Comparative Study for Labor Induction with the Foley Catheter and Double Balloon (cook) Catheter in Women with Unfavorable Cervix

Hossam M Abdelnaby*, Hussin M Abdeldayem, Ehab F Gerbash, Mervat Harira, Mohamed M El-Bakry Lashin and Ahmed Mahmoud Abdou
Hossam M Abdelnaby, M.D Zagig University Zagazig, Egypt

Abstract

Objective: The aim of this study is to compare the efficacy of single- and double-balloon catheters for the induction of labor among women with an unripe cervix.

Study design: This prospective randomized interventional study was performed in emergency department of Obstetrics and Gynecology, Zagazig University and ELGALAA maternity hospitals during the period from 6/2017 till 2/2018. In this study (180 patients) who fulfill inclusion and exclusion criteria were enrolled and were divided into two main groups; single and double balloon group. Each group included equal number of prim gravida and multigravida.

Result: Of 180 pregnant women recruited in this study 160 continued till the end of the study. Pain encountered by using visual analogue scale during the catheter insertion the mean pain perception during catheter insertion was 3.3 ± 2.3 in the Foley catheter group and 3.1 ± 2.47 in the Cook catheter group. In the Foley catheter group there were significantly more spontaneous expulsions of the balloon compared with the Cook balloon group. In the Foley catheter group 82.2% of them delivered vaginally and 17.8% delivered by caesarean section. In Cook catheter group 80% of them delivered vaginally and 18% delivered by caesarean section. Regarding maternal complications There were 4 cases of postpartum hemorrhage (PPH), 3 of them were atonic PPH, and only one case with traumatic PPH due to cervical tear in the Cook catheter group and in Foley catheter group there were 3 cases of postpartum hemorrhage all of them atonic postpartum.

Conclusion: There is significant difference between the two groups regarding Bishop Score after the balloon catheter expulsion or removal and it was significantly higher in the Cook cervical ripening balloon group, but only in the nulliparous group. Putting in mind that the Foley catheter is cheaper than double balloon catheter and at least as effective as Cook catheter or even better, it is recommended to use Foley catheter in induction of labor instead of double balloon catheter.

Keywords: Labor induction; Foley cather; Double balloon cather

Introduction

Induction of labor refers to iatrogenic stimulation of uterine contractions to accomplish delivery prior to the onset of spontaneous labor. Induction of labor is the most common intervention in modern obstetrics, over the past two decades; incidence of induction of labor has increased with the advent of newer methods (Martin 2005). Induction of labor is indicated when benefits to the mother or the fetus outweigh those of continuing the pregnancy such as post-dated pregnancy, pre-clampsia or fetal growth restriction [1]. A balloon catheter is a mechanical option to ripen an unfavorable cervix. The mechanism of cervical ripening with a balloon catheter is from the direct pressure and overstretching of the lower segment and cervix as well as increasing the release of local secretions of prostaglandins [2]. Foley catheter balloon has been established as a safe and effective mechanical method for labor induction. Comparison between trans cervical Foley catheter and prostaglandins (pharmacological agents) did not reveal a significant difference in the duration of induction to delivery interval or in the risk of cesarean delivery; however, Foley catheter use decreases the risk of uterine tachysystole (with or without fetal heart rate changes), rates of hyper stimulation and offers the advantage of lower cost, reversibility, and stability at room temperature [3]. Compared with the Foley catheter, which has a single balloon, a double-balloon catheter has been described to have an additional utility in the unripe cervix by applying pressure on both the external os and internal os [4]. The aim of this study is to compare the efficacy of single and double-balloon catheter for the induction of labor among women with an unripe cervix.

Patients and Methods

This prospective randomized interventional study was performed in emergency department of Obstetrics and Gynecology, Zagazig University and Elgalaa maternity hospitals. Hospitals during period from 6/2017 till 2/2018. In this study (180 patients) who fulfill inclusion and exclusion criteria were enrolled and were divided into two main groups; single and double balloon group. Each group included equal number of prim gravida and multigravida. Sequences of case selection were shown in Figure 1.

Inclusion criteria:
1. Singleton gestation.
2. Intact membranes.
3. Cephalic fetal presentation.
4. Gestational age ≥ 37 weeks as determined by the last menstrual period and confirmed by first trimester ultrasound scan.

Exclusion criteria:
1. Expected fetal weight more than 4000gm.

*Corresponding author: Hossam M Abdelnaby, M.D Zagig University Zagazig, Egypt.

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Sampling method:

All pregnant women meeting the inclusion criteria were enrolled into the study till the sample size is complete. Systematic sampling was used as the method of allocation using quasi-random allocation of patients. Patients counseling with Consent. The way in which to induce labor was clarified for each patient regarding advantages, disadvantages and duration and comparing this with other methods of induction of labor. Written consent was taken from patients that agreed to continue.

Sample size

180 pregnant women were offered participation in the study. The population of this study would be 180 pregnant women planned for elective induction of labor at term due to a medical problem or complete their date without spontaneous labor pain.

Women would be selected and Subjects included in this study would be divided in 2 groups:

**Group I:** Included 90 subjects will undergo induction of labor using A 18-French Foley single balloon catheter with inflation of balloon with 40 ml saline for fixation of catheter, balloons insertion for 12 hours (this group will be subdivided to 45 prim gravidae and 45 multiparous).

**Group II:** Included 90 subjects will undergo induction of labor using cook catheter double balloon device with inflation of balloon with 80 ml saline for fixation, balloons insertion for 12 hours (this group will be subdivided to 45primigravidae and 45 multiparous).

Study strategy

1. **History taking:** personal history, history of present pregnancy, previous pregnancies and past medical history were taken from all the patients.
2. An informed written consent was obtained from all patients participating in the study.
3. General examination was done to exclude medical illness.
4. Abdominal examination was done for previous abdominal scars, fetal size fetal lie, presentation and fetal viability.
5. Vaginal examination: for size of the pelvis and bishop score determination.
6. **Abdominal ultrasonography** for fetal presentation, amniotic fluid index and EFBW.
7. **Cardiotocography (CTG)** was done.

Women recruited to the study were randomized to one of the following cervical ripening catheters:

In group 1, a single-balloon catheter group: An 18-Fr Foley catheter was inserted above the internal cervical os and filled with 40 mL of normal saline. The catheter was strapped to the inner aspect of one leg after tension.

In group 2, a double-balloon catheter group: A double-balloon catheter (Cook® Cervical Ripening Balloon) was inserted according to the recommendations from the manufacturer (1100 West Morgan Street Spencer, IN47460, USA) EC and REP: Cook Ireland Ltd. National Technology Park Lemireck, Ireland. The catheter was taped to the inner thigh, without tension, for patient comfort, because the two balloons place pressure on the cervical os.

Patient preparation for catheter insertion:

1. The patient is placed in the lithotomy position.
2. A large vaginal speculum is inserted to gain cervical access.
3. The cervix is cleaned with an appropriate cleaning solution to prepare for device insertion.

**Insertion steps for Foley’s catheter:**

1. The catheter is introduced into the endocervix by direct visualization or blindly by locating the cervix with the examining fingers and guiding the catheter over the hand and fingers through the endocervix and into the potential space between the amniotic membrane and the lower uterine segment.
2. The balloon reservoir is inflated with 40 mL of normal saline.
3. The balloon is retracted so that it rests on the internal os.
4. Apply pressure by adding weights to the catheter end.
5. Constant pressure: attach 1 L of intravenous fluids to the catheter end and suspend it from the end of the bed.
6. Remove twelve hours later or at the time of spontaneous expulsion or rupture of membranes.

Insertion steps for Cook catheter:

1. The device is inserted into the cervix and advanced until both balloons have entered the cervical canal.
2. The uterine balloon is inflated with 40 mL of normal saline using a standard 20 mL syringe through the red Check-Flo valve marked "U".
3. Once the uterine balloon is inflated, the device is pulled back until the uterine balloon is against the internal cervical os.
4. The vaginal balloon is now visible outside the external cervical os. The vaginal balloon is inflated with 20 mL of normal saline using a standard 20 mL syringe through the green Check-Flo valve marked "V".
5. Once the balloons are situated on each side of the cervix and the device has been fixed in place, the speculum is removed.
6. More fluid is added to each balloon in turn, in 20 mL increments until each balloon contains 80 mL (maximum) of fluid.
7. If desired, the proximal end of the catheter may be taped to the patient’s thigh (Cookmedical.com, 2014).

The device is not left in place for longer than 12 hours. If spontaneous expulsion didn’t occur in this 12 hour period, it is removed.

The Cook catheter is removed by deflating both balloons through the corresponding valves marked "U" and "V" and removing vaginally. If the membranes rupture spontaneously before removal of the device, the balloons will be deflated and the device will be removed to facilitate active labor management. All participants rated their satisfaction with the whole induction process using VAS (0-10, 0 = no pain, 10 = worst possible pain). Where mild pain (VAS 1-3), moderate pain (VAS 4-6), severe pain (VAS 7-10). Insertion difficulty of the catheters is categorized into easy, moderate and difficult. Difficult insertion is defined by the presence of pain interfering with catheter insertion; need to use vulsellum and excessive manipulation with the catheter to achieve successful insertion. If none of the before mentioned insertion difficulty was present, insertion is categorized as easy. Finally, moderate difficulty lies in between. Non stress test was conducted after catheter insertion. Removal of the catheter was planned at approximately 12 hours after insertion if spontaneous expulsion had not occurred. Artificial rupture of the membranes and oxytocin infusion was commenced if labor did not begin spontaneously after removal or spontaneous expulsion of the catheter. Continuous electronic fetal monitoring was used throughout established labor. Labor progress abnormalities (Table 1) were diagnosed and managed according to the recommendations of the American College of Obstetricians and Gynecologists (ACOG 2009).

Dose of oxytocin: Oxytocin is diluted 5 units in 500 mL isotonic solution for an oxytocin concentration of 10 mU/mL. Start dose by 6 mU oxytocin, then infusion by rate of 4-8 mU/min. The FHR and uterine contractions is monitored closely. The incremental increase is reduced to 3 mU/min in presence of hyperstimulation and reduced to 1 mU/min with recurrent hyperstimulation (ACOG 2009). At the end after delivery all participants rated their satisfaction with the whole induction process using VAS (0-10, 0 = not satisfied, 10 = maximum satisfaction).

The following definitions were used in present study: Failed induction of labor was defined as failure to progress to the active phase 12 hours after water breakage combined with oxytocin. Analgesia was administered at maternal request according to the unit protocol. Management of labor was standardized regardless of the catheter type (Rouse 2000). Oligohydramnios is defined as AFI of 5 cm or less (Cunningham 2010). The primary outcomes were cervical ripening and change in Bishop Score. Secondary outcomes were insertion expulsion time, insertion amniotomy time, insertion delivery time and mode of delivery. In addition, the proportion of vaginal deliveries within 24 hours from catheter insertion with adverse events defined as the occurrence of one or more of the following were also examined: abnormal fetal presentation, cord prolapse, and bleeding related to catheter insertion that required removal of the catheter and Apgar score.

Results

The study included 180 pregnant women and they fulfilled the inclusion and exclusion criteria. One hundred sixty women continued till end of the study. Table 2 shows no statistically significant differences between the two groups regarding the maternal age gestational age and parity. Table 3 shows the pain encountered during the catheter insertion in both groups, where the mean pain perception during catheter insertion was 3.3 ± 2.3 to the Foley catheter group and 3.1 ± 2.47 to the Cook catheter group which was statistically non-significant. Most patients felt pain during insertion was nulliparous. In the Cook catheter group, there were significantly more spontaneous expulsions of the balloon compared with the Cook cervical ripening balloon group. Spontaneous expulsion of the catheter occurs more frequent in multiparous women. Table 4 Bishop Score after the balloon catheter expulsion or removal was significantly higher in the Cook cervical ripening balloon group, but only in the nulliparous group.

Table 5 Shows Time from balloon insertion to expulsion and from balloon insertion to delivery was significantly shorter in the Foley catheter group. Table 6 shows mode of delivery in both groups where the Caesarean section was 17.8% in Foley catheter group versus 20% for the Cook catheter group where 6 cases delivered by cesarean section in the Foley catheter group due to failure of progress versus 7 cases in the Cook catheter group. In the Foley catheter group 82.2% of them delivered vaginally and 17.8% delivered by cesarean section. 11.1% of cesarean section was due to non-reactive CTG and 6.6% were due to failure of progress. In cook catheter group 80% of them delivered vaginally and 18 % delivered by cesarean section. 11.1% of cesarean section was due to non-reactive CTG and 7% were due to failure of progress. Table 7 shows maternal complications in both groups, there was no single case with intrapartum fever. There were 4 cases of post-partum hemorrhage (PPH), 3 of them were atomic PPH, and only one case with traumatic PPH due to cervical tear in the Cook catheter group and in Foley catheter group there were 3 cases of post-partum hemorrhage all of them atomic post.

<table>
<thead>
<tr>
<th>Foley group N=90</th>
<th>Cook group N=90</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nulliparous (n=45)</td>
<td>Nulliparous (n=45)</td>
</tr>
<tr>
<td>No</td>
<td>5</td>
</tr>
<tr>
<td>Yes</td>
<td>40</td>
</tr>
</tbody>
</table>

Significant level = 0.05

Table 1: Spontaneous expulsion of the catheters in both groups.

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Range Mean ± SD</th>
<th>Mean ± SD</th>
<th>P - value</th>
<th>Type of test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nulliparous</td>
<td>45 (50%)</td>
<td>45 (50%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiparous</td>
<td>45 (50%)</td>
<td>45 (50%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gestational age (weeks &amp; days)</td>
<td>Range Mean ± SD</td>
<td>Mean ± SD</td>
<td>P - value</td>
<td>Type of test</td>
</tr>
<tr>
<td>Nulliparous</td>
<td>39wks +0d±1wks+ 5d</td>
<td>39wks +0d±1wks+ 5d</td>
<td>39wks +0d±1wks+ 5d</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Significant level = 0.05, GA: gestational age

**Table 2: Demographic characteristics of the study participants age, parity and GA.**

<table>
<thead>
<tr>
<th>Pain severity number (%)</th>
<th>Foley group (n=90)</th>
<th>Cook group (n=90)</th>
<th>P - value</th>
<th>Type of test</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Pain</td>
<td>6</td>
<td>13</td>
<td>0.056</td>
<td>Pearson ChiSquare test</td>
</tr>
<tr>
<td>Mild Pain</td>
<td>15</td>
<td>18</td>
<td>0.59</td>
<td>Pearson ChiSquare test</td>
</tr>
<tr>
<td>Moderate Pain</td>
<td>17</td>
<td>10</td>
<td>0.08</td>
<td>Pearson ChiSquare test</td>
</tr>
<tr>
<td>Severe Pain</td>
<td>7</td>
<td>4</td>
<td>0.32</td>
<td>Pearson ChiSquare test</td>
</tr>
</tbody>
</table>

**Table 3: Pain encountered during insertion of both balloon catheters: comparison of two groups.**

**Table 4: Bishop Score prior to balloon insertion and following expulsion.**

<table>
<thead>
<tr>
<th>Insertion to expulsion time (hours: minutes)</th>
<th>Range Mean ± SD Median</th>
<th>Foley group (n=90)</th>
<th>Cook group (n=90)</th>
<th>P - value</th>
<th>Type of test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insertion to amniotomy time (hours: minutes)</td>
<td>Range Mean ± SD Median</td>
<td>Foley group (n=90)</td>
<td>Cook group (n=90)</td>
<td>P - value</td>
<td>Type of test</td>
</tr>
<tr>
<td>Amount of oxytocin use post-expulsion (Unit/l)</td>
<td>Range Mean ± SD Median</td>
<td>Foley group (n=90)</td>
<td>Cook group (n=90)</td>
<td>P - value</td>
<td>Type of test</td>
</tr>
</tbody>
</table>

**Table 5: Outcome measures after insertion of catheter.**

**Table 6: Mode of Delivery.**

**Discussion**

The primary objective of our study was to compare the efficacy of a double-balloon catheter (Cervical ripening balloon Cook catheter) versus single-balloon catheter (Foley catheter) in pre-induction cervical ripening among women with an unfavorable cervix in order to facilitate the process of labor induction. Our study was a prospective randomized interventional one in which pregnant women (180 patients) who enrolled in the study were divided into two main groups; single and double balloon group. Each group included equal number of primigravids and multigravids. The study was performed at the emergency department of Obstetrics and Gynaecology, Zagazig University and El Galaa maternity hospitals. We designed the study as a prospective randomized one; we used systematic sampling as the method of allocation using quasi-random allocation of patients. As a result of that, there were no statistically significant differences between the two groups regarding the maternal age, gestational age, parity and duration from the last delivery, so both groups were statistically comparable. Perception of pain is one of the troublesome side effects of catheter(s) insertion. The mean pain perception during catheter insertion.
insertion was 3.3 ± 2.3 to the Foley catheter group and 3.1 ± 2.47 to the Cook catheter group as shown in Table 1. However, this difference was not statistically significant. This can be explained by the fact that both catheters were inserted using the same technique. Also, despite that both catheters use different volumes of fluid filling; the main source of discomfort is related to the speculum application prior to insertion of the catheters. Reinforcing this explanation is that only about 10% of cases still felt pain or discomfort after catheter insertion in both groups. In the study of Mei-Dan et al in 2012, the mean pain perception during catheter insertion was 3.3 ± 2.3 to the Foley catheter group and 3.4 ± 2.3 to the Cook catheter group which was statistically non-significant. In the Foley catheter group, there were significantly more spontaneous expulsions of the balloon compared to the Cook cervical ripening balloon group (91.1% versus 86.7%, respectively) as shown in Table 4 and this may be related to fact that the size of Foley catheter’s balloon is smaller than that of the Cook balloon. The Foley catheter balloon is filled with less fluid 40cc while each of two balloons of Cook Catheter (uterine and vaginal) is filled with 80 cc of fluid making it easier for the Foley catheter to be expelled from the cervix and then through the vagina. According to Salim and associates in 2011 although the results of their study showed that 54 (37.2%) and 70 (47.3%) women had spontaneous expulsion of the Foley and double balloon catheters respectively, this difference was insignificant (p=0.1). However, they used a Foley catheter filled with 60cc saline and this may explain their lack of difference in the expansion rate. Mechanical methods are among the oldest approaches used to promote cervical ripening. Advantages of these techniques compared to pharmacologic methods include their low cost compared to some drugs, low risk of tachysystole, few systemic side effects, and convenient storage requirements (no refrigeration or expiration, which are issues for some drugs) [2]. The proposed mechanical methods and their advantages are as follows: (1) Foley catheter: this method consists of a balloon which is inflated inside the cervix and lower uterine segment. In balloon consist of a direct stretching of the balloon on the cervix and lower uterine segment and secretion of prostaglandins by a separation and stripping of the membranes [5]. Compared with the Foley catheter, which has a single balloon and incurs a lower cost, a double balloon catheter has an additional mechanism of action on the unripe cervix that is achieved by the pressure being applied on both the external and internal cervical os. The advantage of the double-balloon catheter is that it is held in place and the dilator vector is applied by the two balloons inflated on both sides of the cervix, avoiding the need for traction [4]. An important finding in our study was the higher second Bishop score (after catheter removal or spontaneous expulsion) with the Cook cervical ripening balloon which was statistically significant in the nulliparous subgroup only (data not shown). However, this fact did not result in a shorter induction to delivery interval. A study held by Mei-Dan (2012), had results similar to this study where the median bishop in the nulliparous group after catheter removal was 6 and 7 for the Foley catheter group and the double balloon catheter groups, respectively. Atad et al. [4] reported that mean increase in Bishop Score after utilizing a Foley catheter was lower than that achieved by the double balloon catheter. In contrast to these studies Salim (2010) reported that the mean increase in Bishop Score after catheter removal was nearly similar between the two catheters, where it was 2.94 (±1.91) and 3.21 (±2.04) for the insertion expulsion time of the Foley catheter is probably the cause of the shorter induction to delivery interval despite the fact that the second Bishop score was lower in this group [6]. We are aware of an additional clinical trial, comparing induction of labor with the Foley catheter to the Cook cervical ripening balloon, published by Pennell (2009). Similar to our results, the authors found no difference in success rates and in cesarean delivery rates in both groups, although cesarean section rates in general were high (double balloon 43%, single balloon 36%), probably due to the exclusively nulliparous population Foley group and the double balloon catheter group, respectively. This can be explained by the of a Foley catheter filled with 60cc saline. The shorter in their study Pennell (2009). Regarding induction to delivery within 24 hours was longer in the double balloon group, in comparison with the Foley catheter group in our study (17:90 ± 2.80 versus 16:77 ± 3.30 hours). In Salim (2011) who found no significant difference between the two groups of their study regarding induction to delivery, but with 64.9% in the Foley catheter group and 64.3% in the double balloon group and this is not comparable to our result. Salim (2009) reported that women who had a spontaneous expulsion of the catheter regardless of the catheter type demonstrated a favorable outcome in terms of a shorter time from induction to delivery and a significantly lower proportion of operative deliveries [7]. The mean length of time from insertion until delivery was not significantly different between the two groups. In our study, we found that there was no statistically significant difference among all women of both groups regarding C.S with slight higher rate of C.S among COOK Double balloon catheter as shown in Table 7. It was 17.8% in Foley catheter group while it was 20% in COOK Double balloon catheter group II but this was statistically insignificant. This is comparable to Atad et al. [4] who demonstrated an overall C.S rate of 16%, while the overall C.S rate demonstrated by Atad (1996) was 22.9% in the double balloon arm, 30% in the PGE2 arm and 73.3% in the oxytocin arm of their study. Also Salim (2011) demonstrated an overall C.S rate of 17.6% in the double balloon group and 10.3% in the Foley catheter group of their study and this is comparable with our results. Also, Mei-Dani showed a C.S rate of 20% in the double balloon group and of 20.7% in the Foley catheter group and this is also comparable to our result. Regarding the C.S rate in primiparous women in our study, we found that it was slightly high in the double balloon COOK catheter compared to Foley’s catheter group and this is statistically insignificant. This result is comparable to Pennell (2009) who also found no significant difference between the three groups of their study with C.S rate of 43% in the double balloon arm, 36% in the single balloon. Also Salim (2011) found no significant difference regarding C.S rate in primiparous women with a rate of 25.6% in the double balloon group and of 15.6% in the Foley catheter group of their study [8]. In parous women in our study we found no statistically significant difference between both groups regarding C.S rate with high rate in group II. This is comparable with Salim (2011) who demonstrated a C.S rate of 8.6% in the double balloon group versus a rate of 4.4% in the Foley catheter group. In our study no significant difference in both groups regarding apgar score of babies, maternal complications and satisfaction, As there was no significant difference in both groups regarding mode of delivery, cause of caesarean section, Apgar score of babies, maternal complications and satisfaction, and due to the big price difference between them as Foley catheter costs 10 LE and the Cook catheter costs 420LE, It is wise to use the Foley catheter as a successful and more cost-effective method of pre-induction cervical ripening. Surprisingly, we did not find any differences in the women’s reported satisfaction rate between the two groups. We assumed that the vaginal balloon of the Cook catheter might cause significant discomfort; however, this was not apparent. Our study’s strength lies in its prospective randomized design along with the fact that the groups were relatively large and with very similar characteristics.

References:


