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# Induction of Labour by Intra-Cervical Balloon at the Pikine National Hospital Centre: A Report of 30 Cases Collected between 2018 and 2024

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## Abstract

**Introduction:** Induction of labour is an obstetric practice aimed at artificially bringing on childbirth when continuing the pregnancy becomes risky for the mother-child pair. The intra-cervical balloon is a mechanical method whose appeal is growing, particularly in low-resource settings. It consists of introducing a catheter fitted with inflatable balloons (a Foley catheter) into the uterine cervix, which induces progressive cervical dilation. The objective of this study was to assess the success rate of the intra-cervical balloon in labour induction as well as the maternal-fetal prognosis. **Methodology:** This is a retrospective, descriptive, and analytical study of 30 cases of labour induction by intra-cervical balloon collected at the Pikine National Hospital Centre over a seven-year period. This retrospective study included singleton and twin pregnancies ≥ 22 weeks' gestation with complete medical records. Labour induction was performed using a 16 Fr Foley catheter (60 - 80 mL balloon inflation) under standardized maternal and fetal monitoring. **Results:** The results show a vaginal delivery rate of 83.3%; a scarred uterus was the main indication for placing the intra-cervical balloon (70.3%). We noted a significant improvement in the Bishop score with the intra-cervical balloon, a low rate of maternal-fetal complications with an Apgar score > 7 at the 5$^{th}$ minute for 93.3% of newborns, with no uterine rupture or maternal death.

## Keywords

Induction of Labour, Intra-Cervical Balloon, Cervical Ripening, Scarred Uterus, Vaginal Delivery

## 1. Introduction

Artificial induction of labour is one of the most frequent medical procedures in modern obstetrics. It relies on several pharmacological methods (prostaglandins, oxytocin) and mechanical methods. The aim is to produce effective uterine contractions in order to allow a vaginal delivery [1].

The choice of method depends mainly on the Bishop score, which assesses cervical maturity; when this score is unfavourable (<6), a cervical ripening method is recommended before any active induction [2]. Among the mechanical methods, the intra-cervical balloon is an effective, well-tolerated, and inexpensive alternative. It consists of introducing a catheter fitted with inflatable balloons into the uterine cervix, which induces progressive cervical dilation [3]. This device is particularly indicated in situations where uterotonics are contraindicated (scarred uterus, associated conditions). This work aims to assess the efficacy and safety of labour induction by intra-cervical balloon in the gynecology department of the Pikine National Hospital Centre (CHNP) and to contribute to a better understanding of this artificial labour-induction method in a referral maternity unit located in the suburbs of Dakar.

## 2. Methodology

This is a retrospective, descriptive, and analytical cohort study carried out at the CHNP, a referral facility in the suburbs of Dakar. Thirty patients who underwent induction by intra-cervical balloon during the study period were collected. All singleton and twin pregnancies for which the clinical and obstetric information was complete and usable were included in this study. The prerequisite for inclusion was the availability of a complete and accurate record of the variables of interest. The gestational age had to be greater than or equal to 22 weeks of amenorrhoea (WA), determined from the date of the last menstrual period when reliable or, failing that, from an ultrasound performed in the first trimester of pregnancy. Excluded from this study were pregnancies with a gestational age below 22 weeks of amenorrhoea (WA), fetuses with a birth weight below 500 g, as well as incomplete or insufficiently documented medical records that did not allow reliable use of the variables required for the study.

Before induction of labour, all patients underwent 30 minutes of fetal heart rate (FHR) monitoring to confirm fetal well-being. A 16 Fr Foley catheter was then introduced into the cervical canal using an aseptic technique. The balloon was initially inflated with 60 mL of isotonic saline, then its volume was gradually increased, if necessary, up to a maximum of 80 mL to promote cervical ripening. The balloon was removed at the onset of labour or after its spontaneous expulsion. Throughout the procedure, standardised clinical monitoring of the mother and the fetus was provided every two hours, including assessment of maternal parameters, uterine activity, and fetal heart rate. Data were gathered from the patients' clinical records computerised in the FileMaker software, and entered into Excel. They were analysed using SPSS software version 25. Continuous variables were

compared using the ANOVA test, and categorical variables using the chi-square test or Fisher's exact test. Quantitative variables were described by their mean ± standard deviation or their median (interquartile range), depending on their distribution, whereas qualitative variables were expressed as numbers and percentages. The comparison of the Bishop score before and after cervical ripening was performed using the Wilcoxon signed-rank test, given the paired nature of the data, the ordinal nature of the Bishop score, and the relatively small sample size, which did not allow the normality assumption to be guaranteed. The statistical significance threshold was set at $p < 0.05$. The variables studied included:

- Socio-demographic parameters;
- The indications for induction by intra-cervical balloon;
- The change in the Bishop score before and after balloon placement;
- The mode of delivery;
- The maternal-fetal prognosis.

## 3. Results

Out of a total of 25,207 admissions recorded during the study period, 1,058 patients underwent induction of labour, *i.e.*, a frequency of 4.19%. Among the induction methods used, the cervical balloon involved 30 patients, representing 2.84% of the inductions performed and 0.12% of all admissions.

The distribution of patients by age, illustrated in Table 1, revealed a mean age of 30.41 years, with a standard deviation of 4.9 years. The distribution by parity showed a predominance of primiparous and pauciparous women, who represented 66.6% of the total sample. Excess weight (BMI ≥ 25 kg/m$^2$) was observed in 30.0% of patients (n = 9), split between 13.3% of overweight patients (n = 4) and 16.7% of obese patients (n = 5).

Table 1. Distribution by parity and mode of delivery.

| Parity | Number (n) | Frequency (%) | Vaginal Delivery (n) | Cesarean (n) |
|---|---|---|---|---|
| Nulliparous | 4 | 13.3 | 2 | 2 |
| Primiparous | 10 | 33.3 | 10 | 0 |
| Pauciparous | 10 | 33.3 | 8 | 2 |
| Multiparous | 6 | 20 | 5 | 1 |
| Total | 30 | 100 | 25 | 5 |

The mean Bishop score before induction of labour was 2.5, reflecting initially unfavourable cervical conditions. After 12 hours of cervical ripening by intra-cervical balloon, this score improved significantly to reach a mean of 6.7, corresponding to cervical conditions that had become favourable. Of the 30 patients who underwent induction of labour by intra-cervical balloon, 22 had a scarred uterus,

73.3% of the sample. The other maternal conditions were not mutually exclusive; a single patient could present several comorbidities or indications for induction. As Table 2 shows, the scarred uterus was the most frequently found maternal condition. Maternal obesity and prolonged pregnancy (gestational age > 41 WA) were each observed in 10 patients (33.3%). Gestational diabetes and post-term pregnancy (gestational age > 42 WA) were the least frequent conditions, each found in 2 patients (6.7%). Analysis of the obstetric characteristics of the study population showed a predominance of singleton pregnancies, observed in 93.3% of cases. The mean gestational age was 38.21 weeks of amenorrhoea (WA), with extremes of 32 and 42 WA + 3 days. An inter-pregnancy interval greater than 24 months was found in 96.7% of patients with a history of cesarean section. In addition, the fundal height was less than 35 cm in 73.3% of cases. Regarding the progression of the process (time between balloon placement and delivery), a duration greater than 24 hours was observed in 75% of the parturients. Induction of labour resulted in a favourable outcome in 83.3% of cases, translating into a vaginal delivery, with the remainder considered a failure of balloon induction, leading to a cesarean section (16.7%).

Table 2. Maternal conditions among women who underwent labor induction with an intracervical.

| Maternal Condition | n (N = 30) | % |
|---|---|---|
| Previous cesarean section (scarred uterus) | 22 | 73.3 |
| Maternal obesity | 10 | 33.3 |
| Prolonged pregnancy | 10 | 33.3 |
| Gestational diabetes mellitus | 2 | 6.7 |
| Post-term pregnancy | 2 | 6.7 |

The immediate neonatal prognosis was satisfactory, with an Apgar score at 5 minutes greater than or equal to 7 in 93.3% of newborns. No maternal death was observed during the study period. Eutrophic newborns were the most represented category (53.3%), followed by hypotrophic newborns (43.3%) and macrosomic newborns (3.3%). We thank the reviewer for this pertinent comment. Indeed, with a sample of 30 newborns, a single case of macrosomia corresponds to a frequency of 3.3% (1/30) and not 3.4%. This difference results from a rounding error in the presentation of the results. The data were rechecked, and the percentage was corrected to 3.3% in the manuscript in order to ensure consistency between the reported numbers and percentages.

The indications for cesarean section were dominated by failure to progress in labour and fetal heart rate abnormalities. No major maternal complication related to the cervical ripening method was observed during the study; in particular, no case of uterine hyperstimulation or uterine rupture occurred.

## 4. Discussion

In this study, cervical ripening by intra-cervical balloon was associated with a substantial improvement in the Bishop score, whose mean rose from 2.5 before induction to 6.7 after 12 hours of ripening (Wilcoxon signed-rank test, $p < 0.001$). This change reflects an improvement in cervical conditions before the induction of labour and suggests the effectiveness of this mechanical method for cervical ripening in our population. This observation is consistent with recent meta-analyses showing that mechanical methods effectively improve cervical ripening while presenting a favourable safety profile [3] [4]. The majority (83.3%) of patients then delivered vaginally, which indicates that satisfactory cervical ripening was achieved in a large proportion of the women included. This result is in agreement with several studies showing that mechanical devices achieve vaginal delivery rates comparable to those observed with pharmacological methods, while limiting the risk of uterine hyperstimulation, particularly in women with a scarred uterus [5] [6]. Recent recommendations from NICE, ACOG, and the SOGC also consider the intra-cervical balloon a relevant option when the use of prostaglandins is not advised or requires particular caution in patients with a history of cesarean section [7] [8]. In our cohort, maternal and neonatal safety appears satisfactory. No case of uterine rupture or other serious maternal complication directly attributable to the intra-cervical balloon was observed. Moreover, the majority of newborns had an Apgar score greater than or equal to 7 at the fifth minute, reflecting good adaptation to extra-uterine life. These results are also consistent with the data from the updated WHO recommendations and recent systematic reviews, which show no increase in perinatal morbidity with mechanical methods of labour induction when they are used according to the indications [3] [9] [10]. In the multicentre study by Landon *et al.*, the risk of uterine rupture was low in patients who underwent cervical ripening by Foley catheter and comparable to that observed with other induction methods [6]. Likewise, several randomised trials and meta-analyses, notably those of Ten Eikelder and Zhang, have shown that the intra-cervical balloon has an efficacy comparable to that of prostaglandins while reducing the risk of uterine hyperstimulation [5]. These results must nevertheless be interpreted with caution. The limited size of our sample reduces the statistical power of the study and does not allow the occurrence of rare complications such as uterine rupture to be ruled out. Furthermore, the absence of a comparator group does not allow the superiority or equivalence of the intra-cervical balloon relative to other induction methods to be established. Nevertheless, the observed results suggest that this technique constitutes an effective option for cervical ripening, with a satisfactory safety profile in our cohort, particularly in patients with a scarred uterus.

## 5. Conclusion

The intra-cervical balloon is a reliable, effective, and safe method for inducing labour, particularly in patients with an unfavourable Bishop score or a scarred uterus.

Its use should be further encouraged in Senegalese maternity units, especially in peripheral facilities. It is recommended that standardised national protocols incorporating this method be developed. Furthermore, prospective, multicentre studies including a larger number of patients would help to consolidate the observed safety and efficacy data.

## Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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