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Original Article

Interest of cervical ripening using double balloon catheters for labour induction in term nulliparous women

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ABSTRACT

Objective: To compare the efficiency of double balloon catheters with that of intravaginal prostaglandins alone for the labor induction of unfavourable cervices in term nulliparous women.

Methods: 50 nulliparous patients induced with a double balloon device were compared to 53 patients induced using intravaginal prostaglandins alone. The main outcome measure was labour induction failure, characterized by the absence of active labour. The secondary outcome measures were the improvement of the Bishop score, the average durations of ripening and labour induction, the average time to active labour, the need for a second cervical ripening agent, the total dose of prostaglandins used in each group, the use of oxytocins, as well as the rates of vaginal delivery, abnormal foetal heart rate during labour and perinatal maternal infection.

Results: The rate of failed labour induction was of 28% in the double balloon group, against 13% in the prostaglandins group. The average durations of ripening and labour induction, as well as the time to active labour were higher in the double balloon group. The improvement of the Bishop score was significantly lower in the double balloon group.

Discussion and conclusion: In our study, the use of double balloon catheters does not seem to reduce the rate of failed labour induction in nulliparous women when compared to the use of prostaglandins alone. In addition, it could lengthen the labour induction duration, although more powerful studies would be necessary not to recommend its use for nulliparous women.

Introduction

The rate of labour induction during pregnancy in France is 22%. The 2016 national survey of perinatal care showed that this rate remained stable between 2010 and 2016 [1]. The goal of artificial labour induction is to mitigate the materno-foetal morbidity and mortality. However, it involves several risks, such as failed labour induction, impaired foetal and maternal tolerance, uterine hyperkinesia, materno-foetal infections, or post-partum hemorrhage. Among the latter, the risk of caesarean section caused by failed labour induction or abnormal foetal heart rate is ever-present. The labour induction methods vary, depending on the patient background (parity, scarred uterus (SU), contraindication to prostaglandins, etc), the course of the pregnancy (twin pregnancy, foetal presentation, hydramnios, suspicion of macrosomia) and the cervical favourability. The Bishop score [2] is a valuable tool in the labour induction process, since it helps evaluating the cervical ripening. It is composed of 5 items rated from 0 to 2 points which, once summed, provide a global score between 0 and 13. The higher the Bishop score, the more favourable the cervix to an artificially induced labour. A cervix is considered to be favourable when the Bishop score is higher or equal to 6. In order to obtain an optimal cervical ripening, pharmacological methods have been widely used in the last decades. Indeed, the use of intravaginal prostaglandins is recommanded as first-line treatment for cervical ripening [3], but is contraindicated for patients with SU. To ensure a satisfying rate of successful induced labour in patients with SU, mechanical methods were validated within the context of a cautious use. In its 2008 recommandations on artificial labour induction, the French National Authority for Health does not advocate the use of mechanical ripening as a routine for the general population, unlike the World Health Organization [3,4]. However, there is little consensus about the use of mechanical methods in nulliparous

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women or in patients without a SU. Although numerous studies were conducted on the general population [5,6], very few were focused on nulliparous parturients requiring an artificial labour induction. On top of filling the gap in the currently-shallow available literature on the topic, the content of the present study helps evaluating the sake of this mechanical method in this population.

In a permanent quest of improvement of the obstetrical practice, we questioned the efficiency and benefits of using double balloon catheters for the cervical ripening in nulliparous patients, compared to the use of prostaglandins alone.

Material and methods

The goal of our study was to compare the efficiency of a cervical ripening with a double balloon catheter (Cervical ripening balloon, Cook R, Cook OB/GYN, Spencer, IN, United States) to that of intravaginal prostaglandins alone in nulliparous women at the Cannes hospital maternity unit (2a level). The study included 50 nulliparous patients whose labour was induced by double balloon catheters between January 1st 2016 and July 31st 2018, and 53 nulliparous patients whose labour was induced by intravaginal prostaglandins during the same period. Due to the imbalance in the number of available patients in each group, patients from the prostaglandins group were selected in order to even the patients characteristics between both groups (age, term, initial Bishop score).

The criteria for inclusion were the medical indication for artificial labour induction, a single pregnancy with a foetus in cephalic presentation, 37 completed weeks of amenorrhea, and a Bishop score strictly lower than 6. The exclusion criteria were previous deliveries, multiple pregnancies and patients with a placenta praevia.

The main outcome measure was labour induction failure, characterized by the absence of active labour. Although there exists no consensual definition of a successful labour induction, we considered that active labour was reached beyond 5 cm of cervical dilatation, as defined by Pesner and Rosen [7].

The secondary outcome measures were the rate of vaginal delivery, the improvement of the Bishop score after 12 h, the average durations of cervical ripening (time required to obtain a Bishop score higher or equal to 6) and time to active labour (time between the start of cervical ripening and active labour), the average time of labour induction (time between the start of cervical ripening and birth), the need for a second cervical ripening agent, the total dose of prostaglandins used in each group, the use of oxytocins during labour, as well as the rates of perinatal maternal infection, post-partum hemorrhage, foetal heart distress and uterine hyperkinesia.

Several neonatal outcomes were also analyzed, such as the Apgar score at 1, 5 and 10 min of life, the presence of meconium stained fluid, the arterial pH at birth, the need for neonatal unit transfer, and the birth weight.

The indication of labour induction was left to the judgment of the clinician. For the" double balloon" group, the patients were admitted in the evening, and the double balloon catheter was installed after cervical evaluation if the Bishop score was stricly lower than 6. The double balloon was put in lithotomy position, under speculum, after cervical disinfection using povidone-iodine solution, and inflated with 80cc of saline solution or sterile water in each balloon. Finally, the double balloon was attached to the interior face of the patient's thigh. A two-hour foetal monitoring was conducted in delivery room before letting the parturient back to her room, or stroll if the monitoring was satisfying. The double balloon was left in place for 12 h, before being withdrawn next morning in delivery room if not spontaneously fallen before. Cervical ripening was then pursued by using intravaginal prostaglandins if the Bishop score was still strictly lower than 6, or by oxytocics if it was higher or equal to 6. The oxytocics were initially dosed at 2.5 mUI/min, and the dose was progressively increased every 20–30 min by 2 mUI/min steps until reaching a good uterine dynamic (3–4 uterine contractions per 10 min).

For the" prostaglandins" group, a cervical evaluation was conducted at 8 in the morning, after which the induction method was left to the appreciation of the doctor on duty. Either a vaginal diffusion system with 10 mg of dinoprostone was put on the posterior vaginal cul-de-sac for 24 h, or a 1 or 2 mg dinoprostone intravaginal gel was administrated on the posterior vaginal cul-de-sac, renewable once. After the use of prostaglandins, the labor induction was pursued with an oxytocin perfusion, even if the cervix remained unfavourable.

The statistical analysis was performed with the online software pvalue.io. In the following, quantitative data are given as means and standard deviations, while qualitative data are provided as amount and percentage in each category. We used the χ^2 test for the statistical comparisons of qualitative variables, and the Fisher test for that of quantitative variables. The significance threshold was defined as $p < 0.05$.

Results

The age, body mass index at term, term at cervical ripening time and initial Bishop score of the patients are indicated in Table 1. All these population characteristics were comparable in both groups. The indications of labour induction and their proportions in each group are shown in Table 2. The indications of labour induction for maternal pathologies were: diabetes ($n = 11$), pre-eclampsia ($n = 6$), inaccurate term ($n = 2$), metrorrhagia ($n = 1$) and anticoagulation therapeutic window ($n = 1$). The indications of labour induction for foetal pathologies were: abnormal foetal heart rate ($n = 7$), suspected macrosomia ($n = 8$), ectasia of the umbilical vein ($n = 1$), oligoamnios ($n = 2$) and intrauterine growth delay ($n = 5$). It should be noted that no mechanical cervical maturation was processed for premature ruptured membranes. The double balloon

Table 2
Indications of labour induction. PMB: premature membranes breaking.

	Doubleballoon group (n, %)	Prostaglandins group (n, %)
PMB	0 (0%)	20 (37.7%)
Exceeded term	15 (30%)	23 (43.4%)
Maternal pathology	13 (26%)	6 (11.3%)
Foetal pathology	22 (44%)	4 (7.5%)

Table 1
Patients characteristics at cervical ripening time. WA: weeks of amenorrhea.

	Double balloon group, n = 50	Prostaglandins group, n = 53
Age (years)	29.2 ± 4.84	28.8 ± 6.03
Body mass index at term	24.6 ± 5.02	24.0 ± 4.65
Term (WA)	39.6 ± 1.55	40.1 ± 1.49
Initial Bishop score	2.72 ± 1.31	2.66 ± 1.43

catheter was more often used in the case of foetal or maternal pathologies, whereas prostaglandins were more regularly used for full-term patients.

The results regarding the course of labour inductions and their outcomes are presented in Table 3. The labour induction failure rate was relatively low in both groups. It was lower in the prostaglandins group, but the difference was not statistically significant.

The average Bishop score improvement after 12 h of cervical ripening was significantly higher in the prostaglandins group, with an average improvement of 3.13 ± 2.94, against 2.12 ± 1.79 in the double balloon group, and this difference was statistically significant ($p = 0.037$). The average duration of cervical ripening (time between the beginning of the ripening and a favourable cervix) was comparable in both groups, as well as that of time to active labour (time between the beginning of ripening and a 5 cm cervical dilatation) and time of labour induction (time between the start of ripening and delivery). The resort to a second ripening agent was more frequent in the double balloon group (48% of the cases) than in the prostaglandins group (32%), although the difference was not statistically significant. As expected, the average total dose of prostaglandins used for cervical ripening was significantly higher in the prostaglandins group, which is inherent to the ripening methods themselves. On the contrary, oxytocins were used in similar rates in both groups. The vaginal delivery rates were also comparable. We observed only one case of maternal infection in our population sample, belonging to the double balloon group. The post-partum hemorrhage rate was globally low with only six cases in total (two in the double balloon group, four in the prostaglandins group), and was not significantly higher in either of the groups. The number of cases presenting an abnormal foetal heart rate was higher in the prostaglandins group (64%) than in the double balloon group (54%), but the difference was not significant. Finally, the rate of uterine hyperkinesia was low and similar in both groups.

Regarding the neonatal outcomes, the Apgar scores at 1, 5 and 10 min, along with the arterial pH values at birth and the average birth weights were similar in both groups. The presence of meconium stained fluid was also equivalent in both groups. Finally, only four transfers in neonatal units were necessary out of the 103 patients (one for the double balloon group, and three in the prostaglandins group).

Discussion

The success rate of labour induction is lower in the nulliparous population than for multiparous women. Indeed, previous vaginal deliveries multiplies the odds of vaginal delivery after 24 h of labour induction by more than 6 [8]. Our population sample was entirely nulliparous, and both groups were comparable in terms of maternal and gestational age, body mass index at term, initial Bishop score and term.

We observed a low rate of labour induction failure in our population, with only 13% in the prostaglandins group, against 28% in the double balloon group. However, the difference was not statistically significant. In his study comparing double balloons to prostaglandins, Cromi observed an even lower rate of induced labour failure, with only 9.7% in the prostaglandins group and 8.6% in the double balloon group [9].

As for the 2012 study by Cromi [9] or the PROBAAT trial in 2011 [10], most studies comparing the efficiencies of double balloon catheters and prostaglandins used the mode of delivery or the improvement of the Bishop score as main outcome measure [10]. In the present study, we chose the labour induction failure rate, considering that caesarean sections occuring during labour (caused by abnormal foetal heart rate or stagnation of cervix dilatation after 5 cm, for example) could not be attributed to the labour induction method. Boyon's study [6] also used the labour induction failure rate as a main outcome measure, although the study was not limited to nulliparous women.

After a double balloon-induced ripening of 0.471 ± 0.111 days (approximately 12 h), we obtained an average Bishop score improvement of 2.12. In his 1997 study about the efficiency of a 12 h cervical ripening using double balloon catheters [11], Atad obtained an average Bishop score improvement of 4.6 points in nulliparous women. In this study, the balloons were inflated using 100 mL of saline solution, against 80 mL in our study. Of course, it seems hard to attribute the improvement of the Bishop score to the amount of saline solution injected in the balloon device. Furthermore, the impact of the duration of the double balloon ripening can also be questionned. In 2011, Cromi showed that the vaginal delivery rate under a 24 h delay was higher for a 12 h long ripening with a double balloon catheter than for a 24 h one [5]. Hence, it does not seem useful to extend the use of the double balloon catheter beyond 12 h. In the prostaglandins group, the

Table 3
Course and outcomes of labour inductions.

	Double balloon group	Prostaglandins group	P
Failed labor induction	14 (28%)	7 (13%)	0.11
Average Bishop score improvement (after 12 hours)	2.12 ± 1.79	3.13 ± 2.94	0.037
Average ripening duration (days)	0.902 ± 0.561	0.856 ± 0.612	0.7
Average labour induction duration (days)	1.06 ± 0.564	0.949 ± 0.594	0.37
Average time to active labour (days)	1.34 ± 0.614	1.18 ± 0.668	0.2
Total dose of prostaglandins (mg)	5.06 ± 5.28	9.94± 2.87	< 0.001
Need for a 2nd ripening agent	24 (48%)	17 (32%)	0.15
Use of oxytocins	39 (78%)	40 (75%)	0.94
Vaginal delivery rate	29 (58%)	33 (62%)	0.81
Maternal infection rate	1 (2%)	0 (0%)	0.49
Post-partum hemorrhage rate	2 (4%)	4 (7.5%)	0.68
Abnormal foetal heart rate	27 (54%)	34 (64%)	0.4
Uterine hyperkinesia	2 (4%)	2 (3.8%)	1
Apgar score at 1 minute	9.22 ± 1.95	9.30 ± 1.69	0.82
Apgar score at 5 minutes	9.85 ± 0.548	9.68 ± 1.03	0.32
Apgar score at 10 minutes	9.92 ± 0.340	9.87 ± 0.482	0.53
Arterial pH	7.27 ± 0 .0835	7.24 ± 0.111	0.091
Birth weight (g)	3301 ± 566	3314 ± 438	0.9
Presence of meconium stained fluid	7 (14%)	10 (19%)	0.69
Need for neonatal unit transfer	1 (2%)	3 (5.7%)	0.62

average Bishop score improvement during the course of action of the prostaglandins was 3.13 ± 2.94, which is significantly higher than that of the double balloon group. Since the average ripening duration was comparable in both groups (0.902 ± 0.561 in the double balloon group against 0.856 ± 0.612 in the prostaglandins group), we can conclude that the use of a double balloon catheter brings no additional benefit compared to the use of prostaglandins alone.

The average labour induction duration is also very close in both groups (less than 3 h' difference with 1.06 ± 0.564 days in the double balloon group against 1.18 ± 0.668 days in the prostaglandins group). In his 2009 study comparing simple and double balloon catheters with prostaglandins, Pennell obtained similar results [12] (24.5 h in the double balloon group against 23.8 h in the prostaglandins group, the difference being non-significant).

The results of our study exhibit comparable rates of vaginal delivery in both groups (58% in the double balloon group against 63% in the prostaglandins group). Delivery modes after artificial labour induction were studied by several authors: in his 2012 randomized trial, Cromi observed a superior rate of vaginal delivery in a 24 h delay after labour induction using double balloons, compared to prostaglandins [9]. However, the difference was not statistically significant. In his 2014 study, Boyon did not find a significant difference regarding the delivery mode when using the double balloon catheter or the prostaglandins for labour induction. Finally, in his 2009 randomized prospective trial, Pennell compared the ceasarean section rates when labour was inducted with a Foley catheter, a double balloon catheter or with prostaglandins in nulliparous women [12]. No difference was found between the three groups. Hence, several studies, including our own, seem to conclude that the use of double balloon catheters to induce labour does not reduce the ceasarean section rate.

In the double balloon group, none of the patients was induced for premature ruptured membranes, while this indication represented 37% of the population in the prostaglandins group. This is understandable, since double balloons are very often seen by obstetricians as a maternal infection source. However, as shown by McMaster et al. in their 2015 meta-analysis, double balloon catheters do not cause more infections than prostaglandins [13], since they obtained similar rates of chorioamnionitis and maternofoetal infections with both methods. Their work suggests that with a correct asepsis and a good observance of the recommandations on maternal prophylactic antibiotic treatments, the use of double balloons could be considered in the case of prolongated ruptured membranes.

In the present study, only one case of *pre partum* maternal infection was identified. It belonged to the double balloon group, but it was not formally possible to link the infection to the labour induction method. This is coherent with what McMaster obtained in his 2015 meta-analysis, where he evaluated the infectious risk linked to the use of double balloon catheters for labour induction [13].

In the literature, numerous authors take into account the economic dimension of the labour induction mode [10,12]. Indeed, the double balloon produced by Cook costs approximately 50 euros, while a 10 mg dinoprostone vaginal diffusion system cost is around 100 euros, and a 1 or 2 mg dinoprostone gel costs about 50 euros. Hence, it is only when a double balloon can be used on its own (without prostaglandins) before injecting oxytocics that the total cost of labour induction would be lower than when using prostaglandins. Yet, in our study, most labour inductions by double balloons were followed with prostaglandins diffusion. Although the difference was not statistically significant, the need for a second ripening agent was more frequent in the double balloon group (48% of cases) than in the prostaglandin group (32% of cases). Considering these results and the cost of the equipments, the systematic use of double ballons in nulliparous patients with a Bishop score lower than 6 does not seem justified.

Regarding the labour inductions caused by foetal pathologies, more can be found in the double balloon group than in the prostaglandins group (42% against 7.4%). Among these pathologies, suspected macrosomia represented 14% in the double balloon group, against 1.9% in the prostaglandins group. Indeed, the double balloon seemed more suited for this indication than prostaglandins since it is associated with a lower risk of hyperkinesia. This was shown by Pennell in his randomized comparative trial [12], where he obtained 16% rate of uterine hyperactivity under prostaglandins, against 0% with double balloons. A distended uterus, as is well known, will be less tolerant to prostaglandins. For this reason, it seems preferable to induce labour with double balloons than with prostaglandins when macrosomia is suspected.

Conclusion

Double balloons catheters for cervical ripening have proved to be efficient tools for labour induction with patients presenting a scarred uterus. They are cheap, easy to use, cause few side effects and provide prompt cervical ripening. In our study, however, they did not prove to be efficient regarding labour induction failure rates or Bishop score improvement in a nulliparous population. The only case of indication for nulliparous women would be in the context of suspected macrosomia.

Although this study is among the first to compare the efficiency of double balloon cervical ripening devices with that of prostaglandins alone, it presents several limitations, such as its retrospective nature and its reduced population size. For an improved statistical significance, a prospective randomized trial on a larger nulliparous population should be conducted, in order to confirm these results.

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