

Double balloon catheter (+oxytocin) versus dinoprostone vaginal insert for term rupture of membranes: a randomized controlled trial (RUBAPRO)

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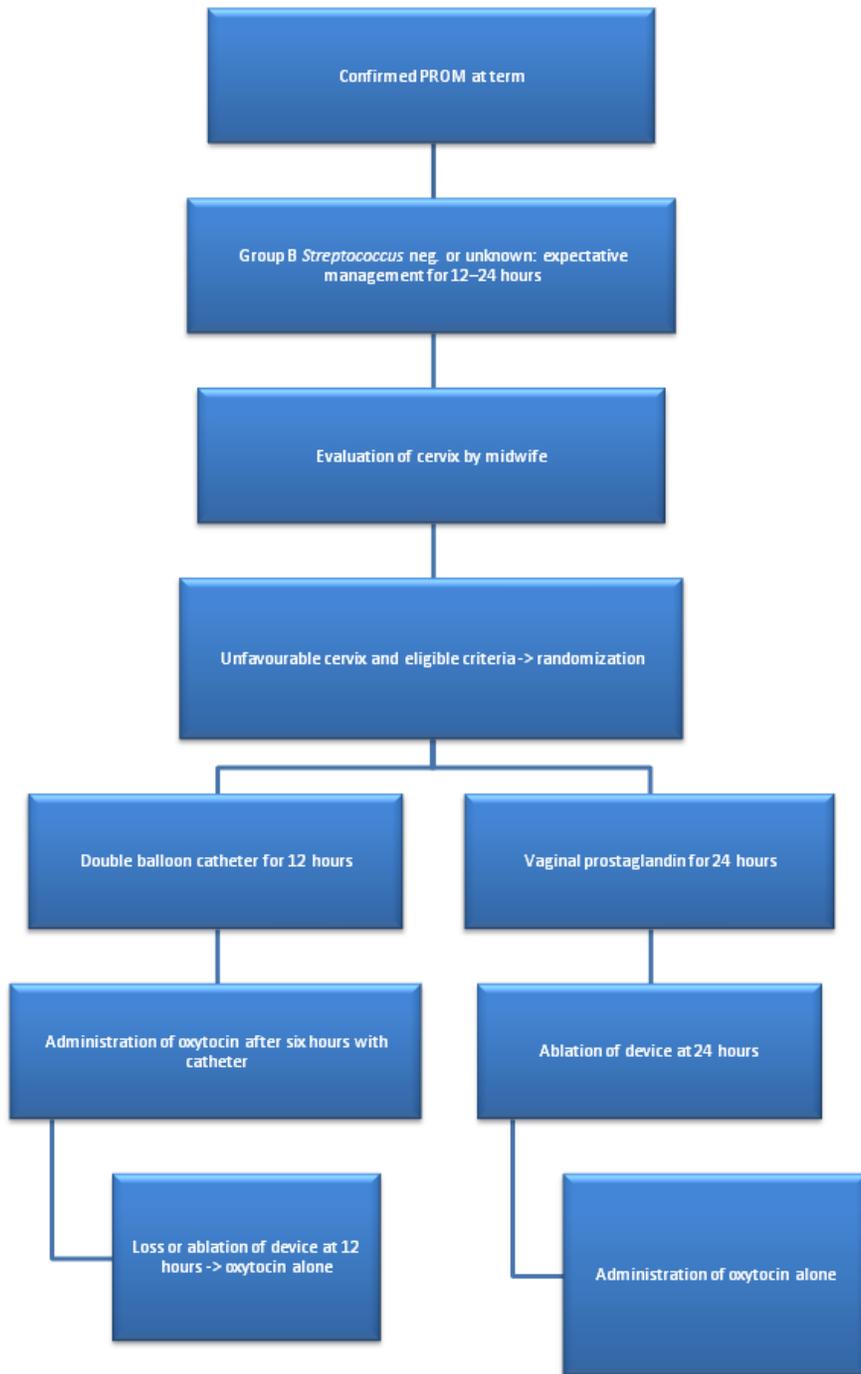
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Abstract

Objective: To demonstrate that a double balloon catheter combined with oxytocin decreases time between induction of labour and delivery (TID) as compared to a vaginal dinoprostone insert in cases of PROM at term. **Design:** Prospective, randomized, controlled trial. **Setting:** French university hospital **Population:** Patients undergoing labour induction for PROM at term with unfavorable cervix. **Methods:** We compared the double balloon catheter over a period of 12 hours with adjunction of oxytocin 6 hours after catheter insertion, versus dinoprostone vaginal insert. After device ablation, cervical ripening continued only with oxytocin. **Main outcome measures:** The primary outcome was TID. Secondary outcomes concerned delivery mode, maternal and fetal outcome and were adjusted for parity. **Results:** 40 patients per group were randomized. Each group had similar baseline characteristics. The study failed to demonstrate reduced TID (16.2 vs 20.2 hours, ES = 0.16 (-0.27 to 0.60), p=0.12) in catheter group versus dinoprostone except in nulliparous women (17.0 vs 26.5 hours, ES = 0.62 (0.10 to 1.14), p=0.006). The rate of vaginal delivery <24h significantly increased with combined induction (88.5% vs 66.6%, p=0.03). No statistical difference was observed concerning caesarean rate (12.5% vs 17.5%, p>0.05), chorioamnionitis (0% vs 2.5%, p=1), postpartum endometritis, maternal or neonatal outcomes. Procedure-related pain and tolerance to devices were found to be similar for the two methods. **Conclusion:** The double balloon catheter combined with oxytocin is an alternative for cervical ripening in case of PROM at term, and may reduce TID in nulliparous women.

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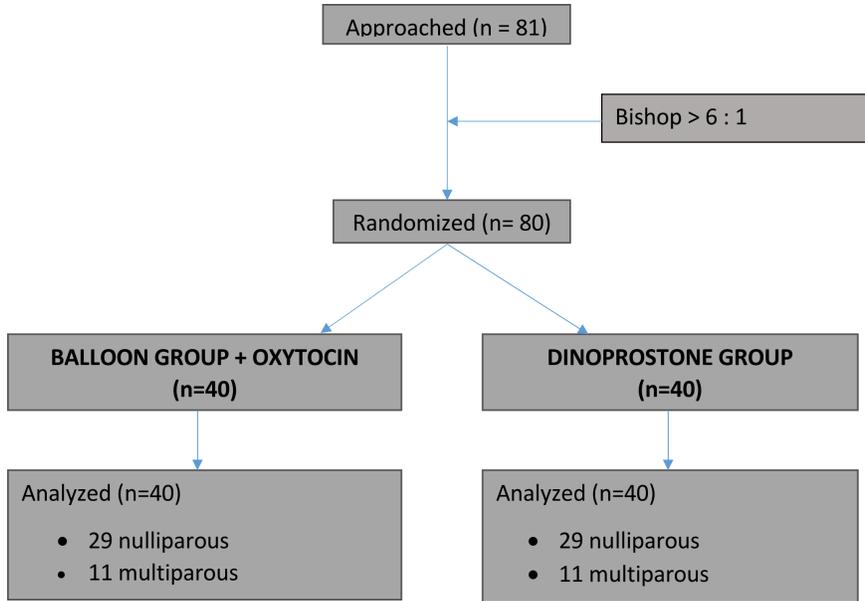
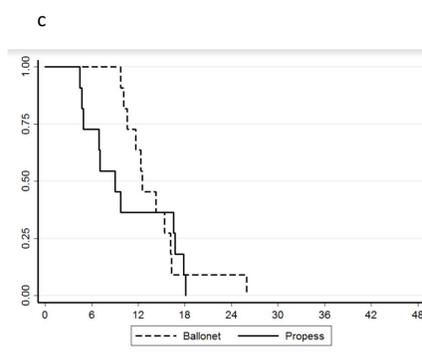
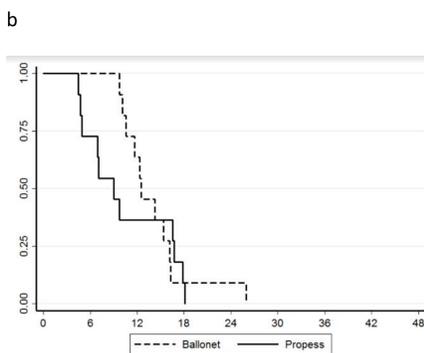
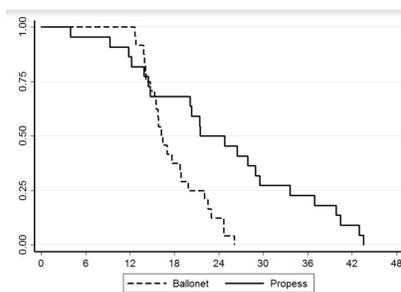
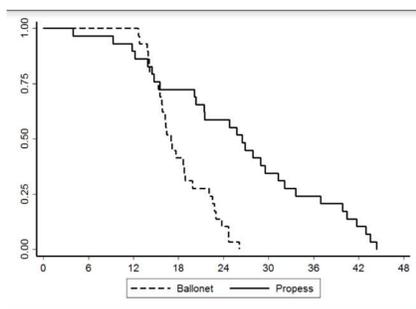
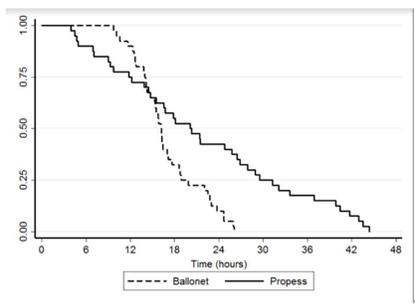


Fig. 2 Flowchart of randomization into treatment groups



a

b : Kaplan-Meier time curve for induction to delivery for entire study population

c : Kaplan-Meier time curve for induction to delivery for nulliparous and all deliveries modes

d : Kaplan-Meier time curve for induction to delivery for nulliparous and vaginal delivery

e : Kaplan-Meier time curve for induction to delivery for multiparous and all deliveries modes

f : Kaplan-Meier time curve for induction to delivery for multiparous and vaginal delivery