

Richiesta inserimento DM: Catetere maturazione cervicale J-CRB-184000

NOME COMMERCIALE	Catetere maturazione cervicale J-CRB-184000
NOME GENERICO	Dispositivo a palloncini per maturazione cervicale con mandrino regolabile.
PRODUTTORE	Cook Incorporated
FORNITORE	Cook
INDICAZIONE D'USO	Dilatazione meccanica del canale cervicale prima dell'induzione del travaglio a termine, nei casi in cui le condizioni della cervice non siano idonee per l'induzione.
INTERVENTO DI RIFERIMENTO	Induzione al parto
DESCRIZIONE	Il dispositivo è costituito da un catetere a due palloncini in silicone che si conformano al profilo del canale cervicale. Il volume di gonfiaggio massimo dei palloncini è di 80 ml ciascuno. È incluso un mandrino modellabile di lunghezza regolabile.
MARCHIO CE	si
NUMERO DI REPERTORIO E CODICE PRODOTTO	1007166 J – CRBS – 184000
CND	U1090969 – Dispositivi per ostetricia – altri
CLASSE DI APPARTENENZA	II a

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NOTE DEL RICHIEDENTE	Si chiede l'adozione del dispositivo CBR nei protocolli di induzione ed in particolare per la maturazione della cervice per il travaglio di parto quando questa si presenta sfavorevole, cioè insufficientemente dilatata e con la non corretta morfologia, nonché nelle pazienti che se trattate col farmaco possono incorrere in eventi avversi o che essendo portatrici di patologie per le quali il farmaco è controindicato (asma, diabete, cardiopatie, glaucoma) non possono essere trattate. Infine, come da linee guida internazionali, anche nelle pazienti con pregresso taglio cesareo.
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NOTE DEL PRODUTTORE

Il dispositivo è stato studiato per maturare e dilatare la cervice senza l'uso di farmaci, consentendo quindi di eliminare i potenziali effetti collaterali della somministrazione degli stessi. Inoltre, il dispositivo è facile da posizionare e rapido da rimuovere. La maturazione e la dilatazione avvengono grazie alla delicata e costante pressione impartita dai palloncini sulla cervice da entrambi gli osti interno ed esterno. La presenza del mandrino nel set offre un controllo, maggiore durante il posizionamento, infatti, il mandrino aiuta il personale ostetrico a collocare il dispositivo esattamente nella posizione prevista.

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<p>STUDI CLINICI (fonte PUBMED)</p>	<ul style="list-style-type: none">• Circa 1/3 delle pazienti sottoposte a taglio cesareo potrebbero essere eleggibili ad induzione meccanica.• Con CRB si ottiene circa l'80% di dilatazione cervicale di almeno 4 cm vs il 55% con PGE.• In gestanti con diabete mellito gestazionale, colestasi intraepatica della gravidanza, pre-eclampsia, gravidanza prolungata, restrizione della crescita fetale o sospetto prenatale di macrosomia l'esito primario è stato il punteggio di Bishop di almeno sei dopo la rimozione di CRB• Il CRB si è dimostrato efficace nel trattamento di gestanti che avevano subito un precedente cesareo e presentavano cervice sfavorevole• L'uso del CRB non è associato ad una aumentato rischio di rottura dell'utero rispetto al parto naturale.
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Double-balloon catheter versus dinoprostone insert for labour induction: a meta-analysis.
Lalys P, PULG J, Werra XY, Werra XY.
@ Author information

Abstract
OBJECTIVE: To assess the efficacy and safety of a double-balloon catheter versus dinoprostone insert for labour induction.
STUDY DESIGN: PubMed, MEDLINE, Embase, ClinicalTrials.gov, and the Cochrane Central Register of Clinical Trials databases were searched from 1985 to April 2018. Randomized controlled trials that compared a double-balloon catheter and dinoprostone insert for cervical ripening were identified. Eligible study populations consisted of women with singleton pregnancies that had any indication for labour induction and were randomly assigned to undergo induction with a double-balloon catheter or dinoprostone insert. The main outcomes were incidence of vaginal delivery within 24 h and caesarean section, and neonatal outcomes.
RESULTS: Five randomized trials (953 women; 305 with a double-balloon catheter and 298 with a dinoprostone insert) were eligible for inclusion. No differences were observed between the two groups in terms of vaginal delivery within 24 h [relative risk (RR) 1.21, 95% confidence interval (CI) 0.93-1.59] and incidence of caesarean section (RR 0.99, 95% CI 0.77-1.27). Compared with the double-balloon catheter, the dinoprostone insert was associated with a reduced need for oxytocin administration in the process of labour induction (RR 1.95, 95% CI 1.45-2.62). However, there was a higher incidence of excessive uterine activity (RR 0.17, 95% CI 0.06-0.54) and neonatal umbilical cord arterial blood pH < 7.1 (RR 0.36, 95% CI 0.15-0.84) in the dinoprostone insert group.
CONCLUSION: This review showed that the efficacy of labour induction using both the double-balloon catheter and dinoprostone insert was similar. However, the double-balloon catheter seemed to be a safer method.

KEYWORDS: Dinoprostone insert, Double-balloon catheter, Induction of labour, Meta-analysis
PMID: 30315411 DOI: 10.1097/00009149-201804000-00028

Predictive factors for successful cervical ripening using a double-balloon catheter after previous cesarean delivery.
Vital M, Gramis J, Le Thuaud A, Omet J, Durieux G.
@ Author information

Abstract
OBJECTIVE: To identify predictors of successful cervical ripening using double-balloon catheter (DBC) for labor induction among women with previous cesarean delivery (PCD) and unfavourable cervix at term.
METHODS: The present prospective observational study was conducted among women who underwent cervical ripening with DBC at a French tertiary care hospital between January 1, 2014, and December 31, 2017. Inclusion criteria were PCD, singleton term fetus, cephalic presentation, and unfavourable cervix (Bishop score < 6). Exclusion criteria were gestational diabetes mellitus, intrahepatic cholestasis of pregnancy, pre-eclampsia, prolonged pregnancy, or prenatal suspicion of macrosomia. The primary outcome was Bishop score of at least six after DBC removal.
RESULTS: Among the 105 patients included, the initial Bishop score was 2.5 ± 1.5; successful cervical ripening occurred among 74 (70.5%) women; and vaginal delivery occurred among 46 (43.8%). The mean time from DBC insertion to delivery was 19.3 ± 6.7 hours. No adverse events were observed. Predictors of successful cervical ripening were initial Bishop score of at least three (adjusted odds ratio [aOR] 12.74, 95% confidence interval [CI] 2.78-58.47), PCD during labor (aOR 4.38, 95% CI 1.10-17.45), and internal cervical os open (aOR 4.94, 95% CI 1.44-17.11).
CONCLUSION: Several factors were found to predict successful cervical ripening using DBC.

KEYWORDS: Bishop score, Cervical ripening, Double-balloon catheter, Induction of labor, Internal cervical os, Previous cesarean delivery, Vaginal birth after cesarean delivery
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Double-balloon catheter for induction of labour in women with a previous cesarean section, could it be the best choice?
De Bonastha, Terebtha G, Terebtha Catherine EL, Marti Gemboe SF, Lacrosta Monos MP, Camalillo Maza JMF, Castán Melero SF.
@ Author information

Abstract
INTRODUCTION: We analysed the efficacy and safety of double-balloon catheter for cervical ripening in women with a previous cesarean section and which were the most important variables associated with an increased risk of repeated cesarean delivery.
MATERIALS AND METHODS: We designed an observational retrospective study of 418 women with unfavourable cervixes (Bishop Score < 5), a prior cesarean delivery, and induction of labour with a double-balloon catheter. Baseline maternal data and perinatal outcomes were recorded for a descriptive, bivariate, and multivariate analysis. A p value < 0.05 was considered statistically significant.
RESULTS: Most women improved their initial Bishop Score (89.5%) although only a 28.8% of them went into spontaneous active labour. Finally, 51.4% of the women achieved a vaginal delivery. Five cases of intrapartum uterine rupture (1.2%) occurred. After multivariate analysis, main risk factors for repeated cesarean section were dystocia in the previous pregnancy (OR 1.744, CI 95% 1.066-2.846), the absence of previous vaginal delivery (OR 2.590, CI 95% 1.066-6.299), suspected fetal macrosomia (OR 2.410, CI 95% 0.959-6.054), and duration of oxytocin induction period (OR 1.005, CI 95% 1.004-1.006). The area under the curve was 0.789 (p < 0.001).
CONCLUSIONS: Double-balloon catheter seems to be safe and effective for cervical ripening in women with a previous cesarean delivery and unfavourable cervix. In our study, most women could have a vaginal delivery in spite of their risk factors for cesarean delivery. A multivariate model based on some clinical variables has moderate predictive value for intrapartum cesarean section.

KEYWORDS: Catheters, Cervical ripening, Induced labour, Obstetric labour, Trial of labour, Vaginal birth after cesarean
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Double-balloon catheter for induction of labour in women with a previous cesarean section, could it be the best choice?
De Bononho Torralba C¹, Tesoro Catenacci EL², Marti Gombosi S², Lorenza Morici MP, Camellozza Mica JM³, Casteln Mabeo S²

Abstract
INTRODUCTION: We analysed the efficacy and safety of double-balloon catheter for cervical ripening in women with a previous cesarean section and which were the most important variables associated with an increased risk of repeated cesarean delivery.
MATERIALS AND METHODS: We designed an observational retrospective study of 410 women with unfavourable cervix (Bishop Score <5), a prior cesarean delivery, and induction of labour with a double-balloon catheter. Baseline maternal data and perinatal outcomes were recorded for a descriptive, bivariate, and multivariate analysis. A p value <0.05 was considered statistically significant.
RESULTS: Most women improved their initial Bishop Score (89.5%) although only a 20.8% of them went into spontaneous active labour. Finally, 51.4% of the women achieved a vaginal delivery. Five cases of intrapartum uterine rupture (1.2%) occurred. After multivariate analysis, main risk factors for repeated cesarean section were dystocia in the previous pregnancy (OR 1.744, CI 95% 1.066-2.846), the absence of previous vaginal delivery (OR 2.590, CI 95% 1.066-6.290), suspected fetal macrosomia (OR 2.410, CI 95% 0.959-6.054), and duration of oxytocin induction period (OR 1.005, CI 95% 1.004-1.006). The area under the curve was 0.788 (p < 0.001).
CONCLUSIONS: Double-balloon catheter seems to be safe and effective for cervical ripening in women with a previous cesarean delivery and unfavourable cervix. In our study, most women could have a vaginal delivery in spite of their risk factors for cesarean delivery. A multivariate model based on some clinical variables has moderate predictive value for intrapartum cesarean section.

KEYWORDS: Catheters; Cervical ripening; Induced Labour; Obstetric labour; Trial of labour; Vaginal birth after cesarean

[Risk of uterine rupture after cervical ripening with balloon catheter on uterus with previous cesarean section].
Lamontagne C¹, Gossel A², Agostini A²

Abstract
OBJECTIVE: To evaluate the rate of uterine rupture after cervical ripening by mechanical methods using balloon catheter in patients with a previous cesarean section.
MATERIALS AND METHODS: A literature search using the Medline database, Cochrane Library(8) database.
RESULTS: We identified 13 studies evaluating four types of balloon catheter. One thousand two hundred and seventy-eight patients underwent cervical ripening by balloon catheter and 8 (0.62%) cases of uterine rupture were reported. The vaginal delivery rate was 741/1278 (58%).
CONCLUSION: The use of balloon catheters in case of previous cesarean section does not appear to be associated with an increased risk of uterine rupture compared with spontaneous labour. However, further studies are required to evaluate correctly this risk.

KEYWORDS: Balloon catheter; Rupture uterine; Sonde à ballonnet; Uterine rupture; Uterus with previous cesarean section; Utérus cicatriciel

[Expansion dilatation balloons for cervical ripening in obstetric practice].
Ducarme O¹, Grasse J², Vidal MP

Abstract
During recent decades, mechanical devices have been substituted by pharmacological methods. Their place in the therapeutic arsenal remains important with a renewed obstetrical interest for these devices. Due to a lack of data they are still not recommended as first-line. This review thus attempted to examine the use of expansion dilatation balloons (Foley catheter and double-balloons) to analyze their effectiveness in case of native uterus and previous cesarean section. The risk of cesarean section did not differ. Mechanical methods seemed to be more effective in achieving delivery within 24 hours, with fewer episodes of excessive uterine contractions, but they necessitated more oxytocin during labor. Ten clinical trials analyzed dilatation balloons in patients with previous cesarean section. More than 70% women had favorable cervical ripening (Bishop score ≥ 6), and vaginal delivery was reported between 35 and 76% of patients. The risk of uterine rupture was low between 0.64 and 0.72%, with neither increased risk of severe neonatal and maternal morbidity nor increased risk of infectious morbidity. Mechanical methods are effective and safe for third trimester cervical ripening, mainly in women with previous cesarean section. Potential advantages may include wide availability and reduction of some of the side effects.

KEYWORDS: Cervical ripening; Cesarean section; Dilatation; Double ballonnet de dilatation; Double-balloon catheter; Déclanchement du travail; Foley catheter; Induction of labor; Maturación cervical; Sonde de Foley

Double balloon catheter for induction of labour in Chinese women with previous cesarean section: one-year experience and literature review.
Chen G¹, Lu J², Lan C³, Youm AP⁴

Abstract
OBJECTIVES: To evaluate the efficacy and safety of double balloon catheter for induction of labour in Chinese women with one previous cesarean section and unfavourable cervix at term.
DESIGN: Retrospective cohort study.
SETTING: A regional hospital in Hong Kong.
PATIENTS: Women with previous cesarean delivery requiring induction of labour at term and with an unfavourable cervix from May 2013 to April 2014.
MAJOR OUTCOME MEASURES: Primary outcome was to assess rate of successful vaginal delivery (spontaneous or instrument-assisted) using double balloon catheter. Secondary outcomes were double balloon catheter induction-to-delivery and removal-to-delivery interval, cervical score improvement, oxytocin augmentation, maternal or fetal complications during cervical ripening, intrapartum and postpartum period, and risk factors associated with unsuccessful induction.
RESULTS: All 24 Chinese women tolerated double balloon catheter well. After double balloon catheter expulsion or removal, the cervix successfully ripened in 18 (75%) cases. The improvement in Bishop score 3 (interquartile range, 2-4) was statistically significant (P<0.001). Overall, 16 (75%) cases were delivered vaginally. The median insertion-to-delivery and removal-to-delivery intervals were 19 (interquartile range, 13-42.0) hours and 6.9 (interquartile range, 4.1-10.8) hours, respectively. Compared with cases without, the interval to delivery was statistically significantly shorter in those with spontaneous balloon expansion or spontaneous membrane rupture during ripening (7.8 vs 3.0 hours; P=0.025). There were no major maternal or neonatal complications. The only factor significantly associated with failed vaginal birth after cesarean was previous cesarean section for failure to progress (P<0.001).
CONCLUSIONS: This is the first study using double balloon catheter for induction of labour in Asian Chinese women with previous cesarean section. Using double balloon catheter, we achieved a vaginal birth after cesarean rate of 75% without major complications.

KEYWORDS: Catheters; Cesarean section; Labor; Induced

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<p>PREZZO DI LISTINO E COSTI</p>	<p>Parti cesarei anno 2017 ASL LT = 952 -Latina 1627 parti: 1137 vaginali, 490 cesarei - Formia 534 parti: 350 vaginali, 184 cesarei - Fondi 768 parti: 490 vaginali, 278 cesarei</p> <p>Costo medio parto: vaginale € 1450,00 circa Vs parto cesareo € 2400,00 circa (Δ € 900,00 circa) + degenza dopo parto: n. 2 notti dopo parto vaginale vs almeno n. 3 notti dopo parto cesareo + Costo induzione: CRB € 60,00 circa/unità Vs Propess € 88,00 circa/unità (Δ € 28,00 circa)</p> <p>Consumo Propess anno 2017 n. 675 unità = € 64.000,00 circa</p>
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NOTE DELL'ESTENSORE DELLA SCHEDA

Si propone un "monitoraggio" che accompagni l'introduzione del DM in Azienda ed in particolare l'impiego del CRB per un periodo di una annualità limitatamente a max n. 250 casi (circa 1/3 del totale dei parti cesarei praticati nell'annualità 2017).

Al termine del periodo di monitoraggio i risultati e le considerazioni maturate saranno comunicate dalle UO interessate (UOC Ginecologia-Ostetrica, Farmacia e controllo di gestione) alla CTA-DM con apposita relazione scritta. Tali risultati consentiranno di concludere, in via definitiva, la parte valutativa e autorizzativa della richiesta.

Per quanto sopra si propone la generazione di uno smart-CIG dell'importo di circa € 15.000,00 (€ 60,00 x 250 pz) necessari per l'acquisizione di n. 25 confezioni del bene di che trattasi.

Qualora i Responsabili UOC Ginecologia-Ostetrica ritengano necessario un preliminare periodo di addestramento del personale, questo dovrà essere effettuato con beni messi a disposizione, a titolo gratuito, dalla ditta fornitrice.