

# EVALUATION OF THE INTRODUCTION OF A MEDICAL DEVICE FOR MECHANICAL INDUCTION OF LABOUR IN WOMEN WITH UNFAVOURABLE CERVIX

2SPD-019

24<sup>th</sup> European Association Of Hospital Pharmacists (EAHP) Congress  
Barcelona, Spain

27<sup>th</sup> - 29<sup>th</sup> March 2019

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<http://www.eahp.eu/24-2SPD-019>

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## Background

Multiple pharmacological, mechanical and complementary methods are available to induce labour and data from the literature suggest that most interventions have similar utility differing mainly in cost. The decision to apply different techniques is linked to the availability of pharmacological treatments and medical devices at the Centre.

To introduce mechanical induction of labour with the Cervical Ripening Balloon (CRB), a pilot-test was conducted to locally assess the necessity and the feasibility of the new technology.

Table 1. Pharmacological, mechanical and complementary methods available for induction of labour

Active intervention versus placebo	Caesarean section OR (95% CrIs)	No VD24 OR (95% CrIs)	Uterine hyperstimulation OR (95% CrIs)	NICU admission OR (95% CrIs)
Titrated (low-dose) oral misoprostol solution*	0.62 (0.47-0.80)	0.10 (0.07-0.29)	1.93 (0.73-4.19)	0.67 (0.39-1.07)
Buccal/sublingual misoprostol*	0.68 (0.51-0.89)	0.11 (0.05-0.19)	4.25 (1.71-9.02)	0.73 (0.42-1.19)
Vaginal misoprostol <50 µg*	0.70 (0.57-0.85)	0.11 (0.09-0.32)	2.75 (1.36-5.04)	0.74 (0.49-1.06)
Mifepristone*	0.71 (0.45-1.08)	0.76 (0.05-0.20)	Not estimable*	1.71 (0.73-3.55)
Oral misoprostol tablet ≥50 µg*	0.72 (0.58-0.88)	0.16 (0.05-0.20)	2.85 (1.41-5.20)	0.83 (0.55-1.20)
Vaginal misoprostol ≥50 µg*	0.73 (0.59-0.88)	0.09 (0.06-0.24)	4.40 (2.22-7.94)	0.85 (0.57-1.23)
Foley catheter*	0.76 (0.61-0.95)	0.19 (0.09-0.46)	0.92 (0.37-1.93)	0.66 (0.41-1.00)
Vaginal PGE <sub>2</sub> (gel)*	0.79 (0.65-0.94)	0.13 (0.08-0.50)	2.33 (1.10-4.40)	0.88 (0.59-1.26)
Nitric oxide*	0.82 (0.62-1.06)	0.22 (0.08-0.36)	0.38 (0.02-1.54)	0.82 (0.54-1.20)
Vaginal PGE <sub>2</sub> pessary (normal release)*	0.82 (0.62-1.09)	0.11 (0.04-0.16)	1.40 (0.37-3.68)	0.88 (0.51-1.40)
Intracervical PGE <sub>2</sub> *	0.83 (0.69-0.98)	0.18 (0.09-0.38)	1.70 (0.87-3.05)	0.76 (0.48-1.12)
Intravenous oxytocin with amniotomy*	0.89 (0.57-1.34)	0.05 (0.07-0.32)	7.44 (0.27-40.66)	1.60 (0.71-3.06)
Intravenous oxytocin*	0.93 (0.75-1.14)	0.20 (0.21-1.97)	2.12 (0.97-4.10)	0.76 (0.50-1.12)
Vaginal PGE <sub>2</sub> pessary (slow release)*	0.89 (0.69-1.12)	0.15 (0.08-0.29)	2.97 (1.36-5.73)	0.73 (0.44-1.11)
Sustained release misoprostol vaginal pessary*	0.98 (0.59-1.55)	0.11 (0.05-0.22)	5.58 (1.58-14.57)	0.59 (0.31-1.03)
Vaginal PGE <sub>2</sub> (tablet)*	1.04 (0.78-1.35)	0.16 (0.03-0.26)	1.99 (0.78-4.25)	0.83 (0.42-1.44)
Double balloon or Cook's catheter*	1.11 (0.73-1.63)	0.18 (0.01-0.16)	0.26 (0.00-1.18)	0.60 (0.26-1.15)
Oral misoprostol tablet <50 µg*	1.11 (0.64-1.81)	0.22 (0.07-0.39)	1.13 (0.28-3.15)	0.69 (0.31-1.63)
Corticosteroids	0.53 (0.20-1.12)	-	-	-
Hyaluronidase	0.61 (0.34-1.00)	-	-	-
PGF <sub>2</sub> gel	0.70 (0.40-1.16)	-	-	0.56 (0.18-1.36)
Oral prostaglandins	0.72 (0.08-2.59)	-	-	0.68 (0.09-2.40)
Membrane sweeping	0.74 (0.53-0.99)	-	-	0.83 (0.43-1.46)
Laminaria including dilapan	0.80 (0.43-1.38)	-	0.52 (0.01-2.62)	1.54 (0.40-4.31)
Acupuncture	0.81 (0.52-1.20)	-	-	0.94 (0.11-3.36)
Sexual intercourse	0.85 (0.54-1.29)	-	-	0.48 (0.14-1.17)
Relaxin	0.88 (0.33-1.96)	-	-	-
Extra-amniotic PGE <sub>2</sub> *	0.98 (0.57-1.57)	0.41 (0.07-1.33)	-	0.40 (0.16-0.82)
Amniotomy	1.06 (0.51-2.02)	-	-	0.84 (0.22-2.26)
Estrogens	1.27 (0.62-2.32)	-	-	1.43 (0.01-2.80)
Intravenous prostaglandin	19.94 (1.61-120.5)	-	-	-

\*Indicates that the intervention was included in the cost-effectiveness analysis.

## Purpose

To evaluate the introduction of CRB at the Centre.

## Material and methods

A clinical pilot-test was conducted to compare CRB to the pharmacological method already used at the Centre (slow release vaginal PGE<sub>2</sub> insert, Propess). The two induction methods were tested during six months in the delivery room (March-August 2018). Patients included were women with intact or ruptured membranes, at different gestational ages, with low (<3) Bishop score. Success of induction was defined as achievement of uncomplicated vaginal delivery. The number of vaginal deliveries within 24 hours and of caesarean sections were investigated and compared for both methods. Economic consequences for both methods were analysed.



Figure 1. Slow release vaginal PGE<sub>2</sub> insert, Propess

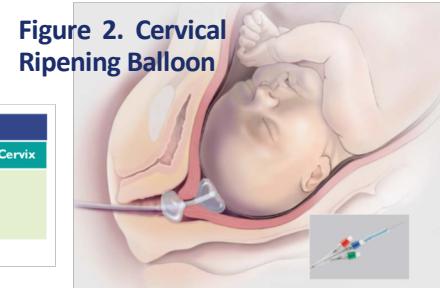


Figure 2. Cervical Ripening Balloon

Assessment Score	Dilation (cm)	Effacement (%)	Station	Consistency	Position of Cervix
0	Closed	0-30	-3 (engaged)	Firm	Posterior
1	1-2	40-50	-2	Moderate	Mid
2	3-4	60-70	-1/0	Soft	Anterior
3	≥5	≥80	+1/+2		

Add the score for each of the clinical assessments. If the total score is greater than 8, the success of induction approaches that of spontaneous labor.

Table 2. Bishop score

## Results

A total of 56 patients were included in 2 groups, homogeneous for indications to induction and obstetric characteristics.

Medical device  
vs  
drug

	CRB	Propess	p
Success rate > 24 h, n (%)	7/28 (25%)	2/28 (7%)	0.04
C-sections (%)	14%	14%	0.1

Table 4. Outcomes

Caesarean sections were comparable in the two groups (14% with CRB; 14% with Propess) however the reasons were different (1 case of uterine hyperstimulation with fetal heart rate changes in the CRB group).

The CRB group was associated with lower costs directly related to the method (-1,371.16 euro) however associated hospitalisation costs were higher due to longer hospitalisation (5 days versus 4 days).

	CRB	Propess	p
N patients	28	28	0.1
Age, mean ± SD	32.5 ± 5.8	32.4 ± 4.9	0.1
Gestational age (wk), mean ± SD	41.5 ± 2.5	41 ± 2	0.1
Nulliparous (%)	17/28 (61%)	22/28 (79%)	0.09

Table 3. Obstetric characteristics and indications for induction

The success of induction was comparable in the 2 groups. The time needed to achieve delivery by the vaginal route was on average longer with CRB (25% > 24 hours) than with Propess (7% > 24 hours), (p<0.05).

	CRB	Propess	
Direct costs (€), mean ± SD	€ 1117.54	€ 2488.64	-€ 1,371.16
Hospital stay (days), mean ± SD	5 ± 2.9	4 ± 1.1	+1

Table 4. Economic consequences

## Conclusion

Even though CRB is an effective method to induce labour at a lower cost than Propess in our pilot-test a longer hospitalisation length was observed with this device. Further studies are needed to evaluate the efficacy, safety and all direct costs involved in these techniques also considering other available methods.