European Journal of Obstetrics & Gynecology and Reproductive Biology xxx (xxxx) xxx

Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: www.elsevier.com/locate/euro

Editorial

Mechanical methods for induction of labor

Introduction

In recent years, numerous studies have been conducted, which have demonstrated the efficacy and safety of using mechanical methods for the induction of labor with an unfavorable Bishop Score (BS $\leq$ 6). Mechanical methods work by stimulating the endogenous production of prostaglandins (PG) by stretching the amnio-chorionic membranes and myometrial cells.

The analysis of the existing literature [1–13] highlights the advantages of mechanical methods over PG:

- Equal rates of caesarean deliveries (CD) compared to the use of prostaglandins (PGE2);
- Effectiveness comparable between PGE2 and PGE1;
- Reduced frequency risk of uterine hyperstimulation and reduced risk of fetal heart rate abnormalities
- Reduction of the risk of CD compared to the use of oxytocin;
- Better safety profile in women with previous CD;
- Lower cost compared to medical induction.

Conversely, there is heterogeneous data with resepect with whether there is an increased risk of maternal-neonatal infections with mechanical methods, particularly with balloon catheters [4,10–11]. Several studies have used premature rupture of membranes and ongoing maternal infections (chorio-amnionitis) as exclusion criteria, although antibiotic prophylaxis in women with Group B Streptococcus (GBS) positive vaginal swab reduces the number of endometritis in the postpartum period [11]. In mechanical induction in patients with preterm premature rupture of membranes (P-PROM) between 34 and 37 weeks of gestation, there were no statistically significant differences in the low rate of intrauterine infection compared to a group of PG-induced P-PROMs [14,15]. Overall, McMaster et al. in their systematic review and *meta*-analysis of the literature on the use of *trans*-cervical catheter and associated infectious morbidity did not report an increased infectious risk for the mother–child couple: similar rates of chorio-amnionitis were reported (7.2% vs 7.2%), endometritis (3.8% vs 3.5%) and neonatal infection (3.2% vs 3.6%) in the mechanical induction group versus prostaglandin groups [16–19].

In this consensus evaluation of current mechanical methods of induction of labor we shall discuss:

1. Membrane sweeping
2. Amniotomy
3. Balloon catheters
4. Synthetic osmotic dilators
5. Outpatient use

Membrane sweeping (Detachment of membranes)

The detachment of the amniotic membranes (also known as "membrane sweeping" and "membrane stripping") during vaginal examination is used to promote the onset of labor, comparable in all respects to a mechanical induction method. This manoeuvre increases the release of local PG [20,21]. In reality, the detachment of the membranes is an "adjuvant" techinque, which can be offered between the 40th and 41st week in nulliparous women and at the 41st week in multiparas, before resorting to a "formal" induction. All women should be advised that this procedure is associated with transient discomfort during the visit with light pain, minor bleeding and the onset of initially irregular contractions within 24 h [1]. This procedure must be documented and requires the patient's consent, even just verbal. The separation of the membranes involves the insertion of the examining finger beyond the inner cervical os followed by gently separating the amnio-chorion membranes from the lower uterine segment. In the case of a closed cervix, it is possible to perform a cervical massage with the index and middle finger for 15–30 s [1]. The data in the literature are conflicting in recognizing a real advantage deriving from this manoeuvre. One study reports that membrane dissection from week 38 onwards did not lead to major clinical benefits, other than an increased risk of premature rupture of the membranes [22]. In the case of women attempting vaginal delivery after CD, serial membrane detachments at term show no significant effect on: duration of pregnancy, onset of labor, induction of labor or CD [23]. A Cochrane review [21] found that routine membrane dissection performed weekly at term (after the 38th week) compared to non-treatment:

- Reduces the frequency of post-term pregnancies (beyond the 41st week);
- Reduces the use of pharmacological induction of labor;

https://doi.org/10.1016/j.ejogrb.2021.10.023
2215-1532/© 2021 Published by Elsevier B.V.

Please cite this article as: J. Gupta, O. Baev, J. Duro Gomez et al., Mechanical methods for induction of labor , European Journal of Obstetrics & Gynecology and Reproductive Biology, https://doi.org/10.1016/j.ejogrb.2021.10.023

- Reduces the likelihood of non-onset of labor within 48 h and failure to deliver within a week;
- No increase in maternal-fetal morbidity.

These favourable effects of the "membrane sweeping" manoeuvre have also emerged from a more recent systematic review and *meta*-analysis [24]. In 2020, an update on the practice of membrane dissection, presenting it as a possible option to initiate labour, showed with a good safety profile for the mother–child couple with no uterine hyperstimulation, no uterine rupture, no fetal distress at cardiotocography (CTG), no case of neonatal encephalopathy, being able to reduce the use of "formal" inductions and, being highly cost-effective. However, several questions remain about what is the optimal number of "membrane sweeps" attempts and the most appropriate timing to carry this manoeuvre [25].

Recommendation

To offer women membrane sweeping before formal induction of labour at antenatal visits from 39 + 0 weeks onwards and repeat this weekly if labour does not start spontaneously.

Amniotomy

Artificial rupture of membranes (also known as amniotomy or amniorexis) is one of the oldest and most performed technique in obstetric practice. It is simple to do when the cervix is favourable and the amnio-chorionic membranes are easily accessible [1]. The primary objective of amniotomy is to increase the intensity and frequency of uterine contractions and, therefore, to reduce the duration of labour related to the release of citokines and endogenous hormones [26]. Contraindications to this procedure are [1]:

- Placenta previa and vasa previa (due to the high risk of bleeding);
- Presenting part not engaged, increasing the risk of cord prolapse. To reduce the risk of this complication, it is necessary to leave the examining fingers in place until the presenting part descends onto the cervix [1],
- HIV infection;
- Active genital infections (excluding GBS).

Timing of amniotomy has been widely debated. A randomized study [27] observed that "early" amniotomy (dilation $\leq$ 4 cm) in primiparas reduces the duration of labor by approximately 2 h, while in another study it was associated with an increased risk of CD in primiparas [28]. In modern obstetric practice, in order to increase uterine contraction activity, oxytocin (OT) infusion is widely used in association with amniotomy, but the exact timing of amniotomy and initiation of OT infusion is highly variable [29]. Bala et al in a recent study observed how the timing of amniotomy ("early or delayed") and the associated oxytocin infusion, in the presence of a favorable BS, effect the course of labour. Amniotomy performed before initiating OT infusion ("early amniotomy"), reduces the induction-delivery time interval (7.35 vs 11.66 h, early vs delayed respectively), increases the rate of women giving birth within 12 h (86.7% vs 60%, early vs delayed respectively) and reduces the OT concentration used (30.05 mU/min vs 39.68 mU/min, early vs delayed respectively). In the group of amniotomy performed between 4 and 8 h after the start of the OT (delayed amniotomy) infusion, a lower rate of CD was reported (2.7% vs 10.7%); neonatal outcomes were similar in the two groups investigated [30]. The study by Beckmann et al compared two induction protocols based on the use of PG in vaginal gel vs amniotomy. The protocol based on the evening administration of one dose of vaginal PG gel, followed by amniotomy the next morning, showed a significant reduction in the induction-delivery interval compared to repeating a second dose of PG gel in place of amniotomy [31]. Regarding the possible risks associated with intentional rupture of membranes for induction/acceleration of labor, the most frequently reported (*albeit* with sometimes conflicting data) are dystocia of labor and the risk of CD. A randomized clinical trial observed that early amniotomy (dilation $\leq$ 4 cm) is associated with lower rates of dystocia and CD in the nulliparous group [32].

There is currently a lack of strong data to support the superiority of amniotomy over other induction methods and no absolute recommendations can be made for clinical practice.

Recommendations

To offer women with a Bishop score of more than 6 induction of labour with amniotomy and an intravenous oxytocin infusion.

Routine amniotomy is not recommended when labour is progressing normally because it does not reduce the duration of labour nor does it modify either the caesarean rate or the Apgar scores at birth. On the other hand, it is recommended as a first-line treatment, before oxytocin, when progress in dilation stops [33].

Balloon catheters

These are represented either by single balloon catheter (Foley catheter - off label use) and double balloon (Cook catheter).

With regard to *trans*-cervical balloon catheters, it is recommended [34]:

- Preliminary CTG tracing for at least 30 min as for any other induction method;
- Bishop score assessment and insertion of the catheter using sterile conditions through the internal os of the cervix.
- Slow introduction of 30 cc of saline solution and applying moderate traction on the catheter
- Slow introduction of another 30 cc (up to a maximum of 80 cc) of saline solution.
- Fixation of the catheter on the patient's inner thigh.
- Continue CTG monitoring for at least 30 min.
- If a double balloon is used: introduce another 50–80 cc of saline solution into the proximal balloon in the vagina.

The balloon catheter must be removed after 12 h in case of the double balloon and after 24 h in case of using a Foley. Pez et al. compared the single-balloon catheter with the double-balloon catheter and the prostaglandin induction with dinoprostone: a similar rate of vaginal deliveries was reported for all study groups (78% single balloon vs 75% double balloon vs 71% dinoprostone). There was an increased need for subsequent oxytocin infusion in the single-balloon catheter patient group. However, there was a significant difference in costs between the the single balloon (9 euros) vs double balloon (55 euros) vs dinoprostone (81 euros) [35].

The catheters must also be removed first in the presence of:

- PROM (heterogeneous literature data; few recent studies have been based on the use of balloon catheters even in cases of PROM and P-PROM);
- Spontaneous expulsion of the catheter;
- Onset of labor;
- CTG abnormalities

There is evidence of an increased risk of umbilical cord prolapse during the use of balloons for cervical ripening, especially in cases involving the use of disk-type and ball-type balloons filled with large amounts of water [36].

Overall, there is equal efficacy with balloon catheters compared to PGE1 and PGE2 but balloon catheters are associated with better safety profile i.e. reduced hyperstimulation and reduced fetal heart rate changes and better maternal satisfaction rates [18,19].

Synthetic osmotic dilators

The use of hygroscopic dilators for "cervical ripening" is an ancient practice, which is being rediscovered in recent years in many countries. It originated with the use of Laminaria, a product of natural origin, which involves the insertion into the cervix of seaweed stems, capable of absorbing liquids, expanding, and therefore gently dilating the cervix. Today the synthetic osmotic hygroscopic cervical dilator (Dilapan-S) is available and now preferred. Dilapan-S is a rigid 4 mm thick stick with a plastic handle that facilitates its insertion through the internal os. After insertion it increases its overall diameter (up to 15 mm) following the absorption of liquids from the cervix by way of osmosis and gradually dilating and softening the cervix. It stimulates the release of endogenous prostaglandins and softens the cervix. It is made with a special acrylic hydrogel, which by exploiting its "memory capacity" reaches an anisotropic swelling i.e. it affects only the diameter and not the length, and therefore guarantees, following hydration, a controlled radial expansion. The controlled radial expansion, combined with the high resistance to fractures of the device ensures a controlled swelling speed over 4–12 (up to 24) hours. Its main advantages compared to natural osmotic dilators is that it is synthetic and sterilized with gamma rays resulting in a level of predictability and safety, which cannot be offered either by the original laminaria analogues.

The manufacturer of the synthetic hygroscopic dilator recommends insertion of up to 5 dilators in succession into the cervical canal, leaving them in place for at least 12 h and in any case no longer than 24 h. The key element, similar to balloon catheters, is to ensure that the tip of the stick passes through the internal cervical os, to avoid the use of second series. Multiple rods insertion requires initial hands on training (learning curve), however once used routinely, it offers considerable short time and budget savings – no need for repeated vaginal examinations during ripening period, no requirement for CTG monitoring, and potential for outpatient (home) cervical ripening. Recommended insertion time is 12–15 h (overnight), however 80% of the swelling effect is reached during first 6–8 h [37].

A large international, multicenter observational study using synthetic osmotic dilators reported a good safety profile with low maternal complication rates (predominantly a reduced infectious risk) and no adverse neonatal outcome [37]. A recent randomized clinical trial (DILAFOL Trial) compared induction with osmotic dilator and Foley catheter. Both methods were comparable in terms of cervical ripening. In legal terms, the Foley bulb is an off-label use of the product while the synthetic osmotic cervical dilator is CE marked and FDA approved for induction of labor. The osmotic dilator showed a good safety profile with the advantage of avoiding a protrusion from the vaginal introitus. There was reduced maternal discomfort and therefore greater patient satisfaction with Dilapan [38]. Similar results have been obtained in another RCT (COMRED trial) comparing the hygroscopic synthetic dilator to oral misoprostol for pre-induction cervical ripening at term [39]. Dilapan-S was non inferior to oral misoprostol in efficacy outcome but showing better safety profile, patient satisfaction and pain scores. Furthermore, the literature data show an important reduction in the costs of the hygroscopic dilator i.e. it requires fewer interventions by healthcare professionals (single application and without continuous monitoring) offering the possibility of resorting to an outpatient induction regimen (so-called "home cervical ripening") particularly useful in this period of COVID 19 pandemia.

The use of osmotic dilators is a widely used practice in Japan. Other geographic areas (Europe and USA in particular) are gradually "rediscovering" the advantages linked to the use of synthetic osmotic cervical dilators. Regarding the presumed infectious morbidity linked to mechanical induction, no significant differences in the risk of intrauterine infection have been reported between hygroscopic dilators and balloon catheters [40].

Previous caesarean delivery

The use of balloon catheters for pre-induction in women with previous CD, although associated with a lower rate of vaginal deliveries, does not appear to be associated with an increased risk of uterine rupture compared to spontaneous labor or induced with amniotomy with or without the use of PGs or OT [41,42]. A cohort study confirmed the good safety and efficacy profile of mechanical induction with balloon catheter alone in women with previous CD who refuse other methods of induction [43]. A prospective study investigating cervical ripening in 100 patients using Dilapan-S after CD compared to a retrospective collective of patients with prostaglandin induction showed a similar outcome but those patients treated with Dilapan-S reported minimal side effects. Although the time until onset of labor was longer in the Dilapan-S group, the time period from onset of labor until delivery was similar and the overall stay in hospital was shorter when the induction were performed as an outpatient procedure [44].

Therefore, the use of osmotic dilators has also been proposed as an induction option in these women. However, there is insufficient information from randomized studies to base the clinical decision on which method is optimal for induction in women with previous CD [45].

Recommendation

Offer balloon catheters or synthetic hygroscopic dilators (Dilapan S) as a method for IOL, particularly in women with a previous caesarean delivery and/or where there is a higher risk of hyperstimulation.

Outpatient 'home' induction of labour

An emerging development of mechanical induction of labor, already in use in some countries, is the so-called *home cervical* ripening (outpatient cervical induction), which involves the insertion of the device and sending the patient home. This management offers the advantage of reducing costs for the health system (reducing the duration of hospitalization), and increasing the satisfaction rates of patients. Policiano et al observed that home cervical ripening with balloon catheter reduced the length of hospitaliza-

tion which was associated with a reduction in the rates of CD due to failed induction [46]. Furthermore, a multicentre randomized controlled trial observed favorable maternal and neonatal outcomes (evaluated on delivery mode, cord arterial pH, admission to neonatal intensive care unit, use of antibiotics). However, this study suggested that the double-balloon catheter is a safe method for induction of labour limited to nulliparous women, having observed an increased risk of unassisted vaginal delivery in the group of the multiparas (77.6% vs 92.3%, respectively) [47]. In nulliparous patients undergoing elective labor induction at term, outpatient cervical ripening with a Foley catheter reduced the time from admission to delivery [48]. Osmotic synthetic cervical dilators have also been proposed as a possible option of "outpatient induction" in nulliparous pregnant women with low-risk pregnancy [49]. In women with low-risk pregnancies, outpatient cervical ripening with dinoprostone or single balloon catheters did not increase caesarean deliveries. Although there were no clear differences in harms when comparing outpatient with inpatient cervical ripening, the certainty of evidence is low or insufficient to draw definitive conclusions [50]. It is to note that the COVID 19 pandemic impacted in some countries increasing the offer of home cervical ripening often linked with a change in method, from pharmaceutical to mechanical [51]. Outpatient cervical ripening has been found to have the potential to reduce hospital costs, hospital stay, and the caesarean section rate. It may potentially allow for better infection-prevention control during the ongoing COVID-19 pandemic and to free up resources such that more women might be offered elective IOL at 39 weeks [52].

In conclusion, the literature data shows a good overall safety and efficacy profile for these mechanical methods of induction of labor, in which there is a growing renewed interest.

Advantages and disadvantages of balloon catheters and osmotic dilators compared with pharmacological methods for induction of labour

PROS.

- Overall reduced applications compared to pharmacological methods
  - single round (balloon catheter)
  - single or multiple rounds (synthetic hygroscopic dilators)
- Minimal uterine hyperstimulation and minimal fetal heart rate abnormalities
- Less need for intensive maternal-fetal monitoring
- Less recourse to CD for failed induction
- Good safety profile in patients with previous CD
- Minimal maternal and neonatal morbidity rate
- Less discomfort with osmotic dilators, which do not protrude externally
- No need for refrigeration
- Potential for home cervical induction
- Reduced costs compared to pharmacological inductions
  - shorter length of hospitalization
  - reduction in health costs
  - better hospital organization
  - improved patient satisfaction

CONS.

- Increased need for amniotomy and oxytocin
- Infectious morbidity (heterogeneous data for balloon catheters but not increased with synthetic osmotic dilators)
- P-PROM (heterogeneous data)
- Lower rate of vaginal delivery within 24 h but equivalent rates at 36 and 48 h

Conclusions

PGEs are still accepted as standard of care for IOL in many settings despite the fact that there is good evidence from RCTs and *meta*-analysis confirming equivalent efficacy and better safety profile of mechanical methods.

Mechanical methods are slower than PGEs in achieveing vaginal birth within 24 h but equivalent at 36 and 48 h.

Along safety benefits compared to PGs, mechanical methods can also offer time and health care budget savings (no need of repeated CTGs and/or vaginal examinations during ripening period), and are more suitable for home outpatient cervical ripening.

Compared to balloon catheters, synthetic hygroscopic cervical dilators offer equal efficacy and safety profile but better maternal compliance and satisfaction.

References

[1] Leduc D et al. Induction of Labour. SOGC Clinical Practice Guideline No. 296, Sep 2013. J Obstet Gynaecol Can 2013;35(9):840–60.
[2] WHO Recommendations for Induction of labour, 2011.
[3] Cromi A, et al. A randomized trial of preinduction cervical ripening: dinoprostone vaginal insert versus double-balloon catheter. Am J Obstet Gynecol 2012; 207(2):125. e1-7.
[4] Jagielska I et al. Evaluation of the efficacy and safety of Foley catheter preinduction of labor. Ginekol Pol. 2013;84(3):180–5.
[5] Jozwiak M, Oude Rengerink K, Ten Eikelder MLG, van Pampus MG, Dijksterhuis MGK, de Graaf IM, et al. Foley catheter or prostaglandin E2 inserts for induction of labour at term: an open-label randomized controlled trial (PROBAAT-P trial) and systematic review of literature. Eur J Obstet Gynecol Reprod Biol. 2013;170(1):137–45.
[6] Fox NS et al. Intravaginal misoprostol versus Foley catheter for labour induction: a meta-analysis. BJOG 2011;118(6):647–54.
[7] Rossard L et al. Cervical ripening with balloon catheter for scared uterus: a three-year retrospective study. J Gynecol Obstet Biol Reprod 2013;42(5):480–7.
[8] Sarreau M et al. Balloon catheter for cervical ripening on scarred uterus with unfavorable cervix: multicenter retrospective study of 151 patients. J Gynecol Obstet Biol Reprod. 2014;43(1):46–55.
[9] Jozwiak M et al. Mechanical methods for induction of labour. Cochrane Database Syst Rev 2012;14(3):1233.
[10] Sciscione AC. Methods of cervical ripening and labor induction: mechanical. Clin Obstet Gynecol 2014;57(2):369–76.
[11] Heinemann J, Gillen G, Sanchez-Ramos L, Kaunitz AM. Do mechanical methods of cervical ripening increase infectious morbidity? A systematic review. Am J Obstet Gynecol 2008;199(2):177–88.
[12] Mozurkewich EL, Chilimigras JL, Berman DR, Perni UC, Romero VC, King VJ, et al. Methods of induction of labour: a systematic review. BMC Pregnancy and Childbirth 2011;11(1). doi: https://doi.org/10.1186/1471-2393-11-84.
[13] Kosec V et al. Cervical ripening balloon as a method of preinduction - one center study. Acta Clin Croat 2018;57(4):762–7.
[14] Tournier A, Clouqueur E, Drumez E, Petit C, Guckert M, Houfflin-Debarge V, et al. Can we induce labor by mechanical methods following preterm premature rupture of membranes? J Gynecol Obstet Human Reprod. 2020;49(8):101745. doi: https://doi.org/10.1016/j.jogoh.2020.101745.
[15] Kruit H, Tolvanen J, Eriksson J, Place K, Nupponen I, Rahkonen L. Balloon catheter use for cervical ripening in women with term pre-labor rupture of membranes: A 5-year cohort study. Acta Obstet Gynecol Scand. 2020;99 (9):1174–80. doi: https://doi.org/10.1111/aogs.v99.910.1111/aogs.13856.
[16] Gommers JSM, Diederen M, Wilkinson C, Turnbull D, Mol BWJ. Risk of maternal, fetal and neonatal complications associated with the use of the transcervical balloon catheter in induction of labour: A systematic review. Eur J Obset Gynecol Reprod Biol. 2017;218:73–84.
[17] McMaster K et al. Evaluation of a Transcervical Foley Catheter as a Source of Infection: A Systematic Review and Meta-analysis. Obstet Gynecol 2015;126 (3):539–51.
[18] Jozwiak M, Oude Rengerink K, Benthem M, van Beek E, Dijksterhuis MG, de Graaf IM, van Huizen ME, Oudijk MA, Papa-tsonis DN, Perquin DA, Porath M, van der Post JA, Rijnders RJ, Scheepers HC, Spaanderman ME, van Pampus MG,

de Leeuw, Mol BW, Bloemenkamp KW, PROBAAT Study Group. Foley catheter versus vaginal prostaglandin E2 gel for induction of labour at term (PROBAAT trial): an open-label, randomised controlled trial. Lancet. 2011;378 (9809):2095–103. doi: https://doi.org/10.1016/S0140-6736(11)61484-0. Epub 2011 Oct 24. PMID: 22030144.

[19] Ten Eikelder ML, Oude Rengerink K, Jozwiak M, de Leeuw JW, de Graaf IM, van Pampus MG, et al. Induction of labour at term with oral misoprostol versus a Foley catheter (PROBAAT-II): a multicentre randomised controlled non-inferiority trial. Lancet 2016;387(10028):1619–28. doi: https://doi.org/10.1016/S0140-6736(16)00084-2. Epub 2016 Feb 3 PMID: 26850983.

[20] McColgin SW, Bennett WA, Roach H, Cowan BD, Martin JN, Morrison JC. Parturitional factors associated with membrane stripping. Am J Obstet Gynecol 1993;169(1):71–7.

[21] Boulvain M et al. Membrane sweeping for induction of labour. Cochrane Database Syst Rev 2005;1:451.

[22] Hill MJ, McWilliams GD, Garcia-Sur D, Chen B, Munroe M, Hoeldtke NJ. The effect of membrane sweeping on prelabor rupture of membranes: a randomized controlled trial. Obstet Gynecol 2008;111(6):1313–9.

[23] Ghafarzadeh M, Moeininasab S, Namdari M. Effect of early amniotomy on dystocia risk and cesarean delivery in nulliparous women: a randomized clinical trial. Arch Gynecol Obstet 2015;292(2):321–5.

[24] Avdiyovski H, Haith-Cooper M, Scally A. Membrane sweeping at term to promote spontaneous labour and reduce the likelihood of a formal induction of labour for postmaturity: a systematic review and meta-analysis. J Obstet Gynecol 2019;39(1):54–62.

[25] Finucane EM et al. Membrane sweeping for induction of labour. Cochrane Database Syst Rev. 2020;2(2):CD000451.

[26] Vadivelu M, Rathore S, Benjamin SJ, Abraham A, Belavendra A, Mathews JE. Randomized controlled trial of the effect of amniotomy on the duration of spontaneous labor. Int J Obstet Gynaecol 2017;138(2):152–7.

[27] Macones GA, et al. The efficacy of early amniotomy in nulliparous labor induction: a randomized controlled trial. Am J Obstet Gynecol. 2012; 207:403.e1-5.

[28] Lee SM, Lee KA, Lee JH, Park C-W, Yoon BH. Early rupture of membranes after the spontaneous onset of labor as a risk factor for cesarean delivery. Eur J Obstet Gynecol Reprod Biol 2010;148(2):152–7.

[29] Clark SL, et al. Oxytocin: new perspectives on an old drug. Am J Obstet Gynecol. 2009; 200:35.e1-6.

[30] Bala A, Bagga R, Kalra J, Dutta S. Early versus delayed amniotomy during labor induction with oxytocin in women with Bishop's score of ≥6: a randomized trial. J Matern Fetal Neonat Med 2018;31(22):2994–3001.

[31] Beckmann M, et al. Prostaglandin vaginal gel induction of labor comparing amniotomy with repeat prostaglandin gel. Am J Obstet Gynecol. 2015;213 (6):859.e1-9.

[32] Takahashi T, Marcus B, Scheerer RG, Katz M. A new model for objective assessment of cervical ripening: the effect of prostaglandin E2 and prelabor contractility. Am J ObstetGynecol 1991;164(4):1115–8.

[33] Petitprez K et al. Normal delivery: physiologic support and medical interventions. Guidelines of the French National Authority for Health (HAS) with the collaboration of the French College of Gynecologists and Obstetricians (CNGOF) and the French College of Midwives (CNSF). J Matern Fetal Neonatal Med 2021:1–10. doi: https://doi.org/10.1080/14767058.2021.1918089.

[34] Tabasi Z, Mesdaghinia E, Abedzadeh-Kalahroudi M, Sehat M, Panahandeh A. Comparing the effects of vaginal misoprostol, laminaria, and extra amniotic saline infusion on cervical ripening and induction of labor. Obstet Gynecol Sci. 2020;63(3):261–9.

[35] Pez V et al. Cervical ripening and labor induction: Evaluation of single balloon catheter compared to double balloon catheter and dinoprostone insert. Gynecol Obstet Fertil Senol. 2018;46(7–8):570–4.

[36] Hasegawa J, Sekizawa A, Ikeda T, Koresawa M, Ishiwata I, Kawabata M, et al. The use of balloons for uterine cervical ripening is associated with an increased risk of umbilical cord prolapse: population based questionnaire survey in Japan. BMC Pregnancy Childbirth. 2015;15(1). doi: https://doi.org/10.1186/s12884-015-0432-4.

[37] Gupta J, Chodankar R, Baev O, Bahlmann F, Brega E, Gala A, et al. Synthetic osmotic dilators in the induction of labour - An international multicentre observational study. Eur J Obstet Gynecol Reprod Biol. 2018;229:70–5.

[38] Saad AF et al. A randomized controlled trial of Dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL trial). Am J Obstet Gynecol 2019;220 (3):275.e1-275.e9.

[39] Gavara R, Saad D, Wapner R COMRED: comparison of misoprostol ripening efficacy with Dilapan-S ACOG Annual Scientific Meeting, poster presented, April 30-May 2, 2021

[40] Shindo R, Aoki S, Yonemoto N, Yamamoto Y, Kasai J, Kasai M, et al. Hygroscopic dilators vs balloon catheter ripening of the cervix for induction of labor in nulliparous women at term: Retrospective study. PLoS ONE 2017;12(12):e0189665.

[41] Bujold E, Blackwell SC, Gauthier RJ. Cervical ripening with transcervical foley catheter and the risk of uterine rupture. Obstet Gynecol. 2004;103(1):18–23.

[42] Lamourdedieu C et al. Risk of uterine rupture after cervical ripening with ballon catheter on uterus with previous cesarean section. J Gynecol Obstet Biol Reprod. 2016;45(5):496–501.

[43] Atia H, Ellaithy M, Altraigey A, Kolkailah M, Alserehi A, Ashfaq S. Mechanical induction of labor and ecbolic-less vaginal birth after cesarean section: A cohort study. Taiwan J Obstet Gynecol. 2018;57(3):421–6.

[44] Maier JT et al. Induction of labor inpatients with an unfavourable cervix after a cesarean unsing an osmotic dilator versus vaginal prostaglandin. J Perinat Med 2018;46(3):299–307.

[45] Jozwiak M et al. Methods of term labour induction for women with a previous caesarean section. Cochrane Database of Systematic Reviews 2013;3: CD009792.

[46] Policiano C, Pimenta M, Martins D, Clode N. Outpatient versus inpatient cervix priming with Foley catheter: A randomized trial. Eur J Obstet Gynecol Reprod Biol. 2017;210:1–6.

[47] Beckmann M, Gibbons K, Flenady V, Kumar S. Induction of labour using prostaglandin E 2 as an inpatient versus balloon catheter as an outpatient: a multicentre randomised controlled trial. BJOG 2020;127(5):571–9.

[48] Ausbeck EB et al. Outpatient Foley Catheter for Induction of Labor in Nulliparous Women: A Randomized Controlled Trial. Obstet Gynecol. 2020;136(3):597–606. doi: https://doi.org/10.1097/AOG.0000000000000404.

[49] Crosby DA, O'Reilly C, McHale H, McAuliffe FM, Mahony R. A prospective pilot study of Dilapan-S compared with Propess for induction of labour at 41+ weeks in nulliparous pregnancy. Ir J Med Sci. 2018;187(3):693–9.

[50] McDonagh M et al. Outpatient Cervical Ripening: A Systematic Review and Meta-analysis. Obstet Gynecol. 2021;137(6):1091–101. doi: https://doi.org/10.1097/AOG.0000000000004382.

[51] Harkness M, Yuill C, Cheyne H, Stock SJ, McCourt C. Induction of labour during the COVID-19 pandemic: a national survey of impact on practice in the UK. BMC Pregnancy Childbirth 2021;21(1). doi: https://doi.org/10.1186/s12884-021-03781-x.

[52] Saunders SJ et al. Out-of-Hospital Cervical Ripening With a Synthetic Hygroscopic Cervical Dilator May Reduce Hospital Costs and Cesarean Sections in the United States—A Cost-Consequence Analysis. Front Public Health 2021. doi: https://doi.org/10.3389/fpubh.2021.689115.

Janesh Gupta [a,*]
Oleg Baev [b]
Jorge Duro Gomez [c]
Charles Garabedian [d]
Lars Hellmeyer [e]
Rhona Mahony [f]
Josefine Maier [e]
Antonin Parizek [g]
Viktor Radzinsky [k]
Jan Stener Jorgensen [h]
Ulla Britt Wennerholm [i]
Gian Carlo Di Renzo [j]

[a] *Birmingham, UK*

[b] *Research Center for Obstetrics, Gynecology and Perinatology, Moscow, Russia*

[c] *Hospital Universitario Reina Sofía, Córdoba, Andalusia, Spain*

[d] *Division of Obstetrics, Hospitalier Régional Universitaire de Lille, Lille, France*

[e] *Department of Gynecology and Obstetrics, Vivantes International Medicine, Am Nordgraben 2, 13509 Berlin - Germany*

[f] *National Maternity Hospital, Dublin, Ireland*

[g] *Department of Obstetrics and Gynaecology of the 1st Faculty of Medicine and General University Hospital, Prague, Czech Rep*

[h] *Department of Obaterics and Gynecology, Odense University Hospital, Denmark*

[i] *Department of Obstetrics and Gynecology, The University of Gothenburg, Gothenburg, Sweden*

[j] *Department of Obstetrics and Gynecology, University of Perugia, Perugia, Italy*

[k] *People's Friendship University of Russia, 6, Miklukho-Maklaya st., Moscow*

* Corresponding author at: Professor of Obstetrics and Gynaecology Centre for Women's and Newborn Health Institute of Metabolism and Systems Research (IMSR) University of Birmingham Birmingham Women's and Children's NHS Foundation Trust, Birmingham, B15 2TG, England.
E-mail address: j.k.gupta@bham.ac.uk (J. Gupta)

Available online xxxx