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Mechanical cervical ripening for prolonged pregnancies with a previous cesarean section: Double-balloon catheter vs Foley catheter

Abstract

Introduction: Mechanical cervical ripening methods are considered safer than prostaglandins. Many centers choose this method for pre-induction in pregnant patients with a previous cesarean section. Our objective was to compare efficacy and safety of two different mechanical ripening methods in prolonged pregnancies with a Bishop score ≤ 6 and a previous cesarean section.

Methods: Non-randomized study during 6 years in which patients were divided in two cohorts: a first period of time (from November 2014 to November 2018) in which Foley catheter was used and a second period of time (from November 2018 to November 2020) in which double-balloon catheter (Cook® balloon) was the method employed. The same protocol was followed in both groups. Efficacy was defined by the achievement of active labor. Ripening success (changes in Bishop score and achievement of active labor), vaginal delivery rate and maternal and neonatal safety were recorded.

Results: The double-balloon was placed in 43 patients and the Foley catheter was inserted in 129 patients. Cook catheter showed better Bishop score difference than Foley but with no statistically significance (3.09 vs 2.76, p=0.271). Active labor was achieved similarly in both groups (81.4% double-balloon vs 78.2% Foley catheter, p=0.726). Although there was a higher vaginal delivery rate in the double-balloon group (62.8%) compared with the Foley group (49.6%), the difference was not statistically significant (p=0.065). Time from catheter insertion to delivery was significantly shorter in the Foley group compared with Cook group (1704 vs 1903 minutes, p<0.05). Newborn weight, umbilical-cord pH, Apgar index and maternal complications were similar in both groups.

Conclusion: Mechanical cervical ripening is a safe and effective method in pregnancies with a previous cesarean section. Double-balloon ripening associated higher vaginal delivery rate compared to Foley catheter, but without statistically significant differences.

Keywords: cervical ripening, previous cesarean section, Cook cervical ripening balloon, double-balloon catheter, Foley catheter

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Introduction

The cesarean section rate has increased in the last decades, with an average rising from 20% in 2000 to 28% in 2015 in the developed countries.[1,2] Thus, the incidence of pregnant women with a prior cesarean section has also increased. Labor induction, which is a common procedure,[3] has become an important clinical situation in these patients, given that their associated risk of uterine rupture is higher compared to pregnant women without a uterine scar (21-39/10000 vs 0,38-1,3/10000).[4,5] In general, a Bishop score below 6 is considered unfavorable and cervical ripening should be considered prior to the initiation of intravenous oxytocin.[6] When choosing a ripening method, obstetricians should consider cost, patient comfort and safety.

Several different methods have been used in order to perform cervical ripening. They can be divided in pharmacological methods, such as prostaglandins, and mechanical approaches, such an intra cervical insertion of balloon catheter.[7] Prostaglandin E1 treatment is associated with a higher incidence of uterine rupture. Therefore this method is not recommended in patients with a previous cesarean section.[8] However, Foley's single balloon catheter has been proved to be a secure method in labor induction, without an increased risk of uterine rupture.[6,9] Many studies have compared this method to the use of prostaglandins, and Foley's catheter is associated with similar vaginal delivery rates (risk ratio vaginal delivery not achieved 1.01[0.82-1.26]) and lower risk of tachysystole (risk ratio 0.27[0.11-0.66]).[10–14]

Double-balloon catheter has been used as an alternative catheter for cervical ripening. This method can apply pressure simultaneously on both the external and the internal os, which could be a potential advantage.[15] However, its use for cervical ripening in patients with a previous caesarean section is still controversial. It has been compared with the use of Foley's catheter for cervical ripening. A metanalysis[16] in which both methods of cervical ripening were compared reveals that there is no difference in the incidence of vaginal delivery. Therefore, Foley would be recommended due to its lower cost. However, it includes only one study that has pregnant women with a previous cesarean section as an inclusion criteria.[17] Thus, the decision of choosing a catheter is difficult with the available published evidence. The objective of the present study was to compare efficacy and safety of two different mechanical methods for cervical ripening in patients with prolonged-pregnancies with a prior cesarean section.

Material and methods

A prospective, non-randomized, cohort study was performed from November 2014 to November 2020. The study was conducted in the maternity unit of the tertiary University and Polytechnic La Fe Hospital, Valencia (Spain). Women recruited for the study were pregnant patients with desire of a trial of vaginal delivery after a

previous cesarean section. Mechanical cervical rinpening method was explained to them. They were informed about risks and benefits by the obstetrician and they signed an informed consent of labor induction and vaginal delivery after a prior cesarean section.

The inclusion criteria were: single pregnancy, gestational age >40+6 weeks (prolonged pregnancy), cephalic presentation, Bishop index 6, prior cesarean section, and signed informed consent for mechanical cervical ripening. The exclusion criteria were: personal history of myomectomy entering in the uterine cavity, more than one previous cesarean section, cesarean section performed within the last 18 months, other fetal presentations than cephalic, multiple pregnancy, macrosomic fetus, premature rupture of membranes or any contraindication of vaginal delivery.

The patients were divided in two groups: Foley catheter and double-balloon catheter. Foley catheter was the employed method during the first 4 years (November 2014 to November 2018) of the study and Cook catheter was used in the last two years (November 2018 to November 2020); when it was introduced in our center. The same protocol was followed in both groups.

Prior to the catheter insertion, fetal heart rate (FHR) was monitored during 30 minutes and the cervical length was measured through vaginal ultrasound. After, the administration of aqueous chlorhexidine in the vagina, a silicon Foley 22 catheter (Folysil ®) or a double-balloon catheter (Cook ®) was used, filling them with 50 cc of sterile water (Foley) or 60 cc intrauterine and 40 cc vaginal (Cook). Correct filling and placement of the balloon was checked by trans-vaginal ultrasound. FHR monitoring was performed during 120 minutes after the catheter insertion.

If the spontaneous expulsion of the catheter did not happened 12 hours after insertion, the catheter was removed and Bishop score was assessed. If the patient was not in active labor, another FHR monitoring was performed for 30 minutes and the following day induction with oxytocin was started. Intravenous analgesia was administered at maternal request. If the patient did not achieve active labor spontaneously, the administration of intravenous oxytocin was initiated 24 hours after the catheter placement.

The aim of the study was to compare efficacy and safety of two different mechanical methods for cervical ripening in patients with prolonged-pregnancies with a previous cesarean section. Efficacy was defined by the achievement of active labor with the use of mechanical cervical ripening and the subsequent administration of intravenous oxytocin. Active labor was defined by the presence of regular uterine contractions and 4 cm cervical dilatation.[18]

Achievement of active labor and a subsequent vaginal delivery, maternal safety or incidence of uterine rupture or other complications, as well as newborn's weight, umbilical cord pH and Apgar score were recorded.

Non-parametric tests (U Mann-Whitney and Kruskal Wallis) were used for statistical analysis. *p* value 0.05 was considered statistically significant.

Results

Participants

A total of 185 patients were included. One catheter was not finally allocated due to alterations in FHR in a basal cardiotocography (CTG). During the study period, the double-balloon was placed in 44 patients and the Foley catheter was inserted in 141 patients. A total of 13 patients were excluded of the final analysis because they revoked consent. At last, 172 pregnant women results were analyzed in this research, 129 in single-balloon catheter group and 43 in double-balloon catheter group (Figure 1).

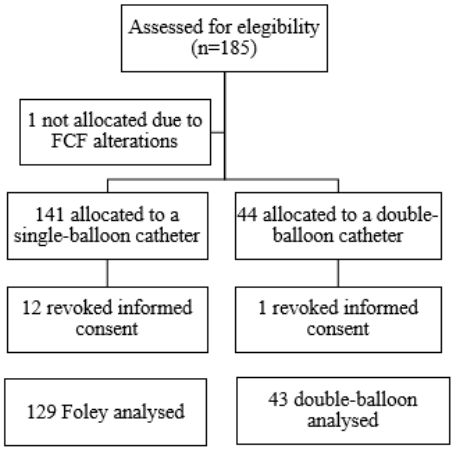

Figure 1 Flow of patients included in the study.

The baseline characteristics of patients in each group are shown in Table 1. No differences between groups were found regarding age, indication of the previous cesarean-section or personal history of prior vaginal delivery. Although both groups had a Bishop score of 6; the cervical length was shorter in Foley group than in double-balloon group.

Table 1 Baseline characteristics

Baseline characteristics	Foley's catheter (n=141)	Cook double balloon (n=44)	P value
Maternal age (years) (mean ± SD)	34±4,38	35±4,21	0.981
Previous vaginal delivery	22	11	0.209
Indication previous cesarean			0.668
Failed induction of labor	29	6	
Cephalopelvic disproportion/ Prolonged labor	29	8	
Other causes	83	30	
Initial cervical length (mm)	30.65	35.19	0.003

NS, no statistically significant difference; SD, standard deviation

Ripening success

After removal or expulsion of the mechanical device, Cook catheter group showed better Bishop score difference than Foley catheter group but with no statistically significant differences. Active labor was achieved similarly in both groups (81.4% double-balloon *vs* 78.2% Foley catheter). Although there was a higher vaginal delivery rate in the double-balloon group (62.8%) compared with the Foley group (49.6%), the difference was not statistically significant (p=0.065). When women were stratified regarding parity, no differences were found. The rate of instrumental delivery was comparable in both groups (Table 2).

Table 2 Delivery outcomes: ripening success, neonatal outcomes and maternal complications

Delivery outcomes	Foley's catheter (n=129)	Cook double balloon (n=43)	P value
Bishop difference	2.76	3.09	0.271
Time from catheter insertion to active labor (min)	1376	1545	0.039
Time from catheter insertion to delivery (min)	1704	1903	0.013
Active labor achieved	101 (78.2%)	35 (81.4%)	0.726
Vaginal delivery achieved	64 (49.6%)	27 (62.8%)	0.065
Mode of delivery			
Spontaneous vaginal	34 (26.4%)	16 (37.2%)	0.24
Instrumental delivery	30 (23.2%)	11 (25.6%)	0.9
Cesarean section	65 (50.4%)	16 (37.2%)	0.18
Newborn weight (g.)	3423±509	3455±435	0.891
(mean ± SD)			
Apgar index 1'	8.8	9.1	0.98
Apgar index 5'	9.9	9.95	0.189
Umbilical-cord pH	7.25	7.24	0.327

NS, no statistically significant difference; SD, standard deviation

Time from catheter insertion to active labor and to delivery showed differences between groups. Time from catheter insertion to delivery was shorter in Foley group compared with double-balloon group (1701 minutes vs 1903 minutes respectively, p=0.013) (Table 2).

Neonatal outcomes

Newborn weight, umbilical-cord pH and Apgar index were similar in both groups. There were 5 cases of pathological cord pH in Foley group. None pathological pH was recorded in Cook group.

Maternal complications

In the Foley group, two cases of postpartum hemorrhage were recorded. There was one case of postpartum hemorrhage in the double-balloon group. All the three postpartum hemorrhage were solved with pharmacological measures. A case of scar dehiscence was recorded in the double-balloon group: the patient was a woman of 38 years old with a previous cesarean section due to a non-reassuring CTG. A fetal bradycardia was observed during expulsive phase of labor and the cesarean section was indicated. A partial dehiscence of the scar, which was covered by the bladder, was observed during surgery. Newborn pH and Apgar were normal and the mother was stable during and after surgery.

Discussion

This research aimed to compare the security and efficacy of single-balloon catheter *vs* double-balloon catheter for cervical ripening in patients with a single pregnancy, a prior cesarean section, a Bishop index ≤6 and a prolonged pregnancy. Efficacy was defined by the achievement of active labor after the mechanical cervical ripening and the subsequent administration of intravenous oxytocin. An elective cesarean section in a patient with a prolonged pregnancy and a prior cesarean section can decrease maternal and perinatal morbimortality.[19] However, cesarean section is also associated with short and long term complications in current delivery and future pregnancies.[20] For this reason, it is essential to find methods to promote vaginal delivery in patients with a prolonged pregnancy, a Bishop score ≤6 and a prior cesarean section. Patients with a uterine scar and a prolonged pregnancy need to receive the most effective and safe method for cervical ripening. Based on previous studies, mechanical methods have shown to be safer than pharmacological ones (such as prostaglandins).[10–14]

The advantages of balloon catheters over prostaglandins are their wide availability, their low cost, as well as the significantly lower rates of uterine hyperstimulation (and lower risk of uterine rupture in women with a scarred uterus). The potential disadvantages are the higher proportion of women requiring oxytocin for labor induction or the risk for increased maternal or neonatal infectious morbidity.[21] Foley's catheter is an easy method, with the lowest price. It triggers cervical ripening by direct mechanical pressure: balloon inflation leads to the release of prostaglandins from the decidua and cervix which enhances stromal breakdown and increases the response to oxytocin and prostaglandins.[22] Cook cervical balloon can generate this pressure simultaneously on external and internal os. Since the double-balloon catheter is more expensive than the Foley, we wondered which of these catheters was more effective.

The double balloon catheter has been evaluated in a few studies. Atad et al.[23] published a randomized controlled study that compared prostaglandin E2 (PGE2), oxytocin and double-balloon in women having an induction (without a uterine scar). Active labor was more frequent with double-balloon compared with PGE2 and oxytocin groups (85.7 vs 50 vs 23.3%, respectively, p<0.01). Vaginal delivery rate was significantly higher with the mechanical device and PGE2 compared with oxytocin group (77.1% and 70.36%, respectively, *vs* 26.7%; p<0.01). Solt et al.[24] compared Foley and double-balloon for cervical ripening in pregnancies without a uterine scar, and they concluded that the double-balloon catheter was more effective than Foley catheter, particularly in the induction of labor of multiparous women: the mean Bishop score increment between pre and post-catheter was significantly higher in the double-balloon catheter than in the Foley group (4.4±1.9 and 3.4±2.0, respectively, p=0.02). In nulliparous women, no statistically significant differences were found in this mean Bishop score, but cesarean section rate was higher in the Foley group than in the double-balloon group (46.5% and 20%, respectively, p=0.02).

The present study has revealed that double balloon group had higher improvement changes in Bishop score compared with Foley group, although this difference was not statically significant. Active labor was achieved similarly in both groups. We found a trend towards a higher vaginal delivery rate in the double balloon group compared with the Foley group. This result is in agreement with some published papers.[17–24] However, the difference was not statistically significant in our study (p=0.065). In the study of Hoppe et al.[17] which included women with a prior cesarean section, the double-balloon catheter offered an advantage in nulliparous women regarding improvement in Bishop score and increase in vaginal delivery rate. Nevertheless, the last study published by Xing et al.[25] which included patients with a uterine scar, showed no differences between single-balloon catheter group and double-balloon catheter group in terms of vaginal delivery and Bishop score improvement. Ahmed et al.[26] showed better Bishop scores with double-balloon group (6 vs 5; p=0.03), but no differences regarding the mode of delivery.

Our study noted a shorter time from catheter insertion to delivery in Foley group. This result agrees with those of Mei-dan et al.[27] Who

found a shorter induction process with Foley catheter. However, no differences were found in the vaginal delivery rate between groups. Ahmed et al.[26] also showed a shorter duration from balloon insertion to delivery in Foley group compared with the Cook balloon group (13 hours and 50 minutes ±4 hours vs 15 hours and 16 minutes ±4 hours and 30 minutes; p=0.03). On the other hand, Pennel et al.[28] revealed a shorter time to delivery with the double-balloon catheter compared to the single balloon but 5% women reported discomfort and/or required double-balloon to be removed.

Instrumental deliveries and all the neonatal outcomes in our study were comparable in both groups. These results agree with those published in the literature. However, Salim et al.[29] found that double balloon associated the same efficacy in inducing labor but with a significantly higher rate of adverse outcomes (including cord prolapse and malpresentation) and more operative deliveries.

When studying the double balloon catheter versus Foley catheter in pre-induction, there is a lack of studies using them in women with a previous cesarean section, and most of the available ones have a small sample size.[17,25,30] There is a considerable heterogeneity among studies regarding definition of uterine rupture, filling volume and the exposure time of balloon catheters as well as the necessity of oxytocin use for labor induction in the published literature. This makes difficult to clarify the efficacy and safety of mechanical devices. This study aimed to provide more information about this topic. At the moment, the use of Cook balloon for cervical ripening in patients with a prior cesarean section and a post term pregnancy is not included in data sheet of the product, but these results show its efficacy and safety in this specific group of patients. Good results could be explained by the force that the two balloons exert on the cervix.

Limitations of this research include the sample size of the double balloon group and the lack of randomization (although two different periods of time were studied). Moreover, the study was performed at a single tertiary institution with high-risk pregnant patients and may not be applicable to other centers with only low-risk pregnant women. More studies with a higher number of participants are needed to justify the use of double balloon instead of Foley catheter, as its price is higher.

Conclusion

Both mechanical cervical ripening are safe and effective methods in pregnancies with a prior cesarean section and a post term pregnancy. Double-balloon ripening associates a higher vaginal delivery rate compared to Foley catheter, but without statistically significant differences. However, time from catheter insertion to delivery was shorter in Foley ripening group. Further studies with larger sample size are required in order to compare properly the safety and efficacy of both methods in this subset of patients.

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Availability of data and material: The dataset used and analyzed during the current study is available from the corresponding author on reasonable request.

Ethics approval: This study has the approval of the local ethics committee (CEIm Hospital Universitario y Politécnico La Fe).

Consent to participate: All patients signed an informed consent of labor induction and vaginal delivery after a prior cesarean section.

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Conflicts of interest

No potential conflict of interest was reported by the authors.

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