



Induction of labour in case of Premature Rupture Of Membranes (PROM) at term with an unfavourable cervix: A randomized controlled trial comparing double balloon catheter (+ oxytocin) and dinoprostone vaginal insert (RUBAPRO)

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Abstract

Objective: To demonstrate that double balloon catheter combined with oxytocin decreases time between induction of labour and delivery (TID) as compared to vaginal prostaglandin in case of premature rupture of membranes (PROM) at term.

Study design: This prospective, randomised, controlled trial compared the use of double balloon catheter during 12 hours with adjunct of oxytocin 6 hours after catheter introduction versus dinoprostone vaginal insert, in patient undergoing labour induction for PROM at term with unfavourable cervix (Bishop score < 6). After device ablation, cervical ripening continued only with intravenous oxytocin regardless the cervix dilatation. The main inclusion criteria were cephalic presentation, PROM without spontaneous labor at 12-24h, and no vaginal or urinary streptococcus B. Antibioprophylaxis was started 12 hours after PROM and was continued until delivery. The primary outcome was TID. Secondary outcomes described mode of delivery, maternal and foetal outcome according to parity.

Results: 40 patients per group were randomised between February 2018 and March 2019. Groups had similar baseline characteristics. The study failed to demonstrate reduced TID (1020 min vs 1308 min, $p=0.12$) except in nulliparous (1021 min vs 1589 min, $p=0.006$). The rate of vaginal delivery <24h were significantly decreased in case of nulliparous with mechanical induction (87.5% vs 50%, $p=0.01$) (Table 1). No statistical difference was observed concerning caesarean section rate (12.5% vs 17.5%, $p>0.05$), chorioamnionitis (0% vs 2.5%, $p=1$), post partum endometritis, maternal or neonatal outcomes (Cf. Table 2). The pain and tolerance were similar for the two devices.

Conclusion: Double balloon catheter combined with oxytocin could be an alternative to dinoprostone vaginal insert for cervical ripening in case of PROM with unfavourable cervix at term. This combination appeared to reduce TID in nulliparous group.

Biography

Devillard gained valuable experience in Obstetrics and in particular in clinical management of PROM in the team of Pr. Gallot (Clermont-Ferrand University Hospital) between 2017 and 2019. The team has a strong expertise in premature rupture of membrane (PROM) and induction of labor (IOL), and aims to assess the optimal device in case of PROM with an unfavourable cervix. For his thesis, he conducted the first prospective randomized trial comparing the association of mechanical ripening device and oxytocin versus vaginal prostaglandin to induce labor in case of PROM and unfavourable cervix at term.

Publication

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3. Kruit H, Tihtonen K, Raudaskoski T, Ulander V-M, Aitokallio-Tallberg A, Heikinheimo O, et al. Foley Catheter or Oral Misoprostol for Induction of Labor in Women with Term Premature Rupture of Membranes: A Randomized Multicenter Trial. *Am J Perinatol.* 2016 Jul;33(09):866–72.

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