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Double Balloon Catheter versus Single Balloon Catheter for Induction of Labour

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Abstract

Background: Inducing labor is a procedure that is becoming an increasingly widespread practice in the field of obstetrics. Inducing labor can be accomplished through a variety of approaches and balloon catheters are a significant component of some of these approaches. It is not yet clear whether the double-balloon catheter that was built expressly for this purposes superior to the single-balloon device in terms of the efficacy, efficiency, safety, and satisfaction of the patient. Finding even minute distinctions between these two machines could be helpful for guiding clinical practices, further exploring their mechanisms, and for promoting a better understanding of the most effective strategies for labor induction.

Aim: to compare the efficacy, safety, and complications of double versus single balloon usage in the induction of labor.

Patients and methods: A randomized prospective comparative study was established at the Basra Hospital for Women and Children from early January to the end of September on 102 pregnant women who attended the delivery room which randomly and anonymously categorized into two groups (51) participants for each one; group (A) was included the participant who has received a single-balloon catheter for labor induction, and group (B) was included those who received double-balloon catheter. The two groups were compared by several comparative parameters and matched for age and parity. We measured the method of delivery (vaginal, assisted, cesarean section), bishop score increment, bleeding at the time of induction, time to labor, need for oxytocin augmentation, maternal adverse events (postpartum hemorrhage, Uterine hyper stimulation), and neonatal adverse events (low Apgar score). This study was based on a well-designed and data was analysed using a statistical package of social sciences 26.

Results: This study included 102 pregnant women divided into two groups. It was recorded that most of the women in groups (A) and (B) were delivered vaginally (78.4%, and 70.6%)

respectively. Most of the studied groups had no history of postpartum haemorrhage and to less extent mild to moderate PPH. Despite that, there was no significant association between the maternal outcomes distribution and the use of a single balloon or double catheters. Regarding neonatal outcomes; both groups had mostly APGAR scores of (7-10), and to slightly differs score (4-6), in addition, most of them were discharged home and small rates of death were recorded which was statistically significant for neonatal fate and non-significant for APGAR score.

Conclusion: The efficacy of both double balloons and single balloons was comparable regarding the time of the delivery and the risk of the caesarean section. Maternal side effects- although it was not significant- they more frequently occur with double rather than a single balloon. Furthermore, neonatal outcomes were more favorable with the single balloon method.

Keywords: single balloon catheter, double balloon catheter, maternal outcomes, neonatal outcomes.

Introduction

The technique of intentionally activating the uterus to initiate labor is known as induction of labor [1]. The medical need for induction of labor originates from situations when it is assumed that the pregnancy's outcomes will be better if it is intentionally interrupted rather than allowed to run its course [2]. The use of labor induction to reduce the period of delivery has increased steadily during the last several decades; developed diagnostic techniques and a better knowledge of maternal and fetal medical issues have resulted in this. In developed countries, the percentage of children born at term after induction of labor might be as high as one in every four births [3]. According to the WHO International Survey on Maternal and Perinatal Wellbeing, 9.6% of deliveries underwent labor induction, with373 health care institutions in24 countries and over 300 000 deliveries. In general, institutions in African countries had lower percentages of induction of labor than those in Asian and Latin American regions [4]. According to current data, induction rates range from 35.5 % in Sri Lanka to 24.5 % in USA and6.8 to 33 % in European countries [5].

The balloons catheter, which includes both double-and single-balloon catheters, seems to be a commonly accepted mechanical approach for induction and is approved by the WHO [1]. By physically and mechanically stretching the cervix, the insertion of a cervical balloon catheter (like a Foley catheter) is hypothesized to trigger cervical ripening, which in turn triggers the secretion of endogenous PGs [6]. Barnes reported the first form of the Foley (single- balloon) catheter in 1863 [7]. The double balloon catheter was initially proposed by Atad et al. in 1991 [8]. The "Atad Ripener Device," an 18 French natural latex, a 3-lumen catheter with double balloons, each with a capacity of 80 ml, spaced 2 cm apart at the distal end, was authorized by the US Food and Drug Administration (FDA) in 2005 [9]. The double balloon is regarded to be superior to a Foley catheter since the forces that generate dilation come from both sides of the cervical of, as opposed to the internal of, where the Foley catheter alone produces force, especially when under traction [10]. Furthermore, the Foley catheter currently lacks permission for pre- induction cervical ripening [11]. The double balloon catheters have low volume (30 ml) and large- volume (60 ml, 80 ml) types, the use of high-volume catheters usually increased the likely hood of achieving a favorable cervix [12].

The use of mechanical methods for induction is generally associated with a potential risk of infection, but there is little data to either confirm or deny this assertion. Interestingly, in the Prostaglandin or Balloon Catheter for Induction of Labor (PROBAAT) study, the risk

of intra partum infection was recorded in a higher rate in the prostaglandin group in comparison to the catheter group [13]. Most of the available data are on mechanical procedures used on women with intact membranes. More recently, a retrospective cohort research found that the use of intra cervical balloons in women with pre-labour rupture of membranes did not increase the incidence of chorioamnionitis [14]

The efficacy and the safety profile of the chosen inductive procedure is a crucial aspects of the delivery process. Foley catheters and prostaglandin E2 vaginal inserts (10 mg slow release) were evaluated side-by-side in the PROBAAT-P experiment. Safety and efficacy were similarly high in both groups. Data synthesis showed that hyper stimulation was lower in groups where Foley catheters were used, although cesarean section rates were similar between groups. There was no statistically significant difference in the number of admissions to the newborn intensive care unit or the pH of the umbilical cord between the two groups [15]. While the PROBAAT-II trial showed no statically significant difference between the studied groups [16]. In the present cohort study, we evaluated the differences between single and double balloon dilatation in concern of the efficacy of cervical ripening and maternal and fetal outcomes.

Patients and methods:

A randomized prospective comparative study was established at the Basra Hospital for Women and Children, Basra governorate, to assess the difference and advantages of a double-balloon catheter compared to the single balloon catheter in labor induction. The study was under taken from early January to the end of September on 102 pregnant women who attended the delivery room which randomly and anonymously categorized into two groups (51) participants for each one; group (A) was included the participant who has received a single-balloon catheter for labor induction, and group (B) was included those who received double-balloon catheter. The two groups were compared by several comparative parameters and matched for age and parity.

Outcomes measurement:

Primary outcome was the method of delivery (vaginal, assisted, cesarean section). The secondary outcome was Bishop score increment, bleeding at the time of induction, time to labor, need oxytocin augmentation, maternal adverse events (postpartum hemorrhage, Uterine hyperstimulation), and neonatal adverse events (low Apgar score)

Data collection:

This study is based on a well-designed questionnaire composed of three parts; part I, socio- demographic features; information about the age, and BMI, part II, obstetrical parameters; information about the obstetrical history and risk factors, and part III, maternal and perinatal complications. After the data was collected, it was categorized, sorted, and analyzed.

Statistical analysis:

This study's statistical evaluation was conducted with the aid of Statistical Package for the Social Sciences software version 26 (SPSS Inc.). The Chi-square test and Fisher's test were used to determine if two groups were statistically different on categorical variables given as numbers and percentages (X2). The continuous variables were presented as means ±SD and the differences between the groups were evaluated using an independent t-test and Mann Whitney test. P-values less than 0.05 were considered statistically significant. This was based on a 95% confidence interval.

Results:

This study included 102 pregnant women divided into two groups, the first group comprises 51 women who received single balloon catheters while the second group comprises 51 women who received double balloon catheters. In the first group, the mean age is

26.75±6.082 year. Most women were between the ages of 20-30 years (56.9%) followed by those whom aged >30 years (29.4%) and lastly those < 20 years (13.7%). In the second group, the mean age is 25.33±6.383. Most women were between the ages of 20-30 years (64.7%) while both age groups of less than 20 years and more than 30 years have the same percentage of 17.6%. Most of the enrolled women in the first group are multiparous (68.6%) followed by nulliparous women (27.5%) and lastly grand multiparous women (3.9%). In the second group, most women were multiparous (64.7%) followed by nulliparous women (33.3%) and lastly by grand multiparous women (2.0%). Both groups have the same history of previous surgery (Cesarean section) with 2 females in each group (3.9%) have a history of previous surgery, while 49 women in each group (96.1%) didn't have a history of previous surgery. Regarding indications of induction of labour, in the first groups, most common indication was postdate pregnancy (45.1%) followed by oligohydramnios (19.6%), preeclampsia(11.8%), intrauterine death (5.9%), hypertension (3.9%), congenital anomaly (3.9%), no fetal movement (3.9%) and lastly diabetes mellitus (2%) and IUGR (2%). While in the second group, the most common indication was postdate pregnancy (37.3%), followed by intra uterine death (15.7%), preeclampsia (13.7%), oligohydramnios (13.6%), diabetes mellitus (9.8%), congenital anomaly (5.9%) and lastly by hypertension (2%), IUGR (2%), and no fetal movement (2%). However, there was no significant association between Demographical and clinical parameter distribution among the studied groups, Table .1.

In this study, the mean fetal age of the pregnant women in the first group was 39.49±2.88, while it was 37.96±4.22 in the second group, additionally, there was significant association between fetal age and the type of catheter used (p=0.035). Regarding Bishop score, in the first group, most women had bishop score of two (54.9%), followed by score of three (39.2%), and lastly a score of one (5.9%). While in the second group, most women had a bishop score two (51.6%) followed by a score of one (23.5%), three (21.6%) and zero (3.9%). Moreover, this was significantly associated with catheter type used in the study group. (p=0.011).

In terms of fluid volume used in catheter, in the first group, the volume used was 80 ml in the catheter for all participant women (100%) , while in the second group, itwas50-60 ml to most of participant women(47.1%), followed by 30-40 ml (21.6%), 30-50 ml (15.7%), 40-60 ml (5.9%), 40-50 ml(5.9%), and lastly 50-50 ml (3.9%).

Most women in the first group had no bleeding during induction of labor (92.2%), the remaining had mild bleeding (7.8%), and none of the participant women had severe bleeding (00.0%). In the second group, most of the women had no bleeding at induction (82.4%), followed by mild bleeding (15.7%), and lastly severe bleeding (2%).however, there was no significant association between bleeding at induction and type of catheter used in the study group (p=0.234). Moreover, the mean of the time between induction and falling in the first group was 5.26±2.15 and 5.90±2.51 in the second group. Furthermore, the mean of the time between falling and labor in the first group was 4.55+1.33 in the first group and 4.52+1.82 in the second group.

In terms of complications during induction, in the first group, the most complication was failure to progress (17.7%), followed by antepartum hemorrhage (2%), fit (2%), and fetal distress (2%). In the second group, the most common complication was failure to progress (21.6%), followed by abruption (3.9%), fit (2%), and fetal distress (2%). Regarding need for oxytocin augmentation, in the first group, most of the women didn't need the augmentation (37.3%), followed by need of 2 units of oxytocin (21.6%), 4 units(19.6%), 6 units (19.6%), and lastly 8 units (2%). While in the second group, most women needed 4 units of oxytocin (27.5%), followed by 2 units (25.5%), no need (23.5%), 6 units (21.6%), and 3 units (2%).

However, there was no significant association between time between induction and falling, complications during induction, Need oxytocin for augmentation and the type of catheter used in the study group, Table .2.

In terms of mode of delivery, in the first group, most of women delivered by vaginal delivery (78.4%) and the remaining by caesarean section (21.6). Also in the second group, the majority of women delivered by vaginal delivery (70.6%), and the remaining by caesarean section (29.4%). In terms of presence of postpartum haemorrhage, the majority of the first group women didn't have PPH (88.2%), followed by mild PPH (7.8%), moderate (2%), and severe(2%).While in the second group, majority had no PPH (86.3%), followed by severe PPH (7.8%), and mild (5.9%). Despite that, there was no significant association between the maternal outcomes distribution and the use of single balloon or double catheter, Table.3.

In studying the Apgar score in this study, most of the neonates from the women of first group had APGAR score of 7-10 (88.2%), and a score of 4-6 in (7.8%). In the second group, most of their neonates had APGAR score of 7-10 (66.7%), and a score of 4-6 in (15.7%), there was significant association between APGAR score and the use of single or double balloon catheter (p=0.026). Regarding neonatal outcome, majority of neonates from the women in first group discharged home (78.4%), some were admitted to neonatal care unit (17.6%), and death in (3.9%). In the second group, nearly half of the neonates discharged home (54.9%), followed by admission to neonatal care unit (27.5%), and lastly death in (17.6%). Moreover, there was significant association between neonatal outcomes distribution among the studied groups (p=0.022), Table.4.

Discussion

Efficiency is best measured by the length of the intervals, although neither measure reaches significance in the present study, it revealed that the time from insertion to falling is longer in the double-balloon catheter group whereas the time from falling to labor is comparable. While Pennell, et al. in their randomized controlled trial in Australia on 330 women who are nulliparous and have unfavorable cervixes discovered that the length of labor did not significantly differ between the two groups [17]. Ahmed, et al. in their study on 78 postdate primigravid women reported that women treated with a single-balloon catheter had a shorter insertion to amniotomy time than women handled with a double-balloon catheter [10,18]. Furthermore, Delaney S showed that the 30 ml of Foley single balloon catheter is superior to the COOK double balloon induced labor [19]. Most studies to date have revealed that single and double balloon catheters are equally effective, safe, and patient-satisfying, although the single-balloon approach is thought to be more economical and is easier for patients to accept [7,20].

Delivery methods, which are of particular clinical importance, provide a thorough evaluation of the efficiency and safety of labor induction protocols and can take economic data in to account. According to our study, there is no significant proof that one mechanical device (neither single nor double balloon) is more efficacious than another in avoidance of caesarian section; this is in agreement with Liu et al., in their meta-analysis regarding double- versus single- balloon catheters for labor induction and cervical ripening, they found that there was no significant difference in the risk of the caesarian section between the two methods [7].

In the present study, 37 % of women in single balloon method required oxytocin for augmentation in comparison to 23% for the double balloon. Lauren and his colleague in their retrospective study on 1133 women who underwent balloon dilatation found that multiparous women who received balloon dilatation alone seemed to have lower rates of vaginal deliveries within 24 hours [21].

Table.1. Demographical and clinical parameter distribution among the studied groups.

Variables		Single Balloon Catheter (No.51)	Double Balloon Catheter (No.51)	P value
Age(years)	Mean ±SD	26.75±6.082	25.33±6.383	0.256‡
	Range	22	27	
	Maximum –Minimum	17-39	15-42	
	<20years	7 (13.7%)	9 (17.6%)	
	20-30years	29 (56.9%)	33 (64.7%)	
	>30	15 (29.4%)	9 (17.6%)	
Parity	Nulliparous	14 (27.5%)	17 (33.3%)	0.869‡
	Multiparous	35 (68.6%)	33 (64.7%)	
	Grand multiparous	2 (3.9%)	1 (2.0%)	
History of previous surgery	Cesarean section	2 (3.9%)	2 (3.9%)	0.99 ⁑
	No history	49 (96.1%)	49 (96.1%)	
Indication of induction of labor	Congenital anomaly	2 (3.9%)	3 (5.9%)	0.816 ⁑
	Decreased fetal movement	4 (8.0%)	0 (0.0%)	
	Diabetes mellitus	1 (2.0%)	5 (9.8%)	
	Hypertension	2 (3.9%)	1 (2.0%)	
	Intrauterine death	3 (5.9%)	8 (15.7%)	
	Intrauterine growth restriction	1 (2.0%)	1 (2.0%)	
	Oligohydramnios	10 (19.6%)	7 (13.6%)	
	No fetal movement	2 (3.9%)	1 (2.0%)	
	Post date pregnancy	23 (45.1%)	19 (37.3%)	
	Preeclampsia	6 (11.8%)	7 (13.7%)	

†Mann Whitney U test ‡X^2 test. ⁑ Fischer Exact test

Table.2. Obstetrical data distribution among the studied groups.

Variables		Single Balloon Catheter	Double Balloon Catheter	P value
Fetal age (weeks)	Mean ±SD	39.49±2.88	37.96±4.22	0.035†*
	Range	13	16	
	Maximum –Minimum	29-42	26-42	
Bishop score	Zero	0)0.0%(	2)3.9%(	0.011‡*
	One	3)5.9%(	12)23.5%(	
	Two	28)54.9%(	26)51.0%(	
	Three	20)39.2%(	11)21.6%(	
Fluid volume used in catheter	80	51 (100.0%)	0 (0.0%)	--------
	30-40	--------	11 (21.6%)	
	30-50	--------	8 (15.7%)	
	40-50	--------	3 (5.9%)	
	40-60	--------	3 (5.9%)	
	50-50	--------	2 (3.9%)	
	50-60	--------	24 (47.1%)	
Bleeding at induction	No bleeding	47 (92.2%)	42 (82.4%)	0.234 ⁜
	Mild	4 (7.8%)	8 (15.7%)	
	Severe	0 (0.0%)	1 (2.0%)	
Time between induction and falling (mean*SD)		5.26±2.15	5.90±2.51	0.175†
Time between falling and labor (mean*SD)		4.55+1.33	4.52+1.82	0.92†
Complication after induction	Abruption	0 (0.0%)	2 (3.9%)	0.673 ⁜
	Antepartum hemorrhage	1 (2.0%)	0 (0.0%)	
	Failure to progress	8 (15.7%)	11 (21.6%)	
	Fetal distress	1 (2.0%)	1 (2.0%)	
	Fit	1 (2.0%)	1 (2.0%)	
Need oxytocin for augmentation	No need	19 (37.3%)	12 (23.5%)	0.485‡
	2 units	11 (21.6%)	13 (25.5%)	
	3 units	0 (0.0%)	1 (2.0%)	
	4 units	10 (19.6%)	14 (27.5%)	
	6 units	10 (19.6%)	11 (21.6%)	
	8 units	1 (2.0%)	0 (0.0%)	

†Mann Whitney U test ‡X^2test.*Significant at P value <0.05; ⁜ Fischer Exact test

Table.3. Maternal outcomes distribution among the studied groups.

Variables		Single Balloon Catheter	Double Balloon Catheter	P value
Mode of delivery	Normal vaginal Delivery	40 (78.4%)	36 (70.6%)	0.363‡
	Cesarean section	11 (21.6%)	15 (29.4%)	
Post-partum hemorrhage	No	45 (88.2%)	44 (86.3%)	0.434 ⁑
	Mild	4 (7.8%)	3 (5.9%)	
	Moderate	1 (2.0%)	0 (0.0%)	
	Severe	1 (2.0%)	4 (7.8%)	

‡X^2test ⁑ Fischer Exact test

Table. 4. Neonatal outcomes distribution among the studied groups.

Variables		Single Balloon Catheter	Double Balloon Catheter	P value
APGAR score	4-6	4 (7.8%)	8 (15.7%)	0.026‡*
	7-10	45 (88.2%)	34 (66.7%)	
Neonatal outcomes	Discharged home	40 (78.4%)	28 (54.9%)	0.022‡*
	Neonatal intensive care unit	9 (17.6%)	14 (27.5%)	
	Died	2 (3.9%)	9 (17.6%)	

‡X^2test.

*Significant at P value <0.05

In this study, 18 % of women with double balloon had vaginal bleeding with induction in comparison to 8% with a single balloon. This in agreement with the finding of Maslovitz et al., and Jagielska et al., who found that a single balloon was associated with a low risk of vaginal bleeding at induction,1.8%,and1.9% respectively [22,23].

Adverse outcomes in both the mother and the newborn are quite concerning. In the present study, no statistically significant differences in the adverse effects that were found. Placental abruption, failure to progress, and post-partum hemorrhage were among the effects that the double cervical balloon group experienced more frequently than the single cervical balloon group. Similar to our findings, in terms of postpartum hemorrhage and placental abruption, Salim et al., concluded that there was no statistically significant difference between the single and double balloon groups [11]. Furthermore, there was no recognizable difference between the two types of induced labor in terms of the severity of postpartum hemorrhage, according to Pennell et al.,[17].

Neonatal health is of special concern regarding choosing methods of cervical ripening, in our study, a better APGAR score (7-10) was significantly associated with a single balloon than a double-balloon (P= 0.026). Furthermore, the number of deaths and new natal care unit admission were significantly associated with the double balloon group (P= 0.022). Pennell et al., 2009, in their study on 330 nulliparous women with unfavorable cervices treated with single and double balloons found that acidosis in the fetal blood

sample was significantly associated with the double balloon than single balloon indicating a worse prognosis with a double-balloon [17]. On the other hand, Xing et al., found that there was no significant difference in the neonatal outcomes between the two groups including neonatal care unit admission and APGAR score value [24].

In conclusion, the efficacy of both double balloon and single balloon were comparable regarding the time of the delivery and the risk of caesarian section. Maternal side effects- although it was not significant- they more frequently occur with double rather than single balloon. Furthermore, neonatal outcomes were more favorable with the single balloon method.

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