Josefine Theresia Koenigbauer*, Julia Kummer, Marcel Malan, Luisa Maria Simon, Lars Hellmeyer, Ioannis Kyvernitakis, Hoger Maul, Peter Wohlmuth and Werner Rath

Preinduction cervical ripening in an outpatient setting: a prospective pilot study of a synthetic osmotic dilator compared with a double-balloon catheter

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Abstract

Objectives: To compare the effectiveness, safety and patient satisfaction of a double balloon catheter (DB) with a synthetic osmotic cervical dilator (OD) for pre-induction cervical ripening in an outpatient setting.
Methods: This is a prospective, dual-center pilot study including 94 patients with an unripe cervix (Bishop Score <6) near term; 50 patients received the DB and 44 patients the OD. The primary outcomes *were the difference in Bishop Score (BS) and cervical shortening*. Pain perception at insertion and during the cervical ripening period was evaluated by a visual analogue scale and patient satisfaction by a predefined questionnaire.
Results: The use of DB was associated with a significantly higher increase in BS (median 3) compared to OD (median 2; p=0.002) and resulted in significantly greater cervical shortening (median −14 mm vs. −9 mm; p=0.003). There were no serious adverse events at placement of devices or during the cervical ripening. There were no significant differences in perinatal outcomes. Pain perception during cervical ripening was significantly higher (p<0.001), and patient satisfaction regarding sleep, relaxing time and performing desired daily activities were significantly lower in patients with DB compared to patients with OD (p<0.001).
Conclusions: DB was superior to OD regarding cervical ripening based on BS and on sonographic measurement of the cervical length. Patients with OD experienced less pain during cervical ripening and were more satisfied with the method compared to patients with DB.

Keywords: cervical ripening; osmotic dilator; double balloon catheter; labor induction; mechanical ripening; outpatient cervical ripening

Introduction

In the last 20 years, labor induction rates have almost doubled in high-income countries. Almost one third of labor induction cases require cervical ripening [1]. The process of cervical ripening in women with an unfavorable cervix is typically extensive, necessitating an extended duration of hospitalization [2]. Inducing uterine contractions when the cervix remains unripe fails to expedite the birthing process. Instead, it may place additional stress on the feto-placental unit due to contraction-related uterine hypoperfusion, and therefore often reduces acceptance among pregnant women [3]. The increasingly advocated strategy is to initially commence cervical ripening, preferably in an outpatient setting, before proceeding to induce labor in the hospital [4]. Hence, mechanical methods (Foley Balloon catheter, double-balloon catheter, synthetic cervical dilators as Dilapan-S) have gained growing interest for pre-induction cervical ripening. The detailed mechanisms by which these mechanical devices achieve cervical ripening have been recently elucidated [5].

Josefine Theresia Koenigbauer and Julia Kummer contributed equally to this work.

***Corresponding author: Josefine Theresia Koenigbauer**, Department of Obstetrics, University Hospital Charité, Charitéplatz 1, 10117 Berlin, Germany, E-mail: josefine.Koenigbauer@charite.de. https://orcid.org/0000-0003-4817-3368
Julia Kummer, Luisa Maria Simon and Lars Hellmeyer, Department of Gynecology and Obstetrics, Vivantes Klinikum Im Friedrichshain, Berlin, Germany
Marcel Malan, Faculty of Medicine, Obstetrics and Gynecology, University Hospital Schleswig-Holstein, Kiel, Germany; and Department of Gynecology and Obstetrics, Asklepios Kliniken Barmbek, Wandsbek und Nord-Heidberg, Hamburg, Germany. https://orcid.org/0000-0001-8154-6950
Ioannis Kyvernitakis and Hoger Maul, Department of Gynecology and Obstetrics, Asklepios Kliniken Barmbek, Wandsbek und Nord-Heidberg, Hamburg, Germany
Peter Wohlmuth, Asklepios Proresearch, Hamburg, Germany
Werner Rath, Faculty of Medicine, Obstetrics and Gynecology, University Hospital Schleswig-Holstein, Kiel, Germany

The Foley Balloon has been the "gold standard" for decades, but it was never officially approved or licensed by national authorities for pre-induction cervical ripening/induction of labor. The double balloon (DB) and Dilapan S (osmotic dilator, OD), both are approved, the latter in 2015 by the Food and Drug Administration (FDA). This may explain why the vast majority of studies on mechanical methods for cervical ripening investigated the use of Foley Balloon and the double ballon catheter, while data on the application of Dilapan S were somewhat limited.

Compared to vaginal prostaglandin E2 (PGE2) and misoprostol balloon catheters as well as synthetic cervical dilators have shown to be equally effective in achieving vaginal delivery [4, 6–12].

The main advantages of mechanical methods in an outpatient setting compared to PGE2/misoprostol for cervical ripening are the significantly lower rate of uterine hyperstimulation, lower monitoring cost during the cervical ripening period, lower socioeconomic costs due to less admission time to delivery, the absence of severe maternal and fetal side effects and higher patient satisfaction [4, 12, 13]. This mechanism may explain the safe and effective use of mechanical methods for cervical ripening in women who have had one prior cesarean section [14–17]. However, oxytocin is required in up to 90 % of cases for induction or augmentation of labor.

As recently highlighted by Chen and Sheehan mechanical methods are safer than pharmacological priming for outpatient pre-induction cervical ripening in low-risk pregnancies [18]. According to some recent systematic reviews and meta-analyses outpatient cervical ripening compared to inpatient cervical ripening in low-risk pregnancies has been found to be associated with a lower rate of cesarean delivery, a shorter admission to delivery interval, a significantly shorter hospital stay duration and lower hospital costs without significant differences in maternal and neonatal outcomes [4, 19–22].

A comparative analysis of Dilapan S and Foley Balloon did not reveal any significant differences between both methods regarding the rate of vaginal delivery with a better patient satisfaction in favor of Dilapan S [7, 23]. A randomized clinical trial comparing inpatient to outpatient preinduction cervical ripening with Dilapan S concluded that outpatient cervical ripening was safe and decreased hospital stay without significant differences in adverse outcomes [24].

The aim of this study was to evaluate the efficacy and safety as well as patient satisfaction of a synthetic cervical dilator (Dilapan-S, OD) vs. a double-balloon catheter (DB) in an outpatient setting.

Materials and methods

This research was a prospective, dual-center pilot study that did not receive any funding. Approvals from both Ethical Committees were obtained (Ärztekammer Berlin Ethik-59/21, Hamburg 2022-200398-Bombet). Written informed consent was obtained from all participating women. Study monitoring was performed by an independent data and safety monitoring committee. Data were stored anonymously and only our research team (authors) had access to the data.

Patients qualified for inclusion if they met the following criteria:

- Pregnant women with an indication of induction of labor
- Maternal age of at least 18 years
- Understanding and capable to sign informed consent
- Singleton pregnancy
- Gestational age >37 0/7 weeks (based on a first trimester dating ultrasound)
- Vital fetus in cephalic presentation
- Intact membranes
- Pelvic exam of Bishop score <6
- Short distance from home to hospital (maximum 30 min)

Exclusion criteria were:

- Active labor
- Active genital herpes lesions
- Chorioamnionitis
- Contraindications for vaginal delivery
- Active vaginal bleeding
- Previous cesarean delivery or uterine surgery
- Non-reassuring fetal status
- Abnormal placenta location (e.g. placenta previa)
- Positive streptococcus B smear test
- Fetal anomaly
- Requirement of inpatient care (e.g. preeclampsia, insulin-depended diabetes) and/or for continuous maternal or fetal monitoring during ripening
- Absence of support person (no adult accompanying the women during outpatient cervical ripening period)

Management

Women presenting for induction of labor and who met eligibility criteria and consented either received the double-balloon catheter (DB/in Hamburg) or the synthetic cervical dilator (OD/in Berlin). Before placement of the devices the Bishop score was obtained, and the cervical

length was measured in a standardized method by vaginal ultrasound in millimeters from the internal to the external os along the cervical canal according to the FMF criteria. Women assigned to both groups underwent continuous cardiotocography for 30 min. Before placement, the cervix was visualized with a sterile speculum. The synthetic cervical dilator (Dilapan-S: rod size: 4 × 45 mm) was inserted by trained medical staff. Up to five rods were placed into the cervical canal under direct visualization and according to the manufacturer's instruction leaflet. It was ensured that the tip of the rod slightly passed the internal os. The synthetic cervical dilators were left in place for at least 24 h. After placement, patients were monitored and cardiotocography was performed for 30 min. If there were no contraindications for outpatient management such as rupture of membranes, active vaginal bleeding, nonreassuring fetal condition according to the FIGO criteria, evidence of labor, or other severe medical conditions excluding outpatient cervical ripening, the patients opted for it and could be readmitted to the hospital within 30 min, if needed. Instructions were given to patients to return to the delivery unit after 24 h, or earlier if indicated (e.g. vaginal bleeding, rupture of membranes, regular uterine contractions, decreased fetal movements or other concerns). Patients were suitable for an outpatient management and were advised not to restrict daily activities during the ripening period. Written information was provided for conditions, which need immediate admission to the hospital. Women in the DB group underwent the same procedures as described. DB was placed under direct visualization and per the manufacturer's instructions for use and both balloons were filled with up to 80 mL of sterile 0.9 % NaCl and left in place for at least 24 h. Pre- and postplacement procedures were identical to the OD group. After 24 h, or earlier, if indicated, at admission the BS was obtained again, and the sonographic cervical length was measured in the same manner in both groups. If the cervix remained unfavorable (BS <6) and the patient was not in labor, a 10 mg PGE2 vaginal insert was applied for 24 h. If the cervix was ripe (BS >6) and the patient was not in labor, induction with intravenous oxytocin was initiated according to the local standard operating procedure until regular uterine contractions were achieved.

Participants were interviewed by research personal immediately after insertion and postpartum and completed questionnaires including eight questions concerning overall satisfaction with each method, ability to rest, sleep and to perform desired daily activities during the ripening period. Additionally, patients were asked, if they want to have an outpatient cervical ripening with the same method in their next pregnancy, and if they would recommend this procedure to other pregnant women. Questions were rated on a scale from 1 to 5. Pain at placement and during the cervical ripening was assessed using a visual analogue scale.

Our primary outcomes were the changes in BS and in the sonographic cervical length at insertion and at removal of the devices. Secondary outcomes were defined *a priori* and included the rate of vaginal delivery and cesarean delivery, time from insertion to delivery in hours and adverse events at insertion and during the cervical ripening period, uterotonic use for induction/augmentation of labor, the rate of uterine hyperstimulation, perinatal outcomes and patient satisfaction including pain at placement and during the cervical ripening period.

Statistical analysis

Maternal age, Bishop score, cervix length, time of insertion, of labor and of birth were collected. Furthermore, data about vaginal birth, the use of oxytocin, uterine overstimulation, complications during insertion and birth, perinatal outcome and satisfaction questionnaire were documented. The data were summarized as follows: metric data were shown with median, lower and upper quartile (in case data were not normally distributed), or mean and standard deviation (in case of normal distribution). Categorical data were presented with percentages and frequencies. Differences between groups were examined using Wilcoxon rank sum test and Pearson's Chi-squared test, respectively. Linear regression models were applied to predict Bishop score and cervix length at admission from group (osmotic dilator or double balloon catheter), adjusted according to pre-insertion values. Ps and differences between pre and post values were shown. Two-sided Ps were calculated. A $p<0.05$ was considered significant. Calculations were performed using the statistical analysis software R (R Core Team, 2024).

Results

Baseline variables

From January 2022 to July 2023 94 women were included into the study and underwent outpatient cervical ripening (44 to OD, 50 to DB). Baseline variables are comparable among the groups and revealed no differences, except for the frequency of gestational diabetes, which was significantly higher in the OD group (Table 1). The median number of rods inserted was 5.00 [4.00, 5.00].

Table 1: Maternal characteristics according to the trial groups.

Characteristics	Treatment groups		p-Value
	DB, n=50	OD, n=44	
Maternal age in years, median [Q1, Q3]	31.5 [28.0, 35.8]	31.0 [27.0, 33.0]	0.26
Pre-pregnancy BMI in kg/m^2, median [Q1, Q3]	26.4 [24.0, 29.1]	24.9 [22.6, 28.3]	0.10
BMI at delivery in kg/m^2, median [Q1, Q3]	32.9 [28.7, 34.7]	30.1 [27.3, 33.8]	0.14
Gestational week at insertion, median [Q1, Q3]	41.00 [41.00, 42.00]	41.00 [40.00, 42.00]	0.28
Nullipara, n, %	15 (30.0)	9 (20.5)	0.21
Number of rods inserted	n/a	5.00 [4.00, 5.00]	
Indications for delivery[a]			
Post-term pregnancy, n, %	24 (48)	26 (59)	0.28
Elective, n, %	8 (16)	1 (2.3)	0.034
Suspected fetal macrosomia, n, %	16 (32)	9 (20)	0.21
Gestational diabetes, n, %	1 (2)	12 (27)	<0.001
Oligohydramnios, n, %	5 (10)	2 (4.5)	0.44
Others, n, %	4 (8)	5 (11)	0.73

Data are presented in the following way: metric data are shown with median, lower and upper quartile. Categorical data are presented with percentages and number of patients. Differences between groups are examined using Wilcoxon rank sum test and Pearson's Chi-squared test or Fisher's exact test as appropriate. p<0.05 was considered statistically significant. [a]Multiple indications possible.

Primary outcomes: Bishop score and cervical length

There was a significant difference regarding the median change in Bishop Score between both groups. The median increase in BS was 3 with DB and 2 with OD which was statistically significant (p=0.002). The median cervical length at insertion did not differ significantly between groups. DB led to a significantly greater shortening of the cervix than OD (median difference – 14 mm and –9 mm; p=0.003) as shown in Table 2.

Secondary outcomes

The mode of delivery was similar in both groups with a vaginal delivery rate of 70.0 and 82.0 %, a vaginal operative delivery rate of 4.0 and 2.3 %, and a cesarean section rate of 26.0 and 15.9 %, respectively (Table 3). Adverse events during insertion of the devices were experienced by 4 women with DB due to a slight vaginal bleeding, discomfort or mild to moderate pain, and by 2 women with OD due to a slight vaginal bleeding and pain. There were no serious adverse events during the cervical ripening period.

Table 2: Primary outcomes according to the trial groups.

Primary outcome criteria	Treatment groups		p-Value
	DB, n=50	OD, n=44	
Difference Bishop score (post-pre)			0.002
Median [Q1, Q3]	3.00 [2.00, 4.75]	2.00 [1.00, 3.00]	
Cervical length, mm pre			0.094
Median [Q1, Q3]	25 [18, 30]	25 [20, 33]	
Cervical length (mm) post			<0.001
Median [Q1, Q3]	10 [5, 15]	15 [10, 29]	
Difference cervical length (post-pre)			0.003
Median [Q1, Q3]	−14 [−20, −8]	−9 [−13, −2]	

Data are presented in median [Q1, Q3]. Differences between groups are examined using Wilcoxon rank sum test. p<0.05 was considered statistically significant.

Table 3: Secondary outcome according to the trial groups.

Secondary outcome criteria	Treatment groups		p-Value
	DB, n=50	OD, n=44	
Mode of delivery, n, %			
Vaginal delivery, n, %	35 (70.0)	36 (82.0)	0.18
Vaginal operative delivery, n, %	2 (4.0)	1 (2.3)	>0.99
Cesarean delivery, n, %	13 (26.0)	7 (15.9)	0.23
Adverse events during insertion, n, %	4 (8)	2 (4.5)	0.68
Adverse events during cervical ripening, n, %	0 (0)	0 (0)	0
Expulsion n, %	16 (32)	3 (6.8)	0.005
Readmission to hospital before 24 h, n, %	22 (44.0)	14 (31.8)	0.317
Time period from insertion to delivery in h, median [Q1, Q3]	33.0 [21, 42]	43.0 [35, 61]	<0.001
Number of patients requiring oxytocin for labor induction n, %	31 (62)	12 (27)	<0.001
Number of patients requiring 10 mg PGE2 vaginal insert for labor induction n, %	6 (12.0)	25 (57)	<0.001
Rate of uterine hyperstimulation during cervical ripening period in n, %	2 (4.0)	0 (0)	0.50
Premature rupture of membranes during cervical ripening period in n, %	6 (12.0)	4 (9.1)	0.75
Chorioamnionitis during delivery in n, %[a]	3 (6.0)	0 (0)	0.25
Postpartum hemorrhage[b] n, %	5 (10)	8 (18)	0.25

Data are summarized in the following way: metric data are shown with median, lower and upper quartile. Categorical data are presented with percentages and number of patients. Differences between groups are examined using Wilcoxon rank sum test and Pearson's Chi-squared test or Fisher's exact test as appropriate. p<0.05 was considered statistically significant. [a]Definition chorioamnionitis: Maternal fever **and** fetal tachycardia>160/min for more than 10 min **or** maternal leukocytosis>15,000/µL **or** purulent leucorrhea from the cervix. [b]PPH, defined as blood loss>500 ml/24 h.

Expulsion of the devices occurred in 16 women (32 %) with DB and 3 women with OD (6.8 %) , which was statistically significant.

Readmission to the hospital before scheduled time was found in 22 patients (44 %) with DB, mainly due to balloon expulsion (n=16) and premature rupture of membranes (n=6), and in 14 patients (31.8 %) with OD due to rods expulsion (n=3) , premature rupture of membranes (n=4) and /or uterine contractions (n=7). The differences between both groups were statistically not significant.

The interval from insertion to delivery was significantly shorter in the DB group with 33.0 h compared to the OD group with 43.0 h (p<0.001);

Thirty one women (62 %) with DB required oxytocin for induction /augmentation of labor and 12 (27 %) with OD. On the other hand, the 10 mg PGE2 vaginal insert was needed for induction of labor in 6 patients (12 %) with DB compared to 25 patients (57 %) with OD. The differences between both groups were statistically significant (Table 3).

The rates of uterine hyperstimulation and premature rupture of membranes during the cervical ripening period were not significantly different between both groups, as well as the frequencies of chorioamnionitis during delivery and of postpartum hemorrhage.

Neonatal outcome

Fetal outcome is shown in Table 4. No significant differences were found between the groups regarding Apgar scores after 1, 5 and 10 min. Arterial cord pH≥7.10 was noted similarly in both groups (p≥0.99). None of the neonates in the DB group were admitted to the neonatal intensive care unit (NICU). Three neonates of the OD group were admitted to NICU, of which two newborns showed a transient neonatal adaptation disorder. One neonate was postnatally diagnosed with a congenital heart defect requiring NICU admission.

Table 4: Neonatal outcomes of the trial groups.

Neonatal outcome criteria	Treatment groups		p-Value
	DB, n=50	OD, n=44	
Apgar 5 min, n, %			0.22
≥ 7	50 (100)	42 (95)	
< 7	0 (0)	2 (4.5)	
Arterial cord pH, n, %			>0.99
≥ 7.10	48 (96)	42 (95)	
< 7.10	2 (4)	2 (4.5)	
Base excess, median [Q1, Q3]	−4.5 [−7.1, −1.3]	−6.6 [−7.4, −2.7]	0.16
NICU admission n, %[a]	0 (0)	3 (6.8)	0.10

Data are presented in the following way: metric data are shown with median, lower and upper quartile. Categorical data are presented with percentages and number of patients. Differences between groups are examined using Wilcoxon rank sum test and Pearson's Chi-squared test or Fisher's exact test as appropriate. p<0.05 was considered statistically significant. [a]NICU – neonatal intensive care unit.

Patient's satisfaction

The patient's satisfaction questionnaire was answered in all 44 women of the OD group and in 39 out of 50 in the DB group (return rate 78 and 100 %, DB and OD, respectively). The median visual analogue scale perception regarding any pain perception upon insertion (Q1) was 4.0 in both groups (p=0.79). Pain perception during the cervical ripening period (Q8) was rated significantly higher with DB group compared to OD with a median visual analogue scale of 4 and 2 (DB and OD respectively, p<0.001, see Figure 1).

The results from questions 2–7 (Q2-Q7) are depicted in Figure 2. Overall patients were very satisfied with this method (Q2, overall satisfaction rate): among the DB group 50 % of patients were completely satisfied with the cervical ripening overall compared to 59 % of patients in the OD group (p=0.082). Ability to rest and sleep during the cervical ripening period (F3) was rated high to very high by 17 % of patients in the DB group and 40 % of patients in the OD group (p<0.001). Ability to pursue daily activities (Q4) was rated high to very high by 45 % of patients in the DB group and 82 % of patients in the OD group (p<0.001). A positive perception of cervical ripening at home was stated by 9 and 27 % of women in both groups (Q5, DB and OD respectively, p<0.001); 42 % of women with the DB would opt against inpatient cervical ripening compared to 69.3 % with the OD (Q6, p<0.001). Furthermore, 55 % of women from the DB group would recommend to highly recommend outpatient cervical ripening to other pregnant women compared to 75 % from the OD group (Q7, p=0.006).

Discussion

However, there is a growing body of evidence that balloon catheters and hygroscopic cervical dilators (Dilapan-S) are effective and safe methods for pre-induction cervical ripening and may be a suitable option for outpatient induction [3, 4, 19, 22, 25, 26]. Clinical trials comparing balloon catheters to Dilapan-S have recently been summarized in an evidence-based review [3].

To the best of our knowledge our study was the first to compare Dilapan-S with double-balloon catheter in an outpatient setting, and which objectively evaluated the cervical ripening effect of both methods by sonographic

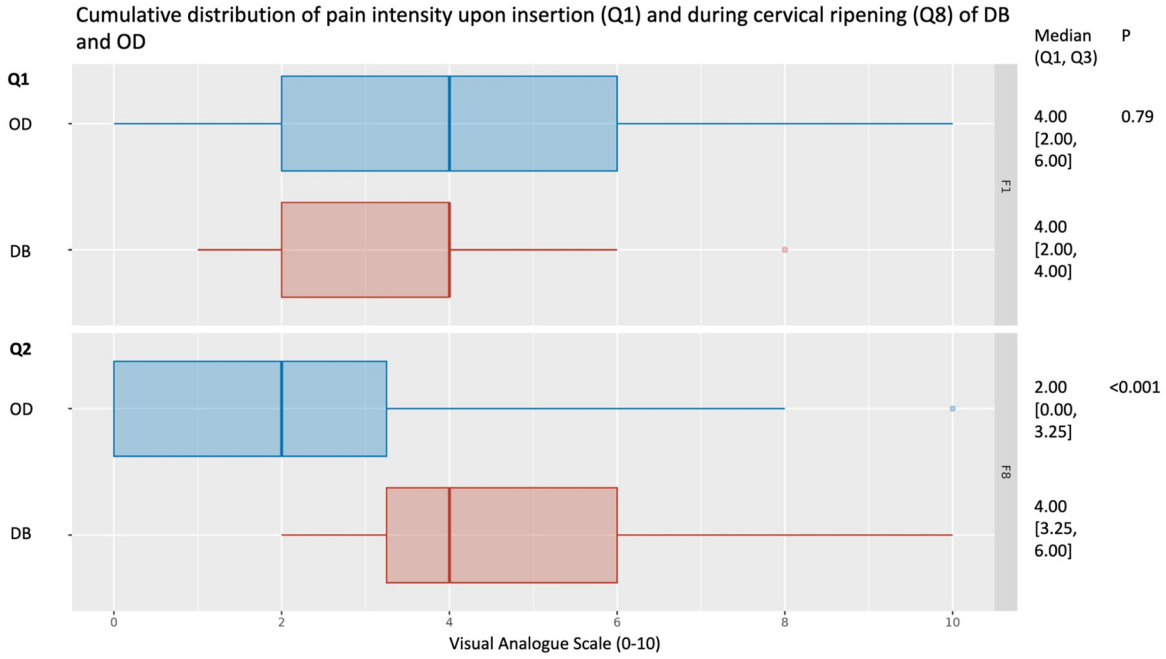

Figure 1: Patient's satisfaction questionnaire question 1 and 8 (Q1 and Q8). Q1: On a scale from 0 to 10, how much pain did you feel upon insertion. Q8: On a scale from 0 to 10, how much pain did you feel during the ripening process. Box blot depicting the median and range of pain perception upon insertion (Q1) and during the cervical ripening period (Q8).

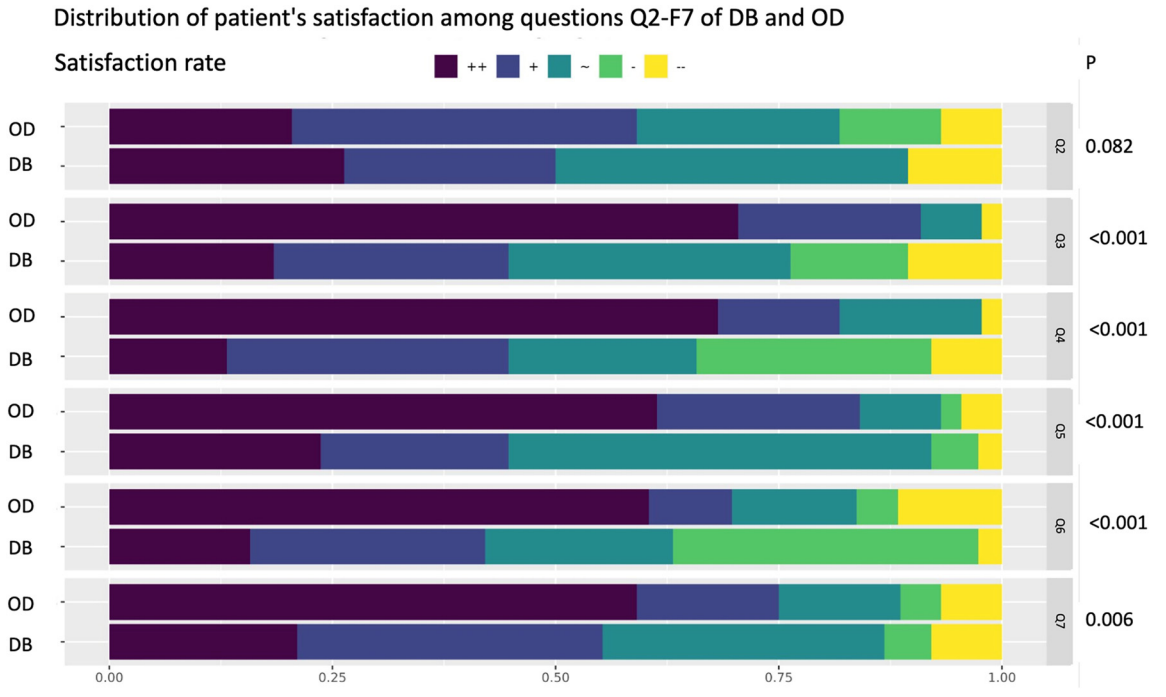

Figure 2: Boxplot of results from questions 2–7 (Q2-Q7). The satisfaction/agreement rate was high, when highlighted with dark blue and low, when shown yellow. The satisfaction rate was assessed in five different steps: ++ agree fully, + agree, ~ approximately, disagree, fully disagree. Q2: How were you overall satisfied with the method? Q3: Did you have any ability to rest and sleep during the cervical ripening period? Q4: Were you able to pursue daily activities? Q5: Did you overall perceive cervical ripening at home as a positive method? Q6: Would you request an inpatient cervical ripening procedure in the future? Q7: Would you recommend this method for other pregnant people?

measurements of the cervical length. We found that the increase in median Bishop Score was significantly higher with DB compared to OD. We hypothesize that the extra amniotic part of the balloon exerts more mechanical stress to the inner cervical os than Dilapan-S thus leading to higher production of endogenous prostaglandins, particularly, if the DB is kept under tension. In line with our study others also found a median change in BS of 2–3 when using Dilapan-S [1, 6, 7, 24]. When comparing the cervical ripening effect with Dilapan-S to Foley Balloon (filling volume 60 mL) Saad et al. and Wood et al. could demonstrate no significant difference between both methods [7, 27]. In this context differences in the balloon design, in the filling volume, in the number of rods inserted into the cervical canal, and duration of the device left in place, should be considered. In our study, changes in BS corresponded to sonographic shortening of the cervix in both groups, which was more effective in the DB group. These results should be interpreted with caution, since there may be an individual investigator-dependent variance in assessing the BS and in measuring the cervical length.

Cesarean delivery rate did not significantly differ between both groups, as reported by Saad et al. and Wood et al. [7, 27]. The rate of adverse events upon insertion such as bleeding, cramping or pain was 8 % (n=4) in the DB and 4.5 % (n=2) in the OD group, which was not significantly different. In the multicenter observational study by Gupta et al., nearly 3 % of patients with Dilapan-S experienced pain and/or bleeding at insertion, while in the study by Gommers et al. up to 4 % of women reported on pain/bleeding, when the Foley Balloon was placed [28, 29]. The expulsion rate was significantly higher in the DB group with 32 % compared to 6.8 % in the OD group. Other groups have reported an expulsion rate of 2 % with Dilapan-S [29]. The expulsion rate of balloon catheters is significantly influenced by the filling volume and the length of time the balloons remain in place. For the DB, which was left in place for 12 and 24 h, the expulsion rate was 10.2 and 33.3 %, respectively [27, 28] the latter is comparable to the 32 % expulsion rate of DB in our study.

The expulsion rate of Foley Balloon (filling volume 40 mL), left in place for 12 h, was reported to be 59 % [30].

During the cervical ripening period uterine hyperstimulation was only found in the DB group (n=2), while the corresponding value in OD was 0. This is in accordance with the study by Saad et al. [7].

More than one third of patients were readmitted before scheduled 24 h (DB 44 %, OD 31.8 %). This is much higher than the 2 % in the study by Saad et al. using Dilapan-S left in place for approximately 12 h in an outpatient setting [7]. We hypothesize, that the duration of time the devices left in place may play a significant role, and the readmission rate may be lower, if the devices are left in place for only 12 h. Time from insertion to delivery was significantly longer in the OD compared to the DB group. which is in line with the DILAFOL trial [7].

The number of patients requiring oxytocin for labor induction was significantly lower in the DB group, while the need for vaginal PGE2 was significantly higher in OD reflecting the better cervical ripening effect with the use of DB. Others used a second round of mechanical dilator, if the cervix remained unfavorable after extraction of the device and allowed pharmacological cervical ripening at the health care professional's discretion (method not specified [7, 24]. Perinatal outcomes were not significantly different between both groups, which is in agreement with other studies [7, 27].

Patient satisfaction has become of growing importance in obstetrics. Using a visual analogue scale, pain perception did not significantly differ between Dilapan-S and DB upon insertion. This agrees with the randomized controlled trial by Wood et al. [27] comparing Foley Balloon to Dilapan-S. However, pain perception was significantly higher during the cervical ripening period in women with DB compared to women with OD. Comparable results have been reported by Saad et al. [7]. In our study, overall patient satisfaction was not significantly different between both groups, however, sleep, relaxing time and performance of desired daily activities were significantly better with the use of Dilapan-S. In the randomized controlled study by Wood et al. overall patient satisfaction was significantly higher with Dilapan compared to Foley Balloon [27]. Using the similar criteria as in our study, Saad et al. [7] concluded that patients were significantly more satisfied with Dilapan-S compared to patients with the use of Foley Balloon.

Further advantages of Dilapan-S compared to Foley Balloon are the approval by national authorities (e.g. FDA), no protrusion through the introitus and no need to keep the device under tension. Dilapan-S is only contraindicated in patients with the presence of clinically apparent genital tract infection, while the approved DB has several contraindications (e.g. prior hysterotomy/caesarean delivery, rupture of membranes, maternal heart disease). On the other hand, our study revealed that DB was superior to Dilapan-S regarding improvement in BS and the lower need for vaginal PGE2 for induction of labor.

Limitations of our study

This is an analysis of a prospective, dual-centre pilot study. One center offered the DB and the other the OD. This explains potential differences in each group concerning cohorts (rate of gestational diabetes). It was not a randomized

trial, and selection bias cannot be excluded. The statistical power of our study is limited due to the small sample size. Differences in local hospital protocols (e.g. the regimen of oxytocin use) may be a further limitation. Cost effectiveness was not evaluated.

Conclusions

Pre-induction cervical ripening using Dilapan-S and balloon catheters is a viable option for outpatient management. Our study revealed that the DB was more effective in cervical ripening based on the Bishop Score and sonographic cervical length measurement. As a result, the need of vaginal PGE2 for labor induction was significantly higher in patients with Dilapan-S compared to DB. However, our results should be interpreted with caution, since the number of patients included was small.

Both methods were not associated with serious adverse events at insertion and during the cervical ripening period, however readmission rates to the hospital before scheduled were high with both method and may be lowered by a reduction of time the devices are left in place. Patients were significantly more satisfied with Dilapan-S regarding sleep, relaxing time and the performance of desired daily activities. Furthermore, significantly fewer patients experienced pain during cervical ripening with the use of Dilapan-S.

Future randomized studies will focus on benefits and harms of both methods in an outpatient setting and implement recommendations for clinical practice.

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Informed consent: Written informed consent was obtained from all participating women. Study monitoring was performed by an independent data and safety monitoring committee. Data were stored anonymously and only our research team (authors) had access to the data.
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