Austin Journal of Obstetrics and Gynecology

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Austin Publishing Group

Research Article

Comparison between Foley Catheter plus Oxytocin and Oxytocin Only For Induction of Labour after Membrane Rupture

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Received: November 09, 2022; **Accepted:** December 16, 2022**; Published:** December 22, 2022

Case report

Premature Rupture of Membranes (PROM) at term is defined as rupture of membrane at least 1 hour before the onset of uterine contractions at a gestational age of 37 weeks or more, it complicates 8% of all pregnancies [1]. It is associated with a risk of chorioamnionitis, which increases with duration of PROM, latency beyond 24 hours increases the incidence of chorioamnionitis and neonatal sepsis [2,3]. Spontaneous labour occurs in 60%–67% of these patients within 24 hours [2,4]. If no labour occurs, labour induction must be the best management for women with PROM at term. Labour induction is usually performed when the risks of continuing a pregnancy are more than the benefits of delivery as in PROM. Cervical ripening is an important factor for a successful induction. Unripe cervix with a lower Bishop score is associated with an increased risk of induction failure, while a favorable cervix significantly predicts a timely delivery [5]. Different methods are used for labour induction but none of the available methods of induction of labour is free of associated medical risks; therefore, labour should only be induced when there is a risk of the continuation of pregnancy. The agents used for induction should simulate spontaneous labour without causing excessive uterine activity. The most common methods of labour induction involve Pharmacological methods which include many agents, such as Prostaglandins (PGs (E2 orE1), progesterone receptor antagonists (mifepristone), oxytocin, and Nitric Oxide (NO) donors, but the most commonly used are PG and oxytocin) [6], and mechanical methods as Intracervical Foley catheter which is the most common mechanical method that was first described by Embrey and Mollison in 1967, where a Foley is inserted into the cervical canal and inflated just past the internal os with mild traction outward dilating the cervix directly, as well as indirectly stimulating (PGs) and oxytocin secretion [7-11]. The American College of Obstetricians and Gynecologists (2009) recommended using oxytocin for induction of labour in case of PROM at term, even if the cervix is unfavorable [12]. Several studies have evaluated the combination of oxytocin and mechanical devices, as oxytocin alone has not been shown to affect the risk of chorioamnionitis [13-15]. Induction of labour by mechanical device is accepted in cases with intact membrane, although mechanical treatment does not show any advantage over vaginal PGs regarding rates of chorioamnionitis, endometritis and neonatal infection [16]. In PROM, a concern with mechanical cervical ripening is increased risk of intraamniotic infection and other infection morbidity, which is not increased when membranes are intact [13]. Although the Foley catheter has been established as safe and effective in women with intact membranes, its efficacy has not been established in women with PROM. Chorioamnionitis was defined as temperature 38°C or greater with at least two of the following: uterine tenderness, maternal tachycardia, fetal tachycardia, foul odor of the amniotic fluid, or maternal leukocytosis (greater than 15,000 cells/mL3) [17].

The objective of this study was to assess the efficacy of Foley catheter plus oxytocin in cervical ripening in decreasing the interval to delivery and associated complications compared with oxytocin alone in women with PROM.

Material and Methods

This randomized clinical study was conducted in the Department of Obstetrics and Gynaecology in El Shat by maternity University Hospital, Alexandria, Egypt during the period from March2020 to December 2020 on 208 patients admitted to the hospital with full term PROM.

Inclusion Criteria

were Patients ages between 20-40 yrs, any parity, a live single fetus in cephalic presentation, at term (≥37 weeks of gestation; gestational age estimated by LMP or first trimester ultrasonog-

Citation: Elbaz ZM. Comparison between Foley Catheter plus Oxytocin and Oxytocin Only For Induction of Labour after Membrane Rupture. Austin J Obstet Gynecol. 2022; 9(3): 1209.

raphy), show PROM without spontaneous labour pain within 12–24 hours of PROM and unfavourable cervix(Bishop score ≤4.

Exclusion Criteria

Women were excluded from the study if there is suspected chorioamnionitis, Contraindication for vaginal delivery (antepartum haemorrhage, contracted pelvis, Uterine scarring or previous cesarean delivery, ect), patients have immunodeficiency syndrome, or meconium stained amniotic fluid at time of admission, or true labour pain, while fetal exclusion criteria were multiple pregnancy, sever fetal congenital anomalies, intrauterine growth restriction,and fetal distress.

Two hundred and eight patients were enrolled in the study, they were randomly divided into two groups: (Group I) included 120 women induced labour with transcervical Folly catheter plus oxytocin and (Group II) included 88 women induced labour with oxytocin alone. The study was completely explained to all women; and they invited to participate in the study and after acceptance to participate, written informed consent was obtained from them. On admission of all included patients who complained from spontaneous rupture membrane, at least one hour before starting induction, at first they underwent confirming the diagnosis. A gynecological examination was performed, where spontaneous rupture of membranes was defined as a clinical history with the presence of at least two of the following four criteria: pooling, ferning, Nitrazine, or oligohydramnios. In the absence of a clinical history, ultrasonographically diagnosed oligohydramnios and pooling were necessary for the diagnosis of rupture of membranes. Oligohydramnios was defined as a maximum vertical pocket less than 2 cm or amniotic fluid index less than 5 cm. Then the fetal condition was assessed by fetal cardiotocography. A course of prophylactic antibiotics—amoxicillin, or clindamycin in case of penicillin allergy—is begun on recruitment and extends to the delivery to prevent chorioamnionitis.

All women in both groups received an intravenous oxytocin infusion, which was started in the form of infusion drip (2.5 or 5 IU in 500 mL of Ringer's lactate solution, and it was titrated according to frequency and intensity of uterine contractions). For women only in group I a 16-French latex Foley catheter with a 30-50cc balloon was introduced past the internal cervical os into the lower uterine segment using a sterile speculum and ring forceps and sterile vaginal examination. The balloon was filled with saline or water solution, (30-50) as tolerated by the patient, then pulled back until taut, and the Foley was taped to the inside of the maternal thigh under tension. If the initial attempt at Foley placement was failed or rupture, another attempt to reintroduce the catheter within 1 hour of the first attempt. If the second attempt remained unsuccessful, oxytocin infusion was continued, which is administered according to contractions. FHR, with monitors temperature, blood pressure and pain. Catheter checks were performed hourly by traction. If the Foley had not been expelled within 12 hours, it was deflated and removed. Clinical management was the same for both groups, Cesarean delivery was performed for maternal or fetal indications.

Outcomes data were recorded. The primary outcome was the interval from induction to delivery. The start of the induction was either the time the Foley catheter was inserted or the time the oxytocin was started, whichever occurred first. Secondary outcomes included abnormal uterine action like uterine hypertonus and uterine hyperstimulation, rate of delivery within the first 24 hours; rate of spontaneous vaginal delivery; rate of cesarean section and indications; rate of postpartum haemorrhage, a non reassuring fetal heart rate pattern, and Apgar score. Maternal and neonatal infectious evaluation and diagnosis of sepsis, neonatal intensive care unit admission.

Results

Two hundred and eight (208) pregnant women, ≥37 weeks, single cephalic complained of PROM without labour pain were included in the study, they were randomly divided into two groups, Group I 120 women induced with Foley catheter and concurrent Oxytocin and Group II, 88women induced with Oxytocin only. According to table1maternal baseline characteristics were similar between the two groups as regard age, parity, gestational age.

As shown in table 2 the overall rate of vaginal delivery within 24 hours of Group I was 60% compared with 59% in Group II, while rate of Cesarean delivery was 40% in group I versus 41% in group II; so there were no significant difference between both groups as regard numbers of vaginal and cesarean section delivery. The overall indications of CS were not different in both groups. As regard time from the start of induction to delivery (mean ± SD) in women in group I was 15.2 ± 4.2 hours while that of women in group II was 15.8 ± 5.3 hours with no significant difference.

From table 3there was no significant differences between both groups in secondary outcome where the results were similar in two groups as regard incidence of abnormal uterine action, Postpartum Hge, neonatal infection and NICU admission. Even chorioamniitis was similar in both groups.

Table 1: Baseline Characteristics.

Parameters	Group I (n=120) Foley+Oxytocin	Group II (n=88) Oxytocin only	P value
AGE (Yrs) (mean ±SD)	25.5±26	25.9±43	>0.05
Gravidity Primigravida Multigravida	 60.7% 39.3%	 64.2% 35.8%	 >0.05 >0.05
Gestational age(wks)	38.81±.81	38.87±1.21	

Table 2: Delivery mode & 1ry outcome.

Mode of delivery	Group I (n=120) Foley+Oxytocin	Group II (n=88) Oxytocin only	P value
Vaginal delivery	72 (60%)	52 (59%)	0.51
Delivery within 12hrs	27 (37%)	16 (31%)	0.006
Delivery within 24hrs	45 (63%)	36 (69%)	0.003
-Failure of progress	30 (62.5%)	21 (58.4%)	0.74
-Fetal distress	14 (29.2%)	12 (33.3%)	0.99
-Maternal causes	4 (8.3%)	3 (8.3)	0.60
Time from start till delivery(hrs)	15.2±4.2	15.8±5.3	0.63

Table 3: 2ry outcomes.

Parameter	Group I N=120	Group II N=88	P value
Abnormal uterine action	13 (11%)	8 (9%)	0.553
Postpartum Hge	14 (12%)	13 (15%)	0,597
Suspected chorioamniitis	7 (6)%	3 (3.5%)	0.602
Apgar score at 1 min Apgar score at 5 min	6.82±0.47 8.70±0.66	6.86±0.12 8.81±0.30	>0.05 >0.05
NICU admission	11.3%	11.6%	>0.05
Neonatal infection	2(2%)	2 (2%)	

Discussion

Labour induction in the presence of an unfavorable cervix is associated with an increased likelihood of prolonged labour and increased incidence of cesarean section especially if associated with PROM. So, the use of cervical ripening agents prior to conventional methods of induction is an important practice. Ideal characteristics of ripening agents include efficacy in decreasing time to delivery, a positive safety profile, and efficacy in increasing the likelihood of vaginal delivery. Different methods for labour induction are used. So the objective is to shorten the time interval between the beginning of ripening and delivery, which could decrease the risk of chorioamnionitis and therefore of maternal or fetal infection.

In this study there was no difference between both groups baseline characteristics and in primary outcome where there was no difference in interval from start of induction to delivery. Also there were no differences in 2ry outcomes between both groups. A recent trial by Amorosa et al comparing Foley plus oxytocin and oxytocin only in the setting of PROM in nulliparous women also found a non significant difference in time to delivery without any statistically significant difference in chorioamnionitis [13]. Connolly et al found that the Foley Balloon Induction of Labor Trial in Nulliparas, indications for cesarean delivery did not differ by induction method [18]. Also in this trial found a reduction in time to delivery for nulliparous women who received simultaneous oxytocin with Foley catheter for induction compared with Foley alone.

A study by Cabrera et al comparing a Foley catheter (with or without oxytocin) with oxytocin alone showed no difference in infection morbidity between groups [19].

A study by Mackeen et al found that no greater reduction in the time interval from induction to delivery in the groups treated with oxytocin and Foley catheters and groups treated with oxytocin alone while the foley plus oxytocin groups suffered higher rates of chorioamnionitis than groups treated with oxytocin alone [20].

Randomized trial by Pettker et al, the addition of oxytocin to FC did not shorten the time to delivery and had no effect on the vaginal delivery rate [21]. The trial by Corina et al found that Labor induction with Foley catheter and concurrent oxytocin shortens the time to delivery and increases the rate of delivery within 24 hours compared with cervical ripening with a Foley catheter followed by oxytocin [22].

Prager et al compared the safety and efficacy of induction of labor using vaginal dinoprostone, vaginal misoprostol, or transcervical catheter and concluded that labor induction with a transcervical catheter is safe and effective and can be recommended as a first-choice method [23].

Conclusion

In the present study the addition of Foley catheter to Oxytocin didn't add any difference on 1ry outcomes or secondary outcomes where did not significantly shorten the interval to delivery and did not affect secondary outcomes as compared with oxytocin infusion alone for labor induction in women with PROM, which may be due to method of insertion, length of time with the Foley in place, size of the balloon or use of prophylactic antibiotics. So much larger study would be required to adequately assess these findings.

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