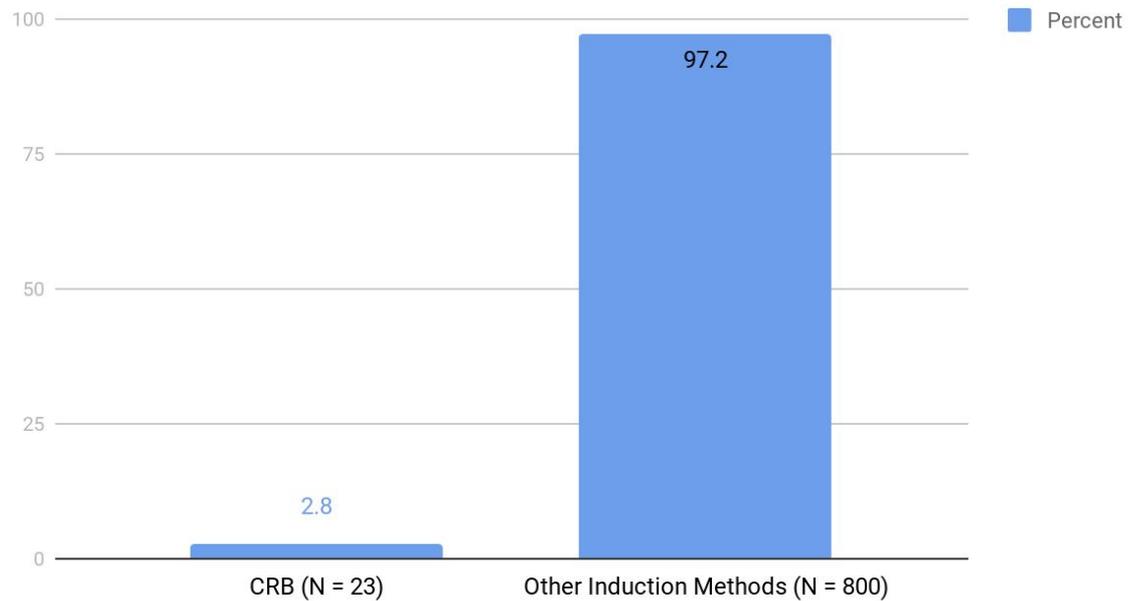




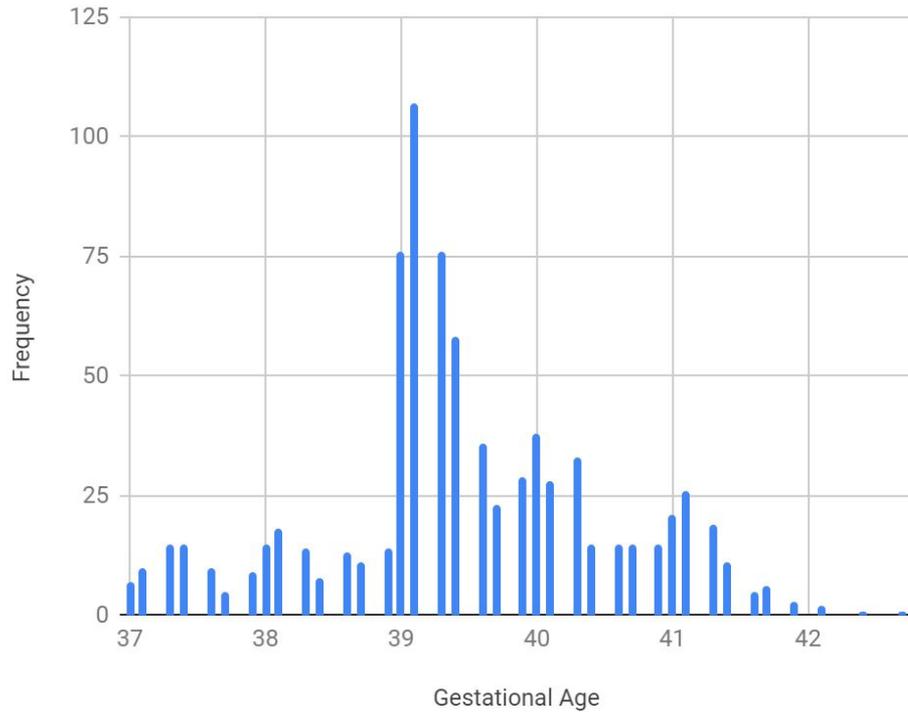
Result



Patients Meeting Inclusion Criteria

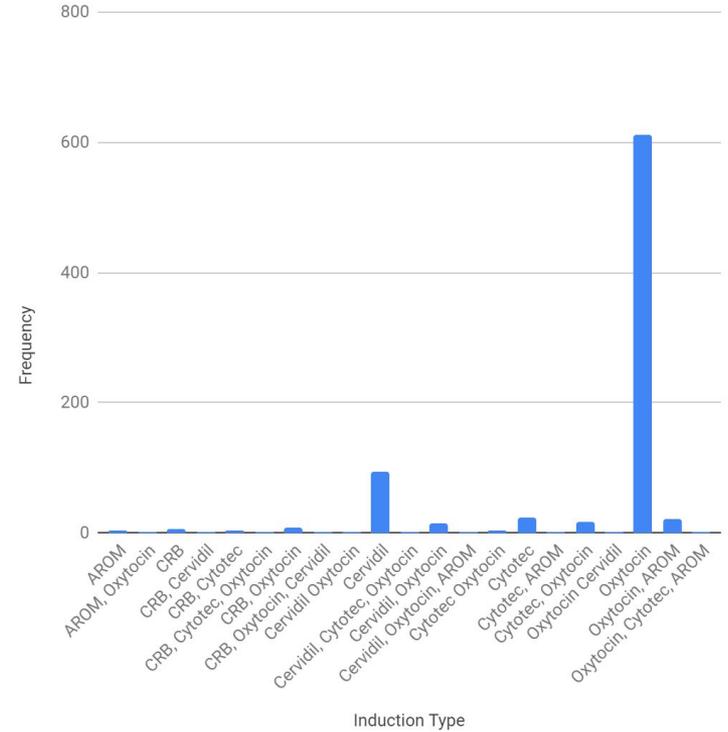


Gestational Age Distribution



Raw Data

Frequency vs. Induction



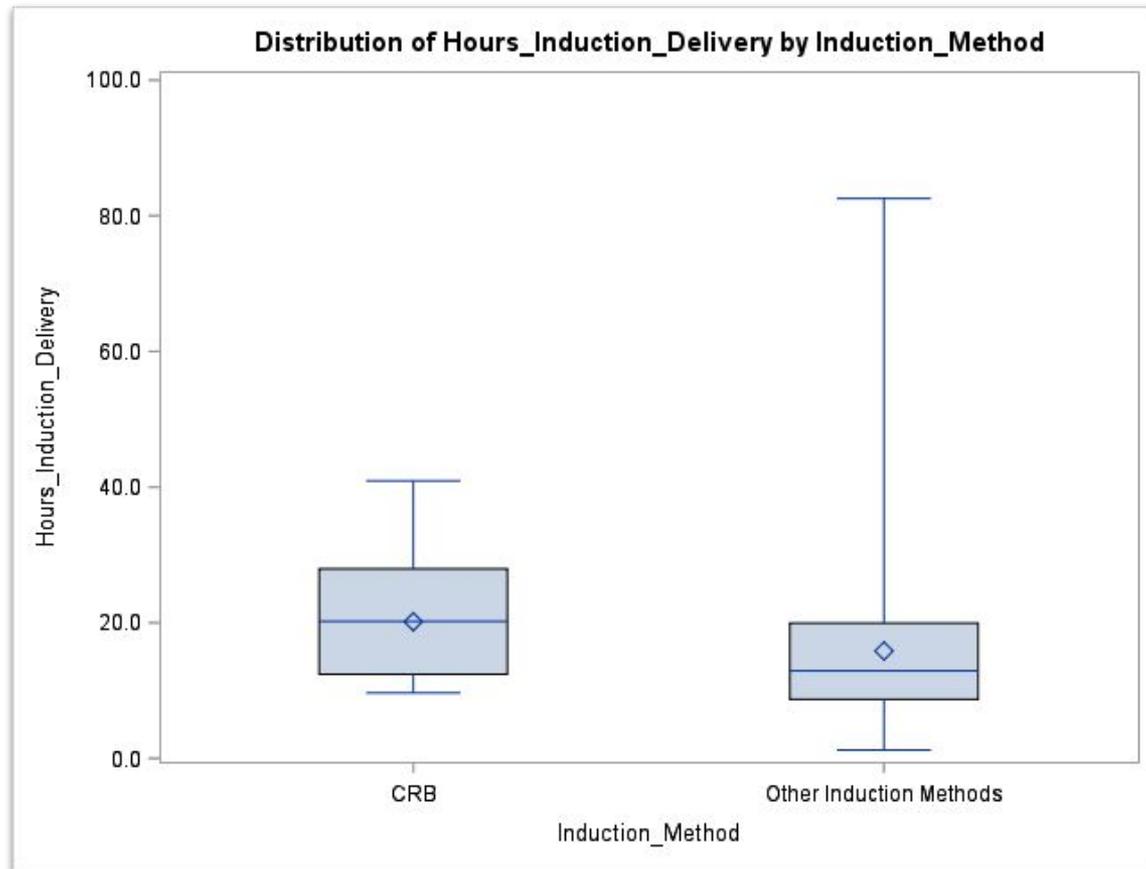


Cervical Ripening Balloon Induction

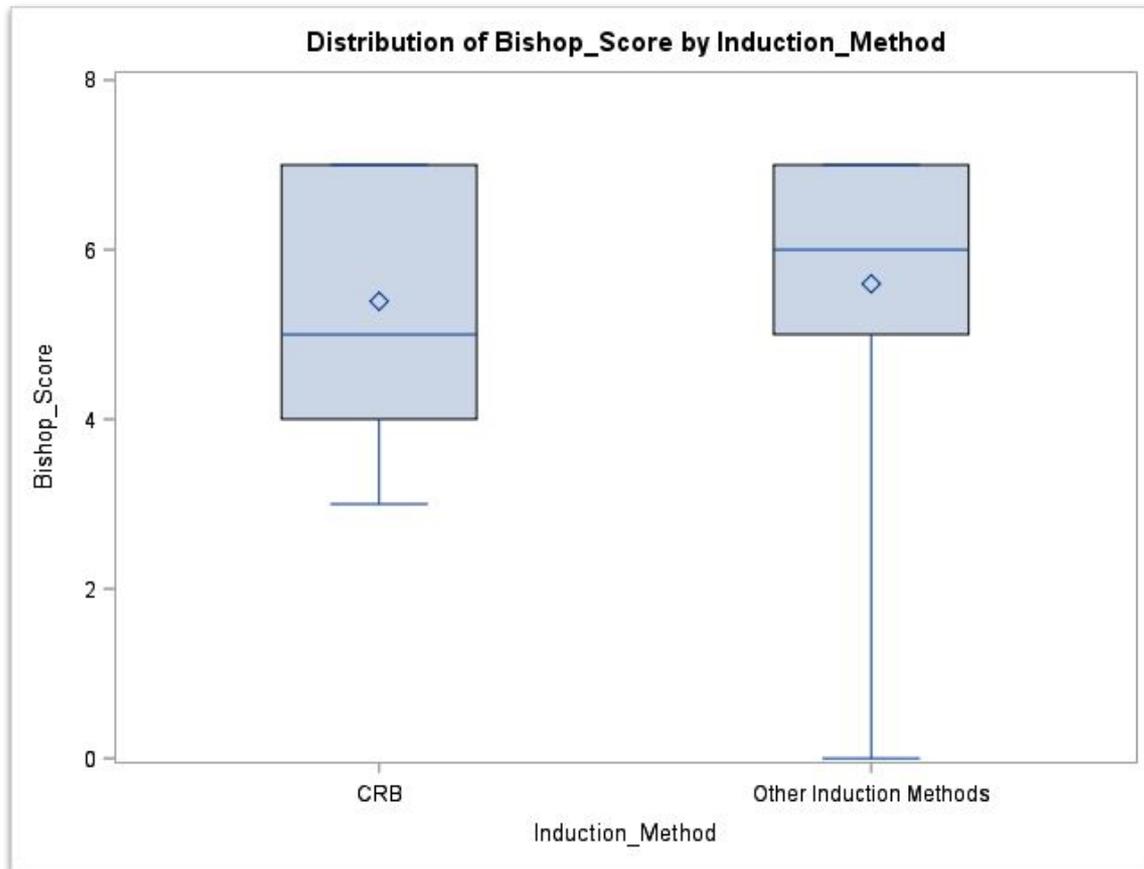
Variable	N	Minimum	Maximum	Mean	Std Dev	Median
Hours Induction to Delivery	23	9.7	40.9	20.1	8.4	20.2
Bishop Score	23	3	7	5.4	1.4	5
Gestation Age	23	37.3	41.9	39.5	1.2	39.4

Other Induction Methods

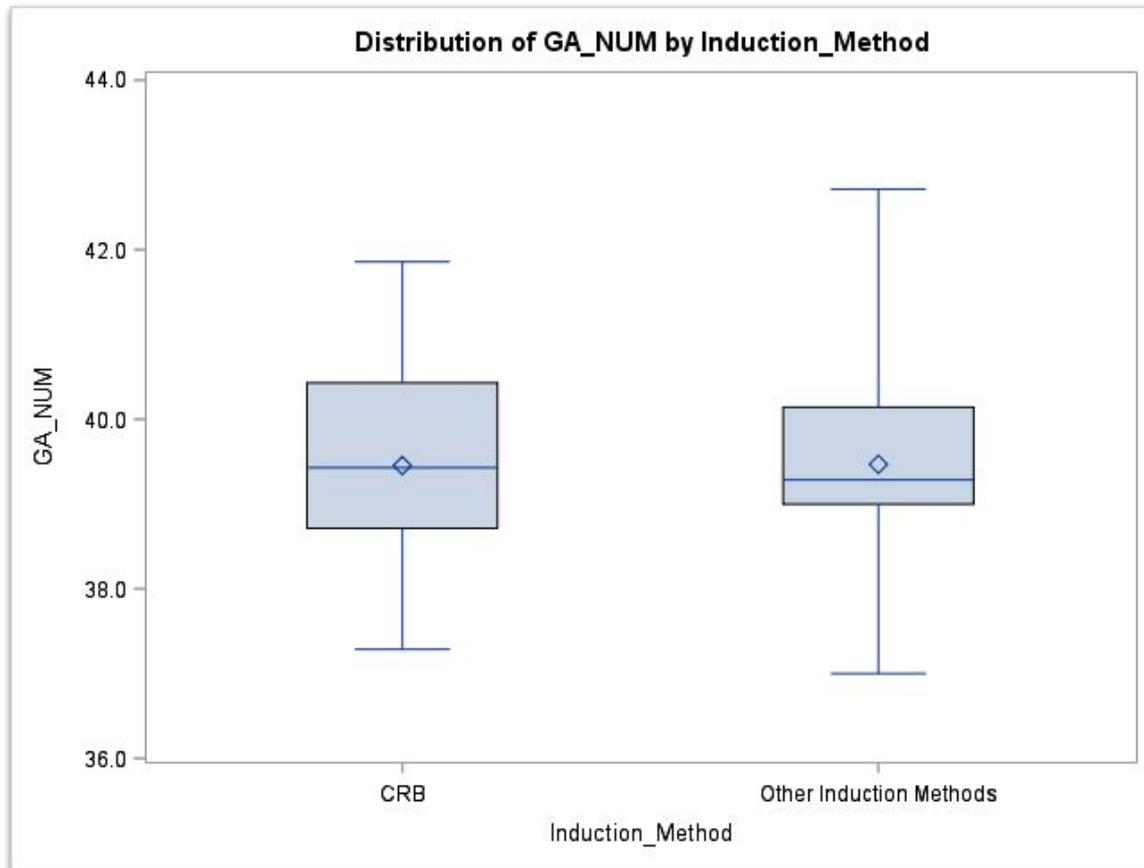
Variable	N	Minimum	Maximum	Mean	Std Dev	Median
Hours Induction to Delivery	800	1.2	82.6	15.8	10.8	12.9
Bishop Score	800	0	7	5.6	1.4	6
Gestational Age	800	37	42.7	39.5	1.1	39.3



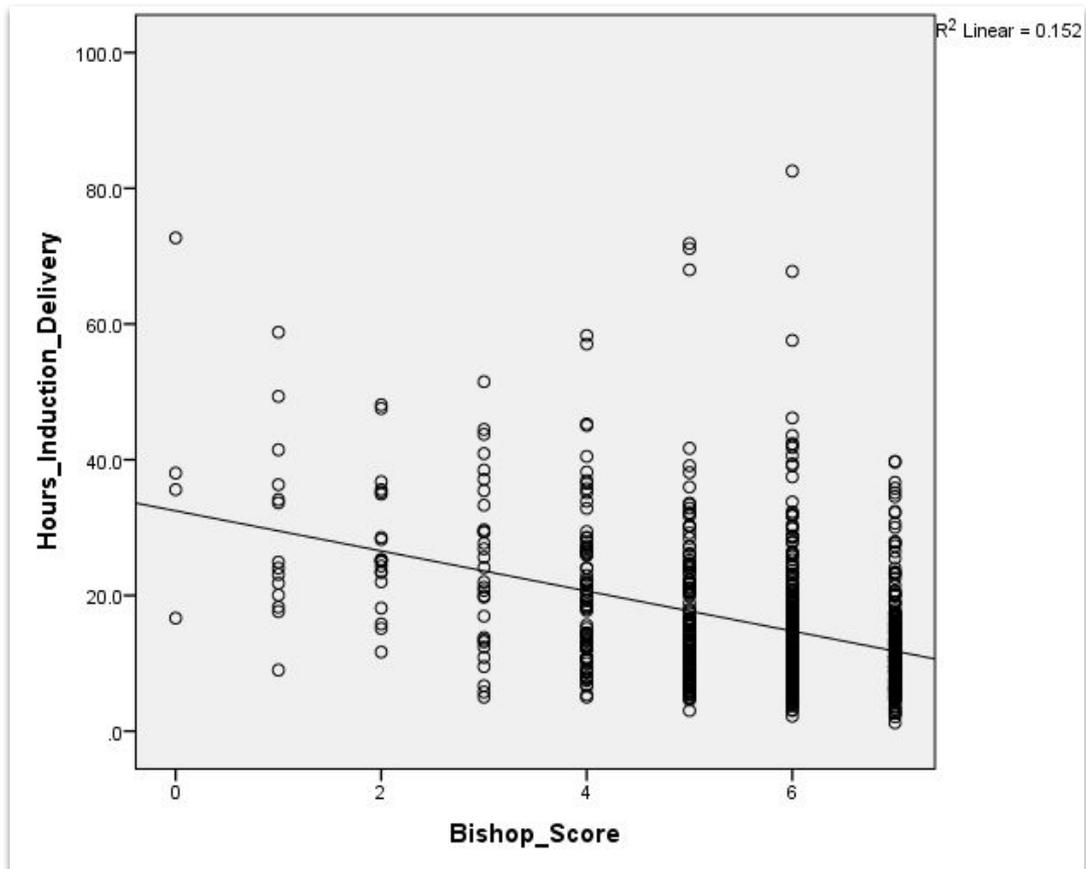
Wilcoxon test was used to compare the difference in hours from induction to Delivery. P value=0.003, which showed significant difference between CRB and other induction methods in terms of the hours from induction to delivery. The patients from CRB group showed longer hours from induction to delivery.



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 .)



Further Analysis

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)

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.

Conclusion

The patients in the cervical ripening balloon group had significantly longer time from induction of labor to time of delivery (p=0.003)



Take Away Points

Use of cervical ripening balloon for induction of labor may not decrease the duration of time from induction to delivery and may be a better option for **outpatient pre-induction cervical ripening** for appropriate candidates

A **higher bishop score** at onset of induction **decreases the total duration** of induction of labor **independent of induction method used**



Limitations



Limitations

Unable to assess time to active labor

Subjective cervical exam, different volumes used in balloons

Small sample size of labors induced with cervical ripening balloon led to unbalanced sample size

- Unable to analyze cervical ripening balloons alone
- Several cervical ripening balloons were placed prior to arrival for induction

Parity was not controlled and may be possible confounder (nulliparous vs multiparous)

Future Recommendations



Future Recommendations

Randomized Controlled Trial with established protocol

- Time to active labor
- Consistent use of and protocol for cervical ripening balloon

Control for parity

Breakdown unique combinations of induction of labor



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Questions