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Pre-Induction of Labor by Intracervical Double Balloon Maturation Transversal Study of 1576 Deliveries

Gbary-Lagaud Eléonore[1,2*], Akobé Privat[2], Loba José[2], Effoh N'Drin[2], Adjoby Roland[2], Kosi-Tuavawa Rémi[3]

[1]Gynecology and Obstetrics Department of the Agglomeration Hospital Center of Nevers, Nevers, France
[2]Department of Mother and Child Medicine, University of Félix Houphouët-Boigny, Abidjan, Côte d'Ivoire
[3]Gynecology-Obstetrics Department, Agglomeration Hospital Center, Nevers, France
Email: *eleonoregbarylag@gmail.com

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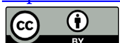

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Abstract

Objective: To describe the results of pre-induction of labor by cervical ripening with a double intra-cervical balloon at the Centre Hospitalier de l'Agglomération de Nevers (France). **Material and Method**: This was a retrospective descriptive and analytical cross-sectional study from January 01, 2022 to June 30, 2023 (18 months). The study population was all patients who gave birth at the Nevers Hospital during the study period. Patients included in the study were those who received a double intra-cervical balloon. Patients who received only other methods of cervical ripening were not included in the study. **Results**: The frequency of use was 4.25% of deliveries. Mean gestational age was 39 SA, most often for gestational diabetes (20.9%). In multiparous women, labor was induced only after use of the double intracervical balloon (81.82%; p = 0.03). In 58.14% of cases, labor was induced within <12 hours (p = 0.01). **Conclusion**: The double balloon is an effective method for inducing labor with vaginal delivery. It should be encouraged, particularly in multiparous women who are more exposed to the deleterious effects of cervical ripening by pharmacological methods.

Keywords

Cervical Ripening, Intracervical Double Balloon, Labor, Delivery

1. Introduction

Artificial induction of labor concerns 22.5% of births in France [1]. Cervical ripening is necessary when local conditions are unfavorable for induction: Bishop

score < 6 or 7, depending on the obstetric team [2] [3]. Several techniques are available for cervical ripening: pharmacological methods (prostaglandins, misoprostol) and mechanical methods (membrane detachment, Foley catheter, synthetic osmotic dilator, double intra-cervical balloon) [4] [5]. Among mechanical means, the double intra cervical balloon (DCB) is a catheter with two silicone balloons.

These 2 balloons (uterine and vaginal), inflated to a maximum of 80 cc, are designed for mechanical and progressive dilation of the cervix. The use of DCB is recommended by certain teams in the event of induction, particularly on a scarred uterus [6] [7].

This technique of cervical ripening with DCB is often used at the Agglomeration Hospital Center of Nevers in France. It therefore seemed appropriate to describe the results of pre-induction of labor by cervical ripening with DCB at this hospital.

2. Materials and Methods

This was a retrospective cross-sectional study with descriptive and analytical aims. The study period was from January 01, 2022 to June 30, 2023, *i.e.*, 18 months. The study population consisted of all patients who gave birth at Agglomeration Hospital Center of Nevers in France during the study period. Patients included in the study were those in whom a DCB had been placed. The DCB could be positioned alone, preceded by the use of intra-vaginal prostaglandins, or introduced in conjunction with an oxytocic infusion. Balloons were inflated to between 60 and 80 cc, depending on maternal and fetal tolerance. The fetal heart rate was recorded at least 20 minutes before each DCB insertion. This was continued for the first 2 hours after insertion of the DCB. Patients who received only other methods of cervical ripening were not included in the study.

We considered the following variables:

-Qualitative variables: indication for cervical ripening, modality of ripening (induction of labor under simple DCB; under DCB combined with oxytocin; under prostaglandins (dinoprostone) then DCB; failure of cervical ripening), mode of delivery (vaginal delivery, cesarean section).

-Quantitative variables: maternal age, parity, body mass index (BMI), gestational age, time to onset of action of DCB.

The data were collected with the approval of the Medical Information Department. The study was conducted in compliance with the Declaration of Helsinki. Data analysis was performed using sphinx SPSS software. When 2 variables were crossed, the chi 2 statistical test was used to compare them. A value of $p \leq 0.05$ was considered a significant threshold.

3. Results

During the study period, we recorded 1576 deliveries, including 371 inductions by all methods (23.54%). DCB was inserted in 67 patients according to the trigger

indications but also the preferences of the senior doctors on call. This represents a frequency of 4.25% of deliveries (Figure 1).

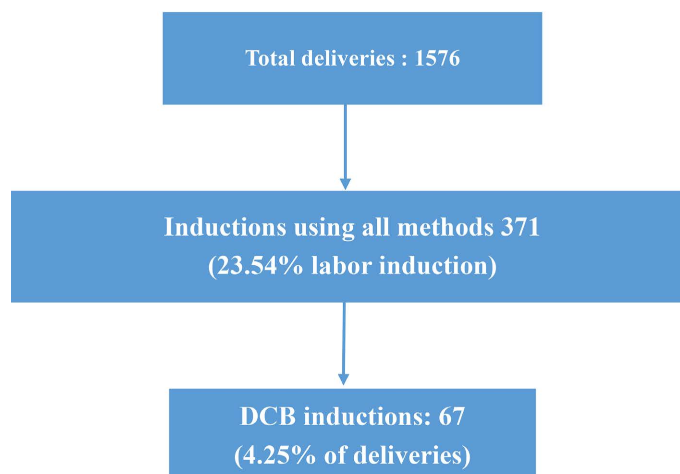

Figure 1. Flowchart of DCB labor induction.

3.1. Athropometric Parameters

The patients in the study (55.2%) were aged between 26 and 35. Patients over 35 accounted for 19.4% of the total. Primiparous women were the most numerous with 44.8% of the total, followed by pauciparous women with 38.8%. Multiparous women accounted for 16.4% of the total. In 37.3% of cases, patients were obese, with a BMI ≥ 30. Overweight patients (BMI between [25 - 30[) made up the second most frequent group (31.3%).

3.2. Characteristics of Cervical Ripening

The mean gestational age for cervical ripening at DCB was 39 weeks' gestation, with extremes of 36 and 42 weeks' amenorrhea.

Indications for cervical ripening were dominated by gestational diabetes (20.9%), Fetal Heart Rate Abnormalities (FHRRA) in equal percentage with Intra-Uterine Growth Retardation (IUGR) (11.9%) and over-term (9%).

Delay of action referred to the time required for CAD to induce significant changes in the cervix. In this case, the DCB fell off on its own. In 52.2% of patients, the DCB remained in place for <12 hours. The results are shown in Table 1.

Table 1. Distribution of patients according to time to onset of DCB.

Action delay	Workforce (n)	Percentage %
<12 hours	35	52.2
[12 - 24 hours[	25	37.3
24 hours	7	10.5
TOTAL	67	100

In 37.75% of cases, the onset of labor was achieved after the use of DCB alone. Cervical ripening failure concerned 21.43% of patients in whom no significant cervical changes were observed, associated with maternal and/or fetal intolerance. It should be noted that the same patient could have 1 to 3 evolutionary modalities, hence the total number of 98. The results are presented in **Table 2**.

Table 2. Distribution of patients by cervical ripening modality.

MODALITY OF CERVICAL RIPENING	Workforce n	Percentage %
Cervical ripening under DCB	37	37.75
Cervical ripening (DCB + oxytocin)	22	22.45
Cervical ripening (Prostaglandins then DCB)	18	18.37
Failure of cervical ripening	21	21.43
TOTAL	98	100

Parity was cross-referenced with cervical ripening modalities. In multiparous women, labor was induced only after the use of DCB (81.82%; p = 0.03). In primiparous women, labor was induced after the combination of DCB and oxytocin (26.92%; p = 0.03). **Table 3** presents these results.

Table 3. Growth in parity and cervical ripening modalities (%).

Parity/Modalities of cervical ripening	Cervical ripening with DCB	Cervical ripening with DCB + oxytocin	Cervical ripening with Prostaglandins then DCB	Failure of cervical ripening	TOTAL
Primiparous	13 (25)	14 (26.92)	12 (23.08)	13 (25)	52 (100)
Pauciparous	15 (42.86)	7 (20)	5 (14.28)	8 (22.86)	35 (100)
Multiparous	9 (81.82)	1 (9.09)	1 (9.09)	0 (0)	11 (100)
TOTAL	37	22	18	21	98 (100)

chi2 = 13.73, ddl = 6, p = 0.03; The dependence is significant. Chi-square = 13.73, df = 6, p = 0.03. Some theoretical numbers are less than 5; the chi-square rules are not really applicable. Chi-square is calculated on the citation table (marginal numbers equal to the sum of row/column numbers).

The time to onset of action of DCB was cross-referenced with cervical ripening modalities. DCB induced significant cervical changes, and thus entry into labor, within <12 hours when DCB was used alone (58.14%; p = 0.01). The results are shown in **Table 4**.

3.3. Delivery Characteristics

In 67.2% of cases, delivery was vaginal. Caesarean section accounted for 32.8% of deliveries.

Cervical ripening modalities were cross-referenced with route of delivery. Cer-

vical ripening with DCB alone enabled vaginal delivery in 72.97% of cases (p = 0.00). Table 5 shows the results obtained.

Table 4. Cross-reference between DCB action time and cervical ripening modalities.

DBC action timeframe/ Evolutionary modalities	Cervical ripening under DCB	Cervical ripening with DCB + oxytocin	Cervical ripening with Prostaglandins then DCB	Failure of cervical ripening	TOTAL
<12 hours	25 (58.14)	6 (13.95)	7 (16.28)	5 (11.63)	43 (100)
[12 - 24 hours[	10 (25)	11 (27.5)	9 (22.5)	10 (25)	40 (100)
24 hours	2 (13.33)	5 (33.34)	2 (13.33)	6 (40)	15 (100)
TOTAL	37	22	18	21	98 (100)

chi2 = 16.72, ddl = 6, p = 0.01; The dependence is significant. Chi-square = 16.72, df = 6, p = 0.01. Some theoretical numbers are less than 5; the chi-square rules do not actually apply. Chi-square is calculated on the citation table (marginal numbers equal to the sum of row/column numbers).

Table 5. Cross-referencing of cervical ripening modalities and delivery route.

Modalities of cervical ripening/Route of delivery vaginal delivery	Vaginal delivery	Cesarean	TOTAL
Induction of work with DCB	27 (72.97)	10 (27.03)	37 (100)
Cervical ripening (DCB+ ocytocin)	10 (45.45)	12 (54.55)	22 (100)
Cervical ripening (Prostaglandines puis DCB)	11 (61.11)	7 (38.89)	18 (100)
Failure of cervical ripening	0 (0)	21 (100)	21 (100)
TOTAL	48	50	98

chi2 = 29.85, ddl = 3, p = 0,00; The dependence is highly significant. Chi-square = 29.85, df = 3, p = 0.00. Some theoretical numbers are less than 5; the chi-square rules do not really apply. Chi-square is calculated from the citation table (marginal numbers equal to the sum of row/column numbers).

4. Discussion

Labor was induced in 1 in 4 women who gave birth at CHAN during the study period. This finding is consistent with that of the World Health Organization, which states that 20 to 25% of women in industrialized countries require induction of labor [8].

4.1. Athropometric Parameters

More than half the patients in the study were aged between 26 and 35. This is the age range of maximum fertility, when women are most likely to be planning a pregnancy.

Induced cervical ripening is often carried out in primiparous women. This is because the physiological, chemical, hormonal and mechanical processes involved in natural cervical ripening take longer in primiparous women, resulting in longer pregnancies.

Most of the patients in the study were obese or overweight. Obesity is now considered a global epidemic [9] [10]. Pregnant women are no exception, with 47% gaining more weight than recommended. Being overweight and/or obese is a factor in induction of labour, probably related to the diabetes it causes.

4.2. Characteristics of Cervical Ripening

The French National Authority for Health recommends that induction of labor, more or less associated with cervical ripening, should take place at a minimum gestational age of 37 weeks [11]. At this gestational age, the fetus is fully formed and well adapted to life outside the womb. Beyond 42 weeks, there is a real risk of fetal death due to the senescence of the placenta.

We have found gestational diabetes to be the first indication of cervical ripening. When diabetes is unbalanced, it is an indication for induction at 38 weeks and 6 days +/- preceded by cervical ripening according to the Bishop score [11]. This is due in particular to the complications it can cause: macrosomia, which increases the risk of Caesarean section, and obstetric mechanical complications (shoulder dystocia). According to some authors, the top 3 medical indications for cervical ripening to induce labour are: prolonged pregnancy, premature rupture of membranes and vasculo-placental syndromes [12].

The majority of patients went into labour within < 12 hours of DCB insertion alone ($p = 0.01$). The DCB, which holds the cervix in a vice-like grip, has a dual action: mechanical, through the double pressure exerted on the cervix, and chemical, through the secretion of endogenous prostaglandins, which it facilitates, thus promoting cervical ripening. In our study, the use of DCB combined with oxytocin or prostaglandins did not reduce the time to onset of labor. The combination of DCB and a pharmacological method would therefore be unlikely to reduce the time to labor. In contrast to our study, a review of the literature in 2020 showed that the combination of a mechanical and pharmacological method for cervical ripening reduced the time to labor by 2.71 hours ($p = 0.00$) [13]. This difference with our results could be explained by the fact that, in addition to the cervical ripening method used, several other factors influence the time to onset of labor, such as maternal age, parity, initial Bishop score and indication for induction [14] [15].

In most patients, the use of DCB alone was sufficient to induce labor. This was particularly true in multiparous women, where labor was induced in 81.82% of cases, compared with 26.92% in primiparous women ($p = 0.0328$). This result demonstrates the effectiveness of DCB in inducing labor, particularly in multiparous women. When the use of DCB is preceded by the administration of prostaglandins, this favors vaginal delivery in 51.7% of cases [16].

4.3. Delivery Characteristics

In the majority of cases (67.2%), delivery was vaginal. This percentage is similar to that of Sarreau, who found 53.7% of vaginal deliveries after DCB ripening. One of the aims of cervical ripening is to promote vaginal delivery. DCB is one method

of achieving this goal. However, it should be noted that even if DCB induces labor, several parameters may be taken into account when determining the route of delivery. These include mechanical parameters (maternal pelvis, fetal weight, presentation, commitment to full dilatation), progress of labor, maternal and fetal tolerance.

DCB is a safe and effective mechanical method for inducing labor. It is a good alternative for patients who do not wish to use pharmacological methods, or in whom this is contraindicated. Several studies have demonstrated the efficacy of DCB [7] [17]. However, DCB may be combined with a pharmacological method in certain situations: primiparity, very unfavorable Bishop score, desire to accelerate induction of labor [18]. DCB and pharmacological methods should be combined with caution. There is a risk of hyperkinesia and uterine rupture, particularly in patients with a history of caesarean section [7].

It is certainly important to mention the limitations of the study linked to the small sample size and a single location of data collection.

5. Conclusions

Despite the small sample size, this study showed that 1 in 20 women will require cervical ripening, in particular by means of DCB, in order to give birth.

DCB therefore appears to be an effective mechanical method of cervical ripening, with a good rate of vaginal delivery. Its use could be encouraged, particularly in multiparous women who are more exposed to the deleterious effects of exogenous prostaglandins or oxytocics, due to their uterine fragility.

Conflicts of Interest

The authors have no conflicts of interest to declare.

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