Intracervical foley catheter balloon versus oxytocin infusion as pre-induction cervical ripening agent in live term pregnancies with unfavorable cervices*

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ABSTRACT

Objective: The purpose of this study was to evaluate the effectiveness and safety as well as maternal and fetal outcome of intracervical Foley catheter balloon versus oxytocin infusion as pre-induction cervical ripening agents in live term pregnancies with unfavorable cervices.

Methods: Forty-two patients who fulfilled the induction criteria were randomized to 2 groups. Group 1= intracervical balloon catheter and Group 2 =oxytocin infusion. Both groups were compared as to: insertion/infusion to active phase interval, induction to delivery interval, uterine hyperstimulation, pain intensity, delivery and fetal outcome. Analysis of data collected was done using Independent T-test.

Results: Statistical analysis showed no significant difference as to insertion/infusion to active phase interval (p 0.814) and induction to delivery interval (p 0.264) between the balloon and oxytocin groups. By percentage comparison, both groups have comparable results in the mode of delivery, likelihood of cesarean section and good fetal outcome. Statistical significance was observed with regards to absence of uterine hyperstimulation (p 0.036) and absence of pain (p 0.000) in favor of the balloon group.

Conclusion: By percentage comparison, intracervical Foley catheter balloon and oxytocin were both effective and safe in achieving cervical dilatation. The Foley catheter showed statistical significance in terms of absence of uterine hyperstimulation and pain. Foley catheter is readily available and affordable. It may be considered as a good alternative to oxytocin.

Keywords: Cervical ripening, Foley catheter, Induction of labor, Oxytocin

INTRODUCTION

Induction of labor is an artificial initiation of labor before its spontaneous onset for the purpose of delivery of the feto-placental unit. It is common in obstetric practice with a role varying from 9.5 to 33.7% of all pregnancies annually.[1] It may be indicated despite an unripe cervix. When the cervix is unfavorable, as determined by the Bishop pelvic scoring system, labor induction is associated with a higher incidence of prolonged labor, operative vaginal delivery and cesarean delivery. Under these circumstances, agents for cervical ripening may be used to soften, thin-out, and dilate the cervix, in order to reduce the induction-to-delivery time and to decrease the likelihood of a failed induction. There is little consensus on the best method for cervical ripening and induction of labor, and published studies have proposed various induction protocols and methods.[2] Methods of induction of labor include the following: Non-pharmacologic methods (membrane stripping, nipple stimulation, castor oil), pharmacologic methods (Misoprostol, Dinoprostone, Oxytocin), and mechanical methods (Foley catheter, Double balloon catheter, Laminaria). Mechanical dilatation of the cervix is among the oldest methods used to induce labor among women with normal pregnancies. Agents that have been used include balloon dilators such as Foley catheter. The transcervical Foley catheter (FC) balloon placement was first described by Krause in 1853 and subsequently introduced to obstetric practice by Ezimokhai and Nwabineli in1980.[3]

In our local setting, there is a published paper using transcervical Foley catheter versus Laminaria in cases of molar pregnancy. Foley catheter was found to have the advantage of simplicity, low cost, availability, lack of systemic serious side effects and causes only minimal discomfort. It may be an effective alternative in facilitating cervical dilatation.[4] Since 1950's, oxytocin has been the most commonly used method of induction for women with a viable pregnancy and favorable cervix.[5] The purpose of this study is to compare these two agents.

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OBJECTIVES

General objective: To evaluate the effectiveness and safety of intracervical Foley catheter balloon versus oxytocin infusion as pre-induction cervical ripening agents in live term pregnancies in a tertiary care center.

Specific objective:

To compare intracervical Foley catheter balloon with oxytocin infusion as to the following variables:

1. Insertion/Infusion to active phase interval
2. Uterine hyperstimulation
3. Pain intensity while awaiting cervical dilatation
4. Induction to delivery interval
5. Likelihood of Cesarean Section
6. Fetal outcome

METHODOLOGY

This is a prospective randomized controlled study with ethical approval from the hospital's Ethics Committee. All pregnant women were evaluated for eligibility for this trial by only one resident physician.

I. Inclusion criteria:
   1. Primi or Parity > = 1;
   2. > = 37 weeks gestation
      2.1 Postdated pregnancies
      2.2 DM type II without other complications
      2.3 Gestational Diabetes Mellitus, controlled
      2.4 Gestational hypretension
      2.5 Chronic Hypertensive Vascular Disease without other complications
      2.5 Preeclampsia without other complications
   3. Fetus in vertex presentation;
   4. An unfavorable cervix, defined as a Bishop score ≤ 5;
   5. Intact membranes
   6. Reassuring fetal heart rate tracing;
   7. Or had no more than two painful contractions in a 20-minute period

II. Exclusion criteria:
   1. Evidence of spontaneous labor
   2. Multiple pregnancies
   3. Previous cesarean section
   4. Placenta previa
   5. Non-reassuring fetal heart rate pattern

After enrollment, baseline data, including maternal age, gestational age, gravidity, parity, cervical Bishop score and indication for induction were recorded. Written consent prior to the procedure was secured.

- The patients were divided randomly into two groups
- The first subject will be determined through a toss-coin technique *(head=oxytocin; tail=intracervical balloon catheter)*. *Succeeding subjects will be assigned alternatingly.*
  - Intracervical Balloon catheter group
  - Oxytocin group
- Admission test was done to all groups prior to induction.

A. For the intracervical catheter group, in the dorsal lithotomy position, a sepsis and antisepsis were done, posterior and anterior vaginal retractors were applied, an 18-gauge Foley catheter was inserted aseptically through the internal os of the cervical canal into the extra-amniotic space.

The catheter balloon was filled with 30 ml of normal saline solution and lodged in the lower uterine segment.

For the balloon to rest on the internal os, the catheter was then pulled down carefully and secured under gentle traction to the inner aspect of the patient's thigh.

The catheter was checked for extrusion every hour by cervical examination and the traction adjusted.

The patient was allowed to ambulate and have oral intake. Fetal heart assessment was hourly.

The patient's vital signs were checked every hour.

Once the catheter spontaneously extrudes out, or is pulled out – usually at the sixth hour after insertion- one of the following options will be done:

(1) Begin oxytocin drip with or without artificial rupture of the membranes,
(2) Artificial rupture of membranes without oxytocin, or
(3) Wait and re-evaluate later depending on the station of the presenting part.

B. The group assigned to receive oxytocin, was managed according to the Department's standard protocol for induction of labor with oxytocin.

Intravenous oxytocin was started at 10-15 gtts/ min until adequate uterine activity was maintained (3 contractions in 10 minutes).

The following data will be gathered:

I. Demographic
   1. Age
   2. Parity
II. Bishop score before and after catheter expulsion in Foley catheter
III. Insertion/Infusion to Active phase interval
IV. Uterine hyperstimulation
V. Pain intensity while awaiting cervical dilatation
VI. Labor and delivery outcomes

1. Induction vaginal delivery time
2. Mode of delivery

VII. Neonatal outcomes
1. APGAR score
2. Need for NICU

Data Processing and Analysis

Statistical significance of differences between Foley catheter balloon insertion versus oxytocin infusion was determined using Independent T-test. Statistical analysis used a 0.05 level of significance.

RESULTS

Forty-two patients were included in this study from November 2015 to May 2016. Twenty-one patients were induced with intracervical Foley catheter balloon, and another twenty-one patients were induced with oxytocin infusion according to the criteria in this study.

Majority of the patients, 18 (85.7%), each in both the balloon group and oxytocin group were in the range of 19-34 years old. Likewise, majority of the patients in both groups were primigravida, that is, 12 (57.1%) patients in the balloon group and 14 (66.7%) patients in the oxytocin group. (Table 1)

In the balloon group, majority of the patients, 10 (47.6%), had a gestational age of 40 1/7 - 41 weeks followed by 8 (38.1%), patients with 41 1/7 - 42 weeks AOG and 3 (14.3%) patients with 39 1/7 - 40 weeks AOG. In the oxytocin group, majority of the patients, 12 (57.22%), had a gestational age 40 1/7 - 41 weeks, followed by 5 (23.8%), patients with 41 1/7 - 42 weeks AOG and 2 (9.5%) patients each with 38-39 weeks AOG and 39-40 weeks AOG respectively. (Table 2)

Among the risk factors, majority, that is, 18 (85.7%) patients in the balloon group and 17 (80.9%) patients in the oxytocin group had postdated pregnancies. Only 2 (9.5%) patients had preeclampsia without other complications and only 1 (4.8%) patient had gestational hypertension in the balloon group. In the oxytocin group, only 2 (9.5%0 patients had gestational hypertension and 1 (4.8%) patient each with chronic hypertensive vascular disease and preeclampsia without other complications respectively. (Table 3)

Pre-induction Bishop score in the balloon group was 3 with a range between 1 to 5. At the time of balloon expulsion, Bishop score value ranged from 6 to 8 with a median of 7. The change in Bishop score value ranged from 3 to 6 with a median of 3.5. (Table 4)

In the balloon group, the insertion to active phase interval lasted from 3 to 5 hours in 12 (57.1%) patients, from 6 to 8 hours in 6 (28.6%) patients and from 9 to 11 hours in 3 (14.3%) patients. In the oxytocin group, the infusion to active phase interval lasted within 2 hours in 2 (9.5%) patients, 3 to 5 hours in 12 (57.1%) patients, from 6 to 8 hours in 6 (28.6%) patients, and from 9 to 11 hours in 1 (4.8%) patient. (Table 5)

Table 1. Demographic profile of Intracervical Foley Catheter Balloon and Oxytocin Infusion groups

	Balloon Group (n=21)	Oxytocin group (n=21)
Age (y)		
<=18	1 (4.8%)	1 (4.8%)
19-34	18 (85.7%)	18 (85.7%)
>=35	2 (9.5%)	2 (9.5%)
Parity		
Primigravida	12 (57.1%)	14 (66.7%)
Para >=1	9 (42.9%)	7 (33.3%)

Table 2. Age of gestation of Intracervical Foley Catheter Balloon and Oxytocin Infusion groups.

AOG	Balloon Group (n=21)	Oxytocin group (n=21)
37-38 weeks	0	0
38 1/7-39 weeks	0	2 (9.5%)
39 1/7-40 weeks	3 (14.3%)	2 (9.5%)
40 1/7-41 weeks	10 (47.6%)	12 (57.2%)
41 1/7-42 weeks	8 (38.1%)	5 (23.8%)

Table 3. Risk factors present in Intracervical Foley Catheter Balloon and Oxytocin Infusion groups

Risk Factors	Balloon Group (n=21)	Oxytocin group (n=21)
Postdated pregnancies	18 (85.7%)	17 (80.9%)
DM type II without other complications	0	0
Gestational Diabetes Mellitus, controlled	0	0
Gestational hypertension	1 (4.8%)	2 (9.5%)
CHVD without other complications	0	1 (4.8%)
Preeclampsia without other complications	2 (9.5%)	1 (4.8%)

Table 4. Bishop Score Before and After Expulsion of Intracervical Foley Catheter Balloon.

Indicator	Range (Median)	Frequency and Percentage
1. Pre-induction bishop score	1-5 (3)	21 (100%)
2. Bishop score after expulsion of balloon catheter	6-8 (7)	20 (95.2%)

Table 5. Insertion/Infusion to Active Phase Interval of Intracervical Foley Catheter Balloon and Oxytocin Infusion groups.

Hours	Balloon Group (n=21)	Oxytocin group (n=21)
2	0 (0%)	2 (9.5%)
3 to 5	12 (57.1%)	12 (57.1%)
6 to 8	6 (28.6%)	6 (28.6%)
9 to 11	3 (14.3%)	1 (4.8%)

Uterine hyperstimulation was absent in all 21 (100%) patients in the balloon group. In the oxytocin group, there was no uterine hyperstimulation in 17 (81.0%) patients and only 4 (19.0%) patients had uterine hyperstimulation. (Table 6)

Pain intensity was evaluated using the Visual analog scale (VAS) with 0 having no pain and 10 having the most excruciating pain. In the balloon group, 17 (81%) patients had no pain while waiting for cervical dilatation and 4 (19%) patients developed mild pain. In the oxytocin group, 18 (85.7%) patients had moderate pain and 3 (14.3%) patients had severe pain. (Table 7)

In less than 12 hours, 12 (57.1%) patients in balloon group versus 14 (70%) patients in the oxytocin group were delivered. Most of the patients in both groups delivered vaginally, 15 (71.4%) patients in the balloon group and 13 (61.9%) patients in the oxytocin group. Cesarean section rate in the balloon group was 28.6% (6 patients) while in the oxytocin group, it was 38.1% (8 patients). (Table 8)

All the babies in both groups hadan APGAR scoresof 8 and 9. There were no babies confined in the NICU. (Table 9)

Statistical analysis of differences between the balloon group and the oxytocin group showed a p value of 0.814 during insertion/infusion to active phase interval, p 0.036 for uterine hyperstimulation, p 0.000 for pain intensity, and p 0.264 for induction to vaginal delivery interval. (Table 10)

Table 6. Uterine Hyperstimulation observed in Intracervical Foley Catheter Balloon and Oxytocin Infusion groups.

Indicator	Balloon Group (n=21)	Oxytocin group (n=21)
(-) Uterine hyperstimulation	21 (100%)	17 (81.0%)
(+) Uterine hyperstimulation	0	4 (19.0%)

Table 7. Pain Intensity evaluation of Intracervical Foley Catheter Balloon and Oxytocin Infusion groups.

	Balloon Group (n=21)	Oxytocin group (n=21)
0 (no pain)	17 (81%)	0
1 to 2 (mild)	4 (19%)	0
3 to 6 (moderate)	0	18 (85.7%)
7 to 10 (severe)	0	3 (14.3%)

Table 8. Labor and Delivery Outcomes of Intracervical Foley Catheter Balloon and Oxytocin Infusion groups.

	Balloon Group (n=21)	Oxytocin group (n=21)
1. Induction-vaginal delivery time		
<12 hours	12 (57.1%)	14 (70%)
12-17 hours	6 (28.6%)	3 (15%)
18-24 hours	3 (14.3%)	3 (15%)
2. Mode of deliver		
NSD	15 (71.4%)	13 (61.9%)
CS	6 (28.6%)	8 (38.1%)

Table 9. Neonatal outcomes of Intracervical Foley Catheter Balloon and Oxytocin Infusion groups.

	Balloon Group (n=21)	Oxytocin group (n=21)
1. APGAR score	21 (100%)	21 (100%)
2. Need for NICU	0 (0%)	0 (0%)

Table 10. Statistical Analysis

	Group	P-Value	Decision
Insertion/Infusion to active phase interval	Balloon Oxytocin	0.814	Not Significant
Uterine Hyperstimulation	Balloon Oxytocin	0.036	Significant
Pain Intensity while awaiting cervical dilatation	Balloon Oxytocin	0.000	Significant
Induction to Vaginal Delivery interval	Balloon Oxytocin	0.264	Not Significant

(Significant at alpha = 0.05)

DISCUSSION

The pharmacologic and mechanical methods are the most important tools used for cervical ripening to induce labor. Embrey and Mollison[6] advanced a theory on the possible mechanism by which Foley's catheter effects changes on the various components of the Bishop score (position, consistency, effacement, dilatation and station). The mechanical action of the Foley's catheter balloon strips the fetal membranes from the lower uterine segment and causes rupture of lysosomes in the decidual cells, part of which is phospholipase A these lytic enzymes act on phospholipids to form arachidonic acid which in turn is converted to prostaglandin A which improves the consistency and effacement of the cervix.[7]

Improved cervical Bishop score leads to faster and improved vaginal delivery.[7] This study showed that the Bishop score value at the time of balloon insertion improved from a range of 1 to 5 and a median of 3 to a Bishop score value of 6-8 and a median of 7. This resulted in short induction and delivery interval of less than 12 hours in 12 (57.1%) patients and low cesarean rate of 28.6% (6 patients). The results were comparable to the oxytocin group. There were 14 (70%) patients who delivered less than 12 hours with a cesarean rate of 38.1% (8 patients). Indications for cesarean section for both groups were similar: arrest in cervical dilatation, arrest in descent and failure in descent except for persistent late decelerations in the oxytocin group. There was no significant statistical difference (p 0.264) in the induction to vaginal delivery interval.

Uterine hyperstimulation was absent in all 21 (100%) patients in the balloon group versus 17 (81.0%) patients in the oxytocin group. Statistical analysis gave a significant p value of 0.036. Likewise, pain intensity has a significant p value of 0.000. Seventeen (81%) patients did not experience any pain as compared to the oxytocin group where all patients developed moderate to severe pain.

Several side effects have been cited resulting from use of Foley catheter for pre-induction cervical ripening like: premature rupture of membranes, displacement of the presenting part, bleeding and fever.[6] None of these side effects occurred in our study. There were no maternal and neonatal morbidity and mortality in both groups.

CONCLUSION

Induction of labor by cervical ripening through the use of mechanical method such as the Foley catheter balloon is an effective tool in obstetric management. It is readily available, safe and affordable. It is an acceptable method comparable to oxytocin. Both groups have comparable results in the insertion/infusion to active phase interval, induction to vaginal delivery interval, likelihood of cesarean section and fetal outcome. Statistical significance was observed as regards to absence of uterine hyperstimulation and absence of pain in the balloon group. Foley catheter balloon insertion may be considered as a good alternative in facilitating cervical dilatation other than oxytocin.

RECOMMENDATIONS

It is recommended that a similar study with bigger samples be conducted to achieve a true representation of the population and reach a more conclusive statement. Vaginal birth after cesarean section (VBAC) and ruptured membranes may also be considered in the inclusion criteria, as done in some published studies. For a better analysis of fetal outcome blood cord sampling of ABGs may be undertaken. ■

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