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A Clinical Study of Efficacy and Safety of Foley's Catheter Method of Induction of Labor

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Abstract

Background: Induction of labor (IOL) is a procedure of artificial initiation of uterine contractions by medical or surgical means before the spontaneous onset of labor. Trans-cervical extra-amniotic Foley catheter (FC) insertion is used in women with an unfavorable cervix. The present study aimed to assess the pre-induction and post-induction Bishop scores to assess the mode of delivery and maternal and neonatal complications with Foley's method of induction. **Methods:** N=80 cases of pregnant women who require labor induction were selected after thorough general examination with Pulse Rate, BP, temperature, CVS/RS, admission NST, USG, and other necessary blood investigations were done in all the cases. Detailed history and general physical examination were done and systemic examination including per abdomen examination was done. Per vaginal examination to assess the status of cervix Bishop's score. **Results:** The most common indication for the induction of labor was postdated pregnancy in 68.5% of cases followed by hypertension in 22.5% cases and Intrauterine growth retardation (IUGR) in 2.5% cases and previous Lower segment cesarean section in 6.25% cases. The mean pre-induction Bishop score was 3.20 and the post-induction Bishop score was 8.75 with a significant improvement of Bishop score by 5.5 which was significant. The mean duration of induction to delivery interval for primigravidae was 16.5 hours and 11.5 hours for multigravidae. **Conclusion:** Foley's catheter was a safe and efficacious method for induction of labor at full-term gestation. It may be utilized when indicated to prevent complications of post-dated pregnancy and in cases where hyperstimulation of the uterus is unwanted such as in cases of hypertension, or intrauterine growth retardation. This method of induction may also be considered in cases of previous LSCS with indications for induction.

Keywords: Foley's Catheter, Induction, Labor, full-term gestation, Bishop score

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Introduction

Induction implies to stimulation of contractions before spontaneous onset of the labor, with or without ruptured membranes. When the cervix is closed or uneffaced, labor induction will often commence with cervical ripening.^[1] Globally, in medium to large healthcare facilities, it is estimated that approximately 10% of all deliveries involve IOL. The primary goal of the WHO recommendations for IOL is stated to be

the improvement of the quality of care and outcomes for pregnant women undergoing the procedure in under-resourced settings.^[2] As per the Who global survey which included 373 healthcare facilities in 24 countries the rate of labor induction has risen to reach 20% of all laborers in developed countries, they included 24 countries and nearly 300,000 deliveries, showing that 9.6% of deliveries by labor induced. Overall, the survey found that facilities in African countries tended to have lower rates

of induction of labor (lowest: Niger, 1.4%) compared with Asian and Latin American countries (highest: Sri Lanka, 35.5%).^[3] The common medical and obstetrical indications for induction of labor include premature rupture of membranes, gestational hypertension, oligohydramnios, intrauterine growth restriction, postdated pregnancy, chronic hypertension, and diabetes, and the most common being post-dated pregnancy.^[4-6] Methods of pre-induction are divided into two categories: pharmacological and non-pharmacological. Foley catheter is a non-pharmacological (mechanical) method. It has advantages such as greater chances of successful labor induction with low costs, easy storage, and its efficacy is comparable to that of pharmacological methods without the disadvantages associated with pharmacological methods.^[7] Apart from the mechanical effects, it produces local prostaglandin production by pressing on the lower part of the uterine.^[8] Foley catheter has undergone a drastic change since it was first used by Antoine Matteifirst with the dilator filled with air.^[9] Recently the effectiveness of mechanical pre-induction was enhanced by 0.9% NaCl infusion into the extra amniotic space, traction, cyclical catheter pulling.^[10, 11] With this background we in the current study tried to evaluate the efficacy and safety of Foley's catheter method of induction of labor by elective induction of labor using Foley's catheter.

Materials and Methods

This cross-sectional study was done in the Department of Obstetrics and Gynecology, Prathima Institute of Medical Sciences, Naganoor, Karimnagar. Institutional Ethical Committee Permission was obtained for the study. Written consent was obtained from all the participants of the study.

Inclusion criteria

1. Gestational age 37-42 weeks
2. Singleton live pregnancy
3. Cephalic presentation
4. Intact membranes
5. Indication for induction
6. Pregnant women with previous LSCS
7. Bishops score less than 5

Exclusion criteria

1. Antepartum hemorrhage
2. Uterine infection
3. Cephalopelvic disproportion
4. Twins/malpresentation
5. Abnormal fetal heart rate
6. Intrauterine death

Patients with full-term gestation who would have fulfilled the above inclusion criteria were selected for the study. N=80 cases of pregnant women who require labor induction were selected after thorough general examination with Pulse Rate, BP, temperature, CVS/RS, admission NST, USG, and other necessary blood investigations were done in all the cases. Detailed history and general physical examination were done and systemic examination including per abdomen examination was done. Per vaginal examination to assess the status of cervix Bishop's score. Admission NST to rule out any fetal heart rate abnormalities. With the use of sterile technique, a Foley catheter No. 16 was selected, and the balloon portion was inserted beyond the internal os either by direct visualization with the assistance of speculum or blindly if possible. Once properly placed, the balloon reservoir was inflated with normal saline 30 ml and the catheter was taped to the patient's inner thigh. After induction, patients were monitored for signs of labor. When labor ensued, they were closely monitored for maternal vital signs, the progress of labor, and fetal heart rate which was monitored by intermittent auscultation. Spontaneous expulsion of the balloon waited for the first 24 hours. if not expelled spontaneously within 24 hours, the balloon was deflated. Post induction Bishop's score was assessed. If the Bishop score was favorable 6-10 and contractions if not adequate, augmentation of labor was done with IV oxytocin drip, which was started at the rate of 4 drops/min, and the drop rate was increased by 4 drops every 20 minutes till the patient entered the active phase of labor and the same drip continued till delivery. If Bishop's score was 6 or less than 6 such cases were considered as failed cases. Such cases were again induced with PGE₂ gel except for cases with previous LSCS. Membranes were ruptured when the cervix was 4 cm dilated. For women who did not expel Foley's balloon spontaneously within 24 hours, the balloon was

deflated and removed, in addition, Bishop's score was assessed. Labor and delivery parameters included pre-induction Bishop score, time of expulsion/removal of the balloon, post-induction Bishop score, augmentation with IV oxytocin drip, induction to delivery interval, mode of delivery, maternal and neonatal complications, and adverse effects.

Results

This study was conducted on n=80 cases who fulfilled the above-mentioned inclusion and exclusion criteria with indications for induction of labor admitted to Prathima Institute of Medical Sciences, Naganoor, Karimnagar. Maximum patients belonged to age group 21 – 25 years the mean age of the patients of the study was 24.5 ± 6.5 years. In this study 58.75% of cases were primigravida and 41.25% of cases were multigravida depicted in table 1.

Table 1: Age distribution of cases in the study

Age group	Frequency (%)	Primigravida (%)	Multigravida (%)
≤ 20 years	3 (3.75)	3 (3.75)	0 (0)
21–25 years	62 (77.5)	38 (47.5)	24 (30)
26 – 30 years	10 (12.5)	4 (5.0)	6 (7.5)
31 – 35 years	5 (6.25)	2 (2.5)	3 (3.75)
Total	80(100)	47(58.75)	33 (41.25)

The most common indication for the induction of labor was post-dated pregnancy in 68.5% of cases followed by hypertension in 22.5% cases and Intrauterine growth retardation (IUGR) in 2.5% cases and previous Lower segment cesarean section in 6.25% cases. The distribution gravida wise is depicted in table 2. The Bishops scores were n=12 cases with a pre-induction Bishop score of 2. N=38 cases with a score of 3 and N=30 cases were with Bishops score of 4

Table 2: Gravida and Indication

Indications	Primigravida (%)	Multigravida (%)	Total (%)
Post Dated Pregnancy	33 (41.25)	22 (27.5)	55 (68.5)
Hypertension	12 (15.0)	6 (7.5)	18 (22.5)
IUGR	2 (2.5)	0 (0.0)	2 (2.5)
Previous LSCS+ Indication For Induction	0 (0.0)	5 (6.25)	5 (6.25)
Total	47(58.75)	33 (41.25)	80 (100)

A total of n=9 cases required balloon deflation at the end of 24 hours out of which n=8, were primigravida and n=1 was multigravida. The post-induction Bishops scores were 10 in 30% of cases. A score of 9 was found in 25% of cases. 20% of cases had Bishops score of 8. Bishops scores of 6 and 7 were found in 8.75% and 3.75% cases respectively given in figure 1. N=10 cases had a post-induction Bishop score of 6 or less than 6 which were considered as failed cases. The mean pre-induction Bishop score was 3.20 and the post-induction Bishop score was 8.75 with a significant improvement of Bishop score by 5.5 which was significant. The mean duration of induction to delivery interval for primigravidae was 16.5 hours and 11.5 hours for multigravidae.

Figure 1: Post-Induction Bishops scores in the cases of study

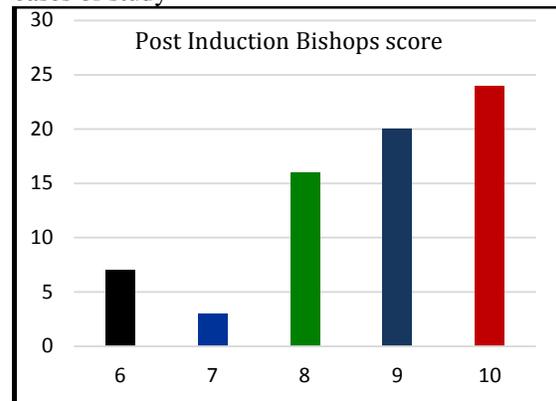


Table 3: Mode of delivery according to parity

Mode of Delivery	Primigravida (%)	Multigravida (%)	Total (%)	
Vaginal	31 (38.75)	21 (26.25)	52 (65)	
Instrumental delivery	Forceps	2 (2.50)	3 (3.75)	05 (6.25)
	Vacuum	2 (2.50)	1 (1.25)	03 (3.66)
Cesarean section	12 (15.0)	8 (10.00)	20 (25)	
Total	47(58.75)	33 (41.25)	80 (100)	

Out of the N=20 cases that underwent LSCS, N=12 was primigravidae and N=8 were multigravidae. The common indication for LSCS was failed induction in n=10 cases and fetal distress in n=9 cases and arrest of dilatation in n=1 case. There were 8 cases with previous LSCS, out of which 3 cases were taken up for LSCS. Two cases because of fetal distress. N=3 cases had a fever, n=2 cases had Post-partum Hemorrhage (PPH) and n=1 case had scar

tenderness. No other maternal complications were found (Table 4).

Table 4: Maternal complications in the cases of study

Complications	Frequency (%)
Fever	3 (3.75)
PPH	2 (2.50)
Scar tenderness	1 (1.25)
Hyperstimulation	0 (0.00)
Others	0 (0.00)

Table 5: Neonatal complications and indications for NICU admissions

Complications	Frequency (%)
Fetal distress	5 (6.25)
Others	0 (0.00)
NICU Indication	
Meconium aspiration syndrome (MAS)	2 (2.50)
Birth asphyxia	1 (1.25)

Discussion

As induction of labor is becoming more and more common procedure in obstetrics (up to now it is carried out in 30% of pregnancies) an optimal method of this procedure has to be found. [12] In the present study of N=80 patients at term gestation, N=47 primigravidae and N=33 cases were multigravidae. Of them, n=10 cases had postinduction Bishop score of 6 or less than 6 which were considered as failed cases. Of the total number of cases, n=60(75%) had a vaginal delivery. Of the cases of vaginal delivery n=5(6.25%) had forceps delivery and n=3(3.66%) had vacuum delivery. Successful induction depends mostly on the maturity of the cervix. [13] An unfavorable cervix, which is closed, firm, and difficult to distend, increases the risk of failure of induction, longer duration of labor, and higher risk of cesarean section. [14] According to Steiner and Creasy, the best way to achieve cervix maturity is to cause biochemical changes as similar to natural ones as possible. [15] The perfect method should be effective, safe, easy to use, cheap and acceptable for the patient at the same time. [7] In the present study, the mean pre-induction Bishop score was 3.20 and the post-induction Bishop score was 8.75 with a significant improvement of Bishop score by 5.5 which was significant. Several studies have reported Bishop score, cervical

length, and cervical dilatation as predictors of cervix maturity. Other authors have reported that both cervical length and Bishop score are reliable predictors of determining the success of induction. [16, 17] In the current study we determined the success of induction by estimation of Bishop score. Gibson et al., [18] and Maja Kufelnicka- Babout et al., [9] have found similar results in their studies. Patro-Malysza's study the change of Bishop score was from 3.29 to 6.85. [7] in our study, the change was from 3.20 to 8.75 which was significant. The mean time in this study for n=80 cases was 13.5 hours VL Deshmukh et al., [19] in a similar study the mean induction to the delivery interval was 15.32 hours. F Ziyauddin et al., [20] found the mean induction to the delivery time of 18.15 hours. AT Owolabi et al., [21] found the mean induction of 11.9 hours. Maternal complications are very minimal with fever in 3.75% of cases, Post-partum Hemorrhage in 2.5% of cases, and scar tenderness in 1.25% of cases. There was no incidence of hyperstimulation of the uterus in the present study. Studies have shown that Foley catheter does not increase the risk of infections. [15] In the present study, fetal distress was found in 6.25% and DL Deshmukh et al., found the incidence of fetal distress was in 8% cases and Abramovici D et al., [22] reported the incidence of fetal distress in 13.1% of cases of their study. In the present, there were no reported neonatal deaths.

Conclusion

Within the limitations of the current study, it can be concluded that Foley's catheter was a safe and efficacious method for induction of labor at full-term gestation. It may be utilized when indicated to prevent complications of post-dated pregnancy and in cases where hyperstimulation of the uterus is unwanted such as in cases of hypertension, or intrauterine growth retardation. This method of induction may also be considered in cases of previous LSCS with indications for induction.

Conflict of Interest: None
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