

## Efficacy of Foley's Bulb for Induction of Labour Madarapu Soumya<sup>1</sup>, Chatla Sunitha<sup>2</sup>

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### Abstract

**Background:** Labor induction is being increasingly used (15-30% of pregnancies). The most common indications include late pregnancy preeclampsia, intrauterine fetal growth retardation (IUGR), hypertension. Preinduction by speeding up the ripening of the cervix increases the chances of successful induction. **Aims:** To assess the efficacy and safety of labor pre-induction using a Foley catheter for cervical ripening.

**Materials and methods:** This is a prospective study involving 100 patients done at Government maternity hospital with Gestational age of 36 to 42 weeks with Single viable fetus with vertex presentation. **Results:** Bishop's score at initial and after expulsion was compared using Student t test. The mean difference was 6.29 with t value 27.36 and was statistically significant. Mean time Interval for induction to expulsion of Foley's bulb is 13.25 +/- 3.788. Mean induction delivery interval for the subjects following Foley's bulb induction is 21.39 ± 6.09. Following induction with Foley's bulb 68% of the patients required acceleration with oxytocin. 89% of the patients delivered by normal vaginal delivery and 11% of the cases landed up in caesarean. The most common maternal complication were pyrexia, bleeding p/v, PROM.

**Conclusions:** The Foley catheter is an effective method of inducing cervical maturation. The Foley catheter is safe method of labor induction for the mother fetus and new-born.

**Keywords:** Foley catheter, Cervical Maturation, Labor Induction

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### Introduction

The American Congress of Obstetricians and Gynaecologists has recommended against elective induction before 41 weeks if there is no medical indication and the cervix is unfavorable. However, recent studies contradict this view. One recent study indicates that labor induction at term or post-term reduces the rate of caesarean section by 12%, and also reduces fetal death. On the other hand, observational/retrospective studies have shown that non-indicated, elective inductions before the 41st week of gestation are associated with an increased risk of requiring a caesarean section. Randomized clinical trials have not been used to study this question. However, it has been found that multiparous women who undergo labor induction without medical indications are not predisposed to caesarean sections. Doctors and patients should have a discussion of risks and benefits when considering an induction of labor in the absence of an accepted medical indication. Studies have shown a slight increase in risk of infant mortality for births in the 41st and particularly 42nd week of gestation, as well as a higher risk of injury to the mother and child. Due to the increasing risks of advanced gestation, induction appears to reduce the risk for caesarean delivery after 41 weeks' gestation and possibly earlier[1,2] Inducing labor before 39 weeks in the absence of a medical indication, like hypertension, IUGR, or preeclampsia, increases the

risk of complications of prematurity including difficulties with respiration, infection, feeding, jaundice, neonatal intensive care unit admissions, and perinatal death[3]. The odds of having a vaginal delivery after labor induction are assessed by a "Bishop Score". However, recent research has questioned the relationship between the Bishop score and a successful induction, finding that a poor Bishop score actually may improve the chance for a vaginal delivery after induction. A Bishop Score is done to assess the progression of the cervix prior to an induction. In order to do this, the cervix must be checked to see how much it has effaced, thinned out, and how far dilated it is. The score goes by a points system depending on five factors. Each factor is scored on a scale of either 0-2 or 0-3, any score that adds up to be less than 5 holds a higher risk of delivering by caesarean section. Catheter for cervical ripening has been shown to be an efficient, reversible method to induce labour, and is associated with a low incidence of uterine contractile abnormalities[1]. This method is one recommended by the World Health Organization, and it provides an option for cervical ripening when there are contraindications to pharmacological agents. In nulliparous women where IOL is necessitated before the cervix is favourable, the single Foley catheter may be the safest, least costly and most accepted choice by women when compared to a double balloon catheter or Prostaglandins. Balloon catheter use has been shown to improve Bishop's scores and decrease the interval until birth. The lower risk for hypertonus when compared to prostaglandins may result in lower risk for uterine rupture in women who had caesarean section. To assess the efficacy and safety of labor pre-induction using a Foley catheter for cervical ripening for vaginal birth after caesarean birth (VBAC).

### Materials and Methods

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This is a prospective study involving 100 patients done at Government maternity hospital Sultan Bazar Hospital period of September 2014 for about 1 year.

**Inclusion Criteria**

Gestational age of 36 to 42 weeks with Single viable fetus with vertex presentation

**Exclusion Criteria**

Non vertex or malpresentation, Multiple gestation, Presence of cephalopelvic disproportion or contracted pelvis, History of difficult or traumatic labour, Symptoms and signs of fetal distress, Chorioamnionitis, placenta previa, un explained vaginal bleeding and Vaginal infections like active herpes simplex agents.

**Primary indications for induction of labour:**

1. Pregnancy induced hypertension
2. Post-dated pregnancy
3. Eclampsia
4. IUD

Data collected from the patients are, maternal age, parity, gestational age, initial bishop's score at the time of induction, Bishop score after expulsion, time for spontaneous expulsion of Foley's bulb, induction delivery interval, mode of delivery, indication for induction, Number of patients requiring oxytocin augmentation, Maternal complications, Weight of the baby, Apgar score and number of cases of MSL, fetal arrhythmias. Explain the procedure to the woman, gain verbal consent, prepare equipment & maintain privacy. Encourage bladder emptying prior & perform abdominal palpation. Apply Cardiotocograph (CTG) for 20 minutes. Proceed if normal fetal heart rate (FHR) trace. If abnormal trace discuss with obstetric team and midwifery co-ordinator. Position the woman in lithotomy wash hands, put on sterile gloves & assess the

[\*\*Table 1: Demographic details in study\*\*](http://webcache.googleusercontent.com/search?q=cache:R1Yt5kmE6ygl:www.kemh.health.wa.gov.au/development/manuals/O%26G_guidelines/sectionb/5/b5.1.4.pdf+&cd=2&hl=en&ct=clnk&gl=in-3Bishop's score on vaginal examination if not assessed prior. Cleanse the vulvo-vaginal area and insert a bi-valve speculum until the cervix visualised. Insert the 16g (30mL size balloon) Foley catheter through the internal os of the cervix using sponge forceps to assist. Inflate the balloon with 50mL sterile water and spigot the catheter. Gently withdraw the catheter until it rests at the level of the internal os. Placement should be confirmed with a vaginal examination. Remove the speculum. Apply traction to the catheter & tape the catheter to the inside of the woman's thigh. Assess the FHR. Discard equipment and wash hands. Document in the patient's medical records & notify medical staff of any abnormalities. Women with an uncomplicated pregnancy and normal maternal & fetal observations 1 hr post insertion may be considered for transfer to an obstetric ward. Return to Labour/ Birth Suite if rupture of membranes or onset of labour pains or expulsion of catheter. High risk pregnancies where there is potential for a change in the maternal or fetal condition should have observations performed overnight observations include 4 hourly FHR, fetal movements, uterine activity, per vaginal loss, temperature, pulse, blood pressure and oxygen saturations. For low risk women undertake 4 hourly observations as above unless the woman is sleeping in which case undertake observations at the earliest opportunity upon waking but within 8 hours of the previous observations. <b>Vaginal examination (VE)</b> done at 12 & 18 hours after insertion to confirm balloon placement. If Foley catheter falls out in <12hours perform a VE. If favourable transfer to labour suite at 12 hours; if unfavourable discuss with medical team. <b>Results</b></a></p>
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Age Distribution	Number of Patients	Percentage (%)
<20 Years	3	3%
20-30 Years	89	89%
>30 Years	8	8%
<b>Parity</b>		
Primi	39	39%
G2	36	36%
G3	20	20%
G4	5	5%
<b>Indications</b>		
Past Dates	80	80%
Preeclampsia	14	14%
Eclampsia	2	2%
Iud	4	4%

Majority of the patients involved in the study group for Induction of labour were in the age group of 20-30. The mean age of the patient is 24.71 +/- 3.554. Majority of the subjects in our study were induced

for past dates, preeclampsia eclampsia IUD. The most common indication being past dates (80%).

**Table 2: Bishop Score Before Induction**

Parity	Bishop score					Total
	0	1	2	3	4	
Primi	7	20	12	--	--	39
G2	4	1	21	8	2	36
G3	--	--	2	7	11	20
G4	--	--	1	1	3	5

The mean Bishop score before Induction is 2.05 +/- 1.209.

**Table 3: Bishop Score After Foleys Exclusion**

Parity	Bishop score			
	4-5	6-7	8-10	11-13
Primi	--	24	14	1

G2	--	7	25	4
G3	--	1	13	6
G4	--	1	4	1

Mean Bishop score after Foleys expulsion is 8.34 +/- 1.955.

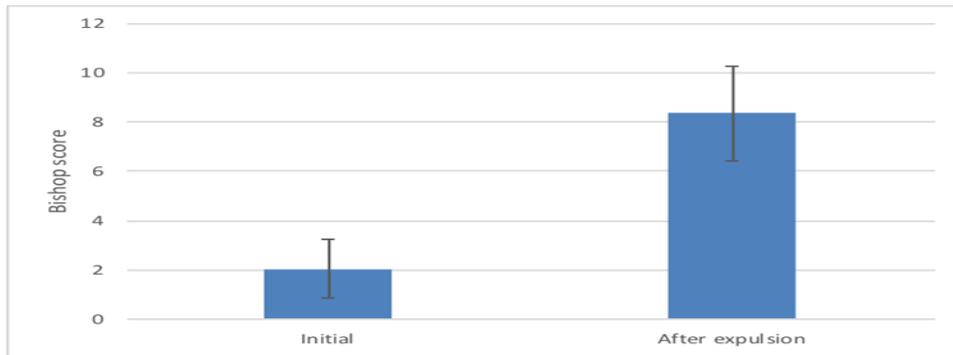


Fig 1: Bishop's score at initial and after expulsion

Mean and standard deviation of Bishop's score at initial and after expulsion was compared using Student t test. The mean difference was 6.29 with t value 27.36 and was statistically significant with p <0.000001.

Table 4: Time interval for induction to expulsion and Induction Delivery

Induction to expulsion	Time interval in hours					
	5-10	11-15	16-20	21-25	26-30	>30
Primi	1	22	12	3	1	---
G2	9	20	7	---	---	---
G3	10	9	---	---	1	---
G4	2	2	1	---	---	---
Induction Delivery						
Primi	--	1	6	9	19	4
G2	--	6	11	14	4	1
G3	2	8	6	2	1	1
G4	--	3	1	--	1	--

Mean time Interval for induction to expulsion of Foley's bulb is 13.25 +/- 3.788. Mean induction delivery interval for the subjects following Foley's bulb induction is 21.39 ± 6.09.

Table 5:Patients requiring syntoacceleration

Parity	Number of patients	%
Primi	32	82%
G2	23	63.90%
G3	10	50%
G4	3	60%
Total	68	68%

Following induction with Foley's bulb 68% of the patients required acceleration with oxytocin. 89% of the patients delivered by normal vaginal delivery and 11% of the cases landed up in caesarean .

Table 6:Maternal complications

Complications	Number of cases	%
Pyrexia	2	28%
Bleeding P/V	1	14%
PROM	3	43%
Hyperstimulation	0	
Total	7	

The most common maternal complications were pyrexia, bleeding p/v, PROM.

**Discussion**

Induction of labour implies stimulation of uterine contraction before spontaneous onset of labour with or without ruptured membranes. Induction of labour is warranted in some cases like PIH, post-dated pregnancy, IUD, PROM, etc. in view of either maternal or fetal well-being, with consequent reduction in maternal and perinatal mortality rate. Ideal inducing agent is that which has short induction delivery interval less side effects with good maternal and fetal outcome and convenience to both doctor and patients.The present study is to find

the efficacy of Foley's bulb in mechanical induction of labour. 100 patients were taken in this study. Informed consent taken and were induced with Foley's bulb. Age of patients was between 18 – 35 years. Most of them were between 20 – 30 years, the mean age being 24.71 years. Binti R. Bhatiyani et al[4] conducted a study with 52 patients, the mean age of their study being 30 years. Jagielska et al[5] conducted a study on evaluation of the efficacy and safety of Foley's catheter preinduction of labour, the mean patient age was 29.3 + 5.35 years. Samreen Iqbal et al[6]conducted a study on outcome of

induction of labour with intracervical Foley's catheter in women with previous one caesarean section, the mean age of the patients being 27.75 + 3.94 years. Toh Lick Tan et al<sup>[7]</sup> conducted a study on cervical ripening balloon as an alternative for induction of labour, the mean age of patients in their study was 28.2 + 5.3. In this study, most of the patients were multiparous, Primigravida constituted for 39%, as in our community most of them are multiparous. Indications for induction in this study were PIH, post-dated pregnancy eclampsia, IUD, the most common being post-dated pregnancy 80%. According to Ekele BA et al conducted a study in which the indication of labour was PIH (42%), post term pregnancy (34%), IUD (20%). Binti R. Bhatiyani et al<sup>[4]</sup> conducted a study with 52 patients in which the indications for induction of labour were postdatism (12), IUFD (6), IUGR (10), Pre-eclampsia (14). Jagielska et al<sup>[5]</sup> have done a study where the most common indication for labour induction was post term pregnancy (55.05%), hypertension and pre-eclampsia (16.51%). The mean Bishop score before induction in my study is 2.05 + 1.209 and after induction the Bishop score improved to 8.34 + 1.955. According to study by Binti R. Bhatiyani et al<sup>[4]</sup>, the mean pre-treatment clinical score was 2.2 and the mean post treatment score was 6. According to the study conducted by Jagielska et al<sup>[5]</sup>, the mean increase in the Bishop score was 2.68 + 1.39.

In this study, most of the patients expelled the bulb spontaneously at an interval 5 – 15 hrs. However, primigravidae took longer time than the multi gravidae. The mean induction to expulsion interval is 13.25 + 3.788. According to study conducted Ekele BA et al, the average duration of catheter stay was 19.6 hrs obtained when pregnancy was 37 weeks or more and 44.8 hrs when the gestational age was 20 – 27 wks. In my study most of the primi's induction delivery interval was between 26 – 30 hrs. But most of the Multi gravida delivered between 15 – 20 hrs. However, the mean induction delivery interval is 21.39 + 6.09. According to Binti R. Bhatiyani et al,<sup>[4]</sup> the mean induction delivery interval was 8 hrs. According to study conducted by Karjane et al<sup>[8]</sup>, the mean induction delivery interval was 21.47 + 9.95 hrs in the Foley's group. According to Toh Lick Tan et al<sup>[7]</sup>, induction delivery with cervical ripening balloon was 21.2 + 6.8. Following Foley's bulb induction, 68% of the patients required oxytocin acceleration for successful progress of labour according to my study. According to the study conducted by Toh Lick Tan et al<sup>[7]</sup>, 77.4% of patients induced with cervical ripening balloon required oxytocin infusion for augmentation. Most of the patients delivered successfully by mean of normal vaginal delivery (89%), three of them underwent instrumental vaginal delivery and 11% of the cases landed up in caesarean section. The common indication for caesarean section being meconium stained liquor with fetal distress and borderline CPD, failed induction. According to previous research, the overall success rate of VBAC is 72–76%<sup>[9-11]</sup>. According to study by Binti R Bhatiyani et al<sup>[4]</sup>, 40 out of 52 patients delivered vaginally, 4 patients failed to progress. Procedure was terminated in 2 patients for foetal distress. 5 had thin MSL with borderline pelvis. One patient had cord prolapse which was taken for caesarean section. According to the study by Karjane et al<sup>[8]</sup>, caesarean delivery rate was 20.1%. According to study by Toh Lick Tan et al<sup>[7]</sup>, vaginal delivery rate was 71.01% following induction with cervical ripening balloon. In study conducted by Jagielska et al<sup>[5]</sup>, the vaginal delivery rate was 66.67%. The most common indication for caesarean section was threatening intra uterine fetal asphyxia. Maternal complications encountered in my study were

pyrexia, bleeding, PROM. 2 cases had fever after delivery but the cause was UTI. There was bleeding in one case following the Foleys bulb insertion. The bleeding was from the cervix and it subsided without any maternal or fetal complication. PROM occurred in 3 cases few hours after Foleys bulb induction but not at the time of insertion. No case of hyperstimulation was encountered.

#### Conclusion

In this study, the use of Foley's catheter resulted in a greater change of Bishop score, shorter induction to delivery interval. Lesser number of caesarean sections and improved maternal and neonatal outcome. Foley's catheter is safe to use in case of LSCS.

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