Josefine T. Maier*, Melanie Metz, Nina Watermann, Linna Li, Elisabeth Schalinski, Ulrich Gauger, Werner Rath and Lars Hellmeyer

Induction of labor in patients with an unfavorable cervix after a cesarean using an osmotic dilator versus vaginal prostaglandin

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Abstract

Background: Trial of labor after cesarean (TOLAC) is a viable option for safe delivery. In some cases cervical ripening and subsequent labor induction is necessary. However, the commonly used prostaglandins are not licensed in this subgroup of patients and are associated with an increased risk of uterine rupture.
Methods: This cohort study compares maternal and neonatal outcomes of TOLAC in women (n = 82) requiring cervical ripening agents (osmotic dilator vs. prostaglandins). The initial Bishop scores (BSs) were 2 (0–5) and 3 (0–5) (osmotic dilator and prostaglandin group, respectively). In this retrospective analysis, Fisher's exact test, the Kruskal-Wallis rank sum test and Pearson's chi-squared test were utilized.
Results: Vaginal birth rate (including operative delivery) was 55% (18/33) in the osmotic dilator group vs. 51% (25/49) in the dinoprostone group (P 0.886). Between 97% and 92% (32/33 and 45/49) (100%, 100%) of neonates had an Apgar score of >8 after 1 min (5, 10 min, respectively). The time between administration of the agent and onset of labor was 36 and 17.1 h (mean, Dilapan-S® group, dinoprostone group, respectively). Time from onset of labor to delivery was similar in both groups with 4.4 and 4.9 h (mean, Dilapan-S® group, dinoprostone group, respectively). Patients receiving cervical ripening with Dilapan-S® required oxytocin in 97% (32/33) of cases. Some patients presented with spontaneous onset of labor, mostly in the dinoprostone group (24/49, 49%). Amniotomy was performed in 64% and 49% (21/33 and 24/49) of cases (Dilapan-S® group and dinoprostone group, respectively).
Conclusions: This pilot study examines the application of an osmotic dilator for cervical ripening to promote vaginal delivery in women who previously delivered via cesarean section. In our experience, the osmotic dilator gives obstetricians a chance to perform induction of labor in these women.

Keywords: Bishop score (BS); cervical ripening; cesarean delivery (CD); cesarean delivery rate; osmotic dilator; repeat cesarean delivery (RCD); trial of labor after cesarean (TOLAC); unfavorable cervix; uterine scar; vaginal birth after cesarean (VBAC).

Introduction

Cesarean delivery (CD) is a major operation that can result in acute neonatal and maternal complications, influencing the future health of mother and child [1–6]. The increasing use of CD over time means there is a growing population of women with a uterine scar. When a patient is counseled regarding birthing options after CD, the peril of uterine rupture during labor and delivery is often the more prominent concern, rather than the risks resulting from an elective repeat cesarean (RCD) [6].

Trial of labor after cesarean (TOLAC) offers a chance of vaginal birth after cesarean delivery (VBAC), which is associated with decreased maternal morbidity while also lowering the socioeconomic costs [7, 8]. Between 60 and 80% of patients undergoing TOLAC will have a successful VBAC [8].

There is insufficient information from randomized controlled trials on which to base clinical decisions regarding the optimal method of induction of labor in women with a prior CD and an unfavorable cervix [9]. In general, induction of labor using mechanical methods results in similar cesarean rates as prostaglandins but at a lower risk of uterine hyperstimulation [9]. Therefore, we conducted a pilot study to compare the application of an osmotic dilator (Dilapan-S®) to vaginal prostaglandin (Minprostin®, SANICO NV, Turnhout, Belgium) to exclude major safety issues.

***Corresponding author: Josefine T. Maier,** Department of Obstetrics and Gynecology, Vivantes Klinikum im Friedrichshain, Affiliate of Charité University, Berlin, Germany, E-mail: Josefine.Maier@gmail.com
Melanie Metz, Nina Watermann, Linna Li, Elisabeth Schalinski and Lars Hellmeyer: Department of Obstetrics and Gynecology, Vivantes Klinikum im Friedrichshain, Affiliate of Charité University, Berlin, Germany
Ulrich Gauger: Institute of Medical Statistics, Berlin, Germany
Werner Rath: Department of Obstetrics and Gynecology, University of Aachen, Aachen, Germany

The dilemma appears to be induction of labor in this subgroup of patients. In cases with an unfavorable cervix [Bishop score (BS) < 6], cervical ripening must be performed before oxytocin can be administered [10]. The literature has shown that cervical ripening can be performed either with prostaglandins or a mechanical agent, with both methods exhibiting similar efficacy and safety [11]. Up to very recently, our tertiary perinatal center only had prostaglandins at hand for cervical ripening. These agents, such as dinoprostone, are not approved in patients with a uterine scar. The application of prostaglandins in patients with a uterine scar is associated with an increased risk of uterine rupture especially in those with an unfavorable cervix [12]. Using this medication for an off-label indication puts the obstetrician at risk for legal consequences and therefore less likely to support TOLAC. The use of the balloon catheter, widely studied by Kehl et al. has shown promising results as a cervical ripening tool [13]. A recent review on the balloon catheter in women with one prior cesarean delivery revealed a vaginal birth rate of 56.4% [14]. However, its application in this subgroup of patients is not officially licensed. Since 2013, our clinic has gained considerable experience on the application of a mechanical agent, called Dilapan-S®, which is not contraindicated for usage in patients with a previous CD. Up-to-date mechanical agents for cervical ripening in women with a previous CD have not been sufficiently studied. With this pilot study we want to share our experience with the osmotic dilator.

Methods

In this pilot study we gathered data from 82 women attempting TOLAC between 2011 and August 2016 at our clinic Vivantes Klinikum im Friedrichshain, a public tertiary care academic affiliate of Charité University, Berlin, Germany (in 2015, the CD rate was 29.21% and 25.91% of deliveries required induction of labor). Included into this study were singleton pregnancies with cephalic presentation. The patients had one previous CD with a low transverse uterine incision (operational technique was known). No other conditions requiring primary RCD such as placenta previa, vasa praevia or severe diseases were apparent.

Data was analyzed using R version 3.2.5. Among others Fisher's exact test for count data, the Kruskal-Wallis rank sum test and Pearson's chi-squared test were utilized.

The primary outcome was mode of delivery, the secondary outcome was time period from admission to delivery. Prior to induction of labor, the BS is assessed by the specialized obstetrician. It is a score on a scale from 0 to 10 including cervical length, effacement, consistency, as well as position and station of the fetal head [15]. The score was originally introduced by Bishop in 1964 and further modified in 1966 by Burnett [16, 17].

Overall, this study analyzes and retrospectively compares two groups: cervical ripening with Dilapan-S® (medicem, Prague, Czech Republic) or dinoprostone. Prior to cervical ripening the BS is assessed [10, 18]. All patients had a BS of <6. Dinoprostone was applied for cervical ripening in this subgroup of patients in our clinic before the introduction of the osmotic dilator. The patient consented the off-label use after signing an informed consent form. Since 2013, the mechanical device was used in patients with an unfavorable cervix and a history of CD. In some cases dinoprostone was applied in the course of cervical ripening after the application of Dilapan-S®. These patients were excluded from the analysis (due to double use of the osmotic dilator and dinosprostone and potential data alteration). We used a standardized prospective protocol that implements cervical ripening by the dinoprostone or the osmotic dilator as well as subsequent management of latent phase and active phase of labor. Dinoprostone is applied as a vaginal gel insert during an internal vaginal examination (1 mg and 2 mg, max. 3 mg in 24 h), initially commenced with 1 mg and continued after 6–8 h. Oxytocin is administered intravenously (6IE in 500 mL) by an infusion pump starting at 15 mL/h (0.18 IE/h). Oxytocin flow is increased every 30 min, with the highest flow at 60 mL/h (0.72 IE/h). Once oxytocin administration is initiated, amniotomy had to be performed within 24 h. If the BS was >6, labor induction with oxytocin was continued.

Dilapan-S® is a small rod made out of hydrophilic material (Figure 1A). It is inserted into the cervical canal during a gynecological exam using a speculum. Prior to insertion, a disinfectant appropriate for mucosal skin is applied (Octenisept®). Up to five rods can be inserted during one session and left for 12 h to a maximum of 24 h in the cervical canal. Changing the osmotic dilator and subsequent new insertion was repeated individually up to three times (Figure 1B). The mechanical device acts by absorbing fluids in the cervix, increasing the rod circumference. Consequently the cervix is ripening and shortening as well as effacing. After the insertion fetal heart rate is monitored via CTG for 45 min. Patients are admitted to our labor ward and monitored regularly.

Results

Basic results

Data was collected from 82 women presenting at our tertiary perinatal clinic. All patients had a previous CD and a median age of 31 years. They presented at a median gestational week of 41 on average. All pregnancies were live singletons with cephalic presentation at term and without premature rupture of membranes. Group B streptococcus screening was negative. Patients were divided into two groups: (1) cervical ripening using the osmotic dilator and (2) cervical ripening using dinoprostone vaginal gel. Reasons for induction of labor were prolonged pregnancy [≥40 + 6 gestational week (gw)] in 40% and 30% of cases (Dilapan-S® group, dinoprostone group, respectively). A maternal indication (such as pregnancy induced hypertension, preeclampsia, HELLP syndrome, cholestasis in pregnancy, thrombocytopenia, etc., as well as maternal request) was given in 60% and 40% of cases. And a fetal indication for induction of labor [suspicious fetal heart tones (FHT), intrauterine growth restriction (IUGR),

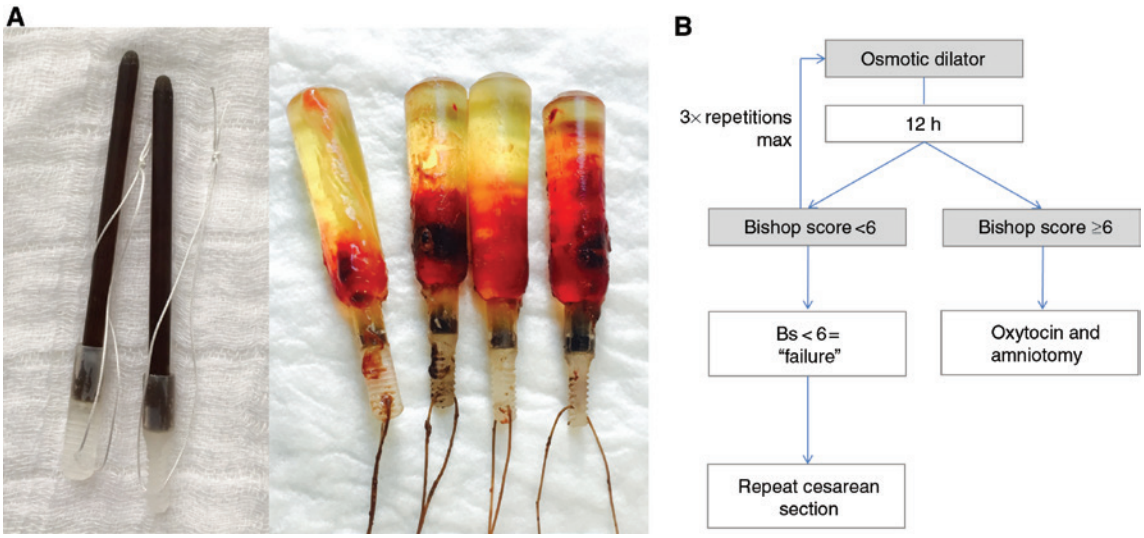

Figure 1: (A) Two osmotic rods before insertion compared to four rods, that have been extracted after 12 h. (B) Flow-chart depicting the application of the osmotic dilator and subsequent steps depending on Bishop Score.

macrosomia, etc.] was found in 0% and 30% of cases (Dilapan-S® group, dinoprostone group, respectively).

Table 1 analyzes the delivery prior to this pregnancy. The amount of vaginal births was assessed: 82% and 78% of patients had no vaginal delivery, only the CD (Dilapan-S® group, dinoprostone group, respectively). A small proportion of patients had one or more vaginal delivery after CD: 12% and 6% (Dilapan-S® group, dinoprostone group, respectively).

The indication of the prior CD was evaluated: half of CDs were performed primarily due to maternal or fetal conditions and half were carried out in the course of labor either due to failure to progress in the first stage or in the second stage (see Table 1).

Delivery mode

Table 2 illustrates the delivery mode compared to cervical ripening agent/induction agent and spontaneous onset of labor.

Overall, results concerning the delivery mode were analogous. In women who received cervical ripening using the osmotic dilator (n = 33) the CD rate was as high as 45%. Forty-five percent of patients delivered vaginally and 10% by ventouse. In those patients who required cervical ripening with dinoprostone (n = 49) 49% gave birth via CD, 45% vaginally and 6% by ventouse.

Fetal outcome

No significant differences were found in this pilot study concerning fetal outcome. Analyzing the Apgar score after 1, 5 and 10 min, fetal outcomes were very similar (Table 3). Overall, between 92% and 97% (100%, 100%) of neonates had an Apgar score of more than 8 after 1 min (5, 10 min, respectively). No significant differences were found in the average umbilical artery pH. The lowest single incidence of umbilical artery pH was found in the group of patients where dinoprostone was applied for cervical ripening (pH 6.86, base excess –18.6, vaginal delivery, Apgar 6/10/10). This group had a slightly higher percentage of umbilical artery pH lower than 7.20 (12% vs 20%, Dilapan-S® group, dinoprostone group, respectively).

Time from admission to birth

Time from admission to time of birth was assessed. Different time points were analyzed. Patients received their cervical ripening agent after a delay of 2–6 h (mean, Dilapan-S® group, dinoprostone group, respectively). The period from administration of the agent to onset of labor was 36 and 17.1 h (mean, Dilapan-S® group, dinoprostone group, respectively). Time from onset of labor to delivery was similar in both groups with 4.4 and 4.9 h (mean, Dilapan-S® group, dinoprostone group, respectively). Therefore, the period from application of the cervical ripening agent to onset of labor was longer in those who received the osmotic dilator, but the time from onset of labor to delivery was similar.

Further induction

For further induction, oxytocin was administered. Patients receiving cervical ripening with Dilapan-S®

Table 1: Study group: Baseline characteristics of the two study groups.

Characteristic	Dilapan-S® (n = 33)	Dinoprostone (n = 49)	Statistical test and P value
Maternal age, y	31 (20–41)	31 (18–41)	Welch's two sample *t*-test, 0.8828
Prepregnancy BMI, kg/m²	23.7 ± 4.9	24.2 ± 4.8	Welch's two sample *t*-test, 0.625
Parity	1 (1–3)	1 (1–4)	Fisher's exact test for count data, 0.716
Primiparous	27 (80%)	38 (80%)	Fisher's exact test for count data, 1
Parous	6 (20%)	11 (20%)	Fisher's exact test for count data, 1
Gestational week at birth, wk	41 (38–42)	41 (39–42)	Welch's two sample *t*-test, 0.7403
Baseline Bishop score	2 (0–5)	3 (0–5)	Welch's two sample *t*-test, 0.6026
Reason for induction of labor			Fisher's exact test for count data
Prolonged pregnancy (≥40 + 6 gw)	12 (40%)	14 (30%)	0.2231
Maternal condition (PIH, preeclampsia, HELLP, cholestasis in pregnancy, thrombocytopenia, etc.) maternal request	21 (60%)	21 (40%)	
Fetal condition (suspicious FHT, IUGR, macrosomia)	0	14 (30%)	
History of preceding mode of delivery			
Vaginal delivery			Fisher's exact test for count data 0.7833
No vaginal delivery	27 (82%)	38 (78%)	
≥1 vaginal delivery	6 (18%)	11 (22%)	
Vaginal delivery after cesarean			Fisher's exact test for count data 0.7539
No vaginal delivery after CD	29 (88%)	41 (84%)	
≥1 vaginal delivery after CD	4 (12%)	8 (6%)	
Prior CD: Indication for CD			
Primary: fetal condition (breech, pathological FHT, IUGR, macrosomia)	8 (24%)	14 (29%)	Fisher's exact test for count data 0.0077
Primary: maternal condition (PIH, preeclampsia, HELLP, cholestasis in pregnancy, thrombocytopenia, PPROM before 32 0/7gw)	5 (15%)	12 (24%)	
Secondary: failure to progress in first stage	11 (33%)	22 (45%)	
Secondary: failure to progress in second stage	9 (27%)	1 (2%)	

Data are presented as number (%), median (range), or mean ± SD, BMI = body mass index Table 1: Demographic and baseline characteristics.

Table 2: Obstetric outcome: Mode of delivery, time from admission to the hospital to delivery, with different time points analyzed (Welch's two sample t-test), Induction of labor with oxytocin and amniotomy (Fisher's exact test for count data).

Characteristic	Dilapan-S® (n = 33)	Dinoprostone (n = 49)	Statistical test and P-value
Vaginal birth	15 (45%)	22 (45%)	Fisher's exact test for count data 0.8649
Ventouse	3 (10%)	3 (6%)	
Secondary CD	15 (45%)	24 (49%)	
Time from admission to the hospital to delivery (h, mean ± SD)			
Dilapan-S® insertion/dinoprostone application to onset of labor	36 ± 19.7	17.1 ± 14.2	< 0.001
Onset of labor to delivery	4.4 ± 8.2	4.9 ± 4.6	0.7474
Induction of labor with oxytocin and amniotomy			
Oxytocin application	32 (97%)	25 (51%)	0.2584
Amniotomy	21 (64%)	24 (49%)	

required oxytocin in 97%. Some patients presented with spontaneous onset of labor, mostly in the dinoprostone group (49%). Without spontaneous rupture of membranes amniotomy was utilized to enhance labor. Amniotomy was performed in 64% and 49% (Dilapan-S® group and dinoprostone group, respectively).

Table 3: Neonatal outcome: Apgar outcomes in both groups compared to each other, umbilical artery pH in both groups compared to each other.

Characteristic	Dilapan-S® (n=33)		Dinoprostone (n=49)	
	<8	8–10	<8	8–10
5 min Apgar	1 (3%)	32 (97%)	4 (8%)	45 (92%)
10 min Apgar	0	33 (100%)	0	49 (100%)
15 min Apgar	0	33 (100%)	0	49 (100%)

Mantel-Haenszel Test P value 0.006

	Dilapan-S® (n=33)	Dinoprostone (n=49)	P-value
Umbilical artery pH			
≥7.20	29 (88%)	39 (80%)	Fisher's exact test for count data 0.3841
<7.20	4 (12%)	10 (20%)	

Discussion

Principal findings

TOLAC is a cost-effective and viable option for counteracting the overall rising CD rate [19–22]. Around 20%–40% of patients who aim for VBAC will end up having an RCD [8]. Certain factors have been found to be associated with a positive outcome of TOLAC [23, 24], such as previous vaginal delivery (especially VBAC), spontaneous onset of labor, normal progress of labor, previous CD because of breech presentation, only one prior CD, and a prior CD having been performed before full cervical dilatation.

In this pilot study the sample size is relatively small but representative, reflecting our experiences in daily clinical life. Patients who presented at our clinic were approximately the same age (around 31 years) and at a very similar gestational age (41 gestational weeks). The pre-pregnancy body mass index (BMI) in both groups were borderline normal to lightly overweight in both groups (23.7 to 24.2). Most women only delivered one child before this pregnancy, via CD (80% in both groups). A large proportion of patients required cervical ripening due to prolonged pregnancy (≥40 6/7 gw) (40% and 30%, Dilapan-S® group, dinoprostone group, respectively) as well as maternal condition or maternal with for induction of labor (60% and 40%, Dilapan-S® group, dinoprostone group, respectively). All patients presented with an unfavorable cervix, with an average BS of 2.

Meaning of these findings and clinical implications

When looking at mode of delivery, dinoprostone and the osmotic dilator revealed a CD rate of 49% and 48%, respectively. The success rate of VBAC is described in the literature to be between 60 and 80% [8, 25, 26]. A recent review on cervical ripening with another mechanical device – the balloon catheter – in women with a previous CD revealed a vaginal birth rate of 56.4% [14]. Recent studies comparing the balloon catheter with prostaglandins for cervical ripening indicated similar rates of vaginal delivery in both groups [27–29]. The highest success rate is found in women who previously delivered vaginally and present with a favorable cervix [26, 30]. When compared to spontaneous onset of labor, the literature indicates that induction leads to a lower rate of vaginal birth [31]. Jozwiak et al. [9] were able to demonstrate in their Cochrane review from 2012 that there is no discrepancy in cesarean rates when comparing mechanical with pharmacological agents.

The longest duration from administration of cervical ripening agent to onset of delivery was observed in those patients who received the osmotic dilator as a cervical ripening agent (36 ± 19.7 compared to 17.1 ± 14.2 with dinoprostone). This can be explained by the differences in applying the cervical ripening agent. The osmotic dilator is renewed every 8 to 12 h, usually starting with one dilator and then gradually increasing the amount with each session, accounting for a longer latent period. In some cases the renewal of Dilapan-S® after 8–12 h falls into the night time, when the patient usually prefers to rest. Therefore, we recommend changing the osmotic dilator every 8 h and commencing it again during the morning, so that the renewal falls into the early evening time. Dinoprostone is applied every 6 to 8 h and thus has a shorter latent period. Once the cervix is ripened (BS ≥6), oxytocin administration is initiated. Cromi et al. observed a similar pattern with their study on the transcervical Foley vs. prostaglandins for cervical ripening: the mechanical device had a lower rate of vaginal birth within 24 h compared to

prostaglandins, but the same chance of vaginal birth [28]. A longer interval from cervical ripening to the active phase of labor has been described in patients with a previous CD [32]. The literature revealed that mechanical methods for labor induction lead to a longer interval into active labor when comparing to prostaglandins [33]. This agrees with our findings where cervical ripening with the osmotic dilator resulted in longer periods to delivery compared to all other groups. Interestingly, the actual time between onset of labor and delivery is in both groups is similar (4.4 ± 8.2 and 4.9 ± 4.6, Dilapan-S® group, dinoprostone group, respectively).

Mechanical methods were found to have a decreased chance of hyperstimulation and fetal heart rate modulation when comparing to prostaglandins [34]. In a review from 2011, mechanical agents were found to be more successful in women with an unfavorable cervix compared to the usage of oxytocin alone [35]. Metanalysis has shown that a higher BS is associated with a higher chance of vaginal birth [10]. These findings mirror the literature, where oxytocin was described as the most effective method for shortest induction to delivery intervals in TOLAC [36]. A higher rate of oxytocin usage was noted in the Dilapan-S® group. This is most likely due to the mechanical action of the osmotic rod. By its intracervical insertion it effaces, shortens and ripens the cervix. It is most likely influencing the expression of endogenous prostaglandins. It should be noted that when comparing to dinoprostone and other prostaglandins, Dilapan-S® does not release any drugs. In the dinoprostone group the medication is applied vaginally and acts from there continuously. This explains the fact, that oxytocin use is less frequent in this group (51% vs. 97%), as well as, that the need for amniotomy is slightly lower (49% vs. 64%). These findings agree with a small study from Du et al. [27] on the comparison of double-balloon catheter vs. dinoprostone for cervical ripening. There, they were able to demonstrate, that those patients that received cervical ripening with the balloon catheter required more oxytocin than those in the dinoprostone group. Delivery mode and neonatal outcome were similar.

Research implications

The study of Dodd and Crowther [5] revealed a significant preference for induction of labor for trial of vaginal birth after CD, with 68% of patients preferring induction of labor to elective repeat CD, although it puts those patients at risk of a uterine rupture during labor potentially harming mother and baby [3]. Research has shown, that cervical ripening/induction agents impose different risks on uterine rupture, with the highest among misoprostol [6%, 95% confidence interval (CI) 0.74–51.4], followed by dinoprostone (2%, 95% CI 1.1–3.5%) and the lowest using oxytocin (1.1% 95% CI 0.9–1.52%) [14, 37–40]. In addition, the risk of uterine rupture is related to the type of uterine incision performed in the previous CD (0.2–1.5% in transverse uterotomy vs. 4–9% in vertical or T-shaped uterotomy). Overall, the risk of uterine rupture is higher in RCD than in VBAC [8]. An analysis on cervical ripening with the balloon catheter in patients with a prior CD revealed a very low uterine rupture rate of 1.2% (18/1447) [14]. In the literature, the risk of uterine rupture during TOLAC is as high as 0.4– < 1% and elevated at 1–3% with an induction of labor [12, 41]. Interestingly, another study revealed an increase of uterine rupture in patients undergoing cervical ripening due to an unfavorable cervix [hazard ratio (HR) 4.09, 95% CI 1.82–9.17] [12]. The application of oxytocin is associated in the literature with a dose-response relationship between the maximum dose and uterine rupture [42].

In the Dilapan-S® group one patient had a uterine scar dehiscence and another woman was treated for postoperative peritonitis after CD. In the dinoprostone group, one patient had a uterine rupture with an overall bloodloss of 10 L, another had a uterine scar dehiscence. Due to the small size of the cohort, these numbers are not representative. More data has to be collected to make a validated assertion.

Recent studies revealed that attempted operative vaginal delivery during TOLAC is associated with less fetal morbidity when compared to RCD. Interestingly, Brock et al. found an increase in maternal morbidity whereas Son et al. could not confirm this finding [43, 44].

Data have shown that fetal outcome is similar in the two groups. Apgar scores were comparable in all neonates. No significant differences were noted. Only a slight trend towards lower umbilical artery pH was found in those patients receiving cervical ripening with dinoprostone. This might be due to the higher incidence of uterine hyperstimulation and pathological fetal heart rate tracing found in those women who received cervical ripening with prostaglandins [45]. In the literature, prostaglandins have been linked to uterine hyperstimulation in up to 20% of cases [13].

Strength and weaknesses

In this pilot study we present our clinical experiences in mechanical cervical ripening prior to induction of labor in TOLAC in an observational setting with a small group of patients. Vaginal prostaglandin that was in the past

utilized off-label in patients with an unripe cervix and a uterine scar was compared to the osmotic dilator applied as in-label use. At this time point there is no convincing evidence on the best agent for cervical ripening in this subgroup of patients. This is why this study is important for providing information on this issue. The sample size is small but reflects our experience from daily clinical life. The results agree with findings from the literature when analyzing other cervical ripening/induction methods. Kehl et al. [14] were able to gather very promising results on the application of the balloon catheter as a cervical ripening device in order to perform TOLAC. But again, this method is an off-label usage and requires a particular informed consent.

Currently we are conducting an observational study on the application of Dilapan-S® for cervical ripening in TOLAC at our clinic to acquire more information. In the future we will gain more information as the sample size increases. Ideally, we would like to encourage clinicians, with our results, to support TOLAC and decrease the CD rate.

Conclusions

This pilot study takes the initiative to address this long-standing question of how to proceed in patients after CD with an unripe cervix and a wish for TOLAC. To date there is no study published analyzing the usage of Dilapan-S® in patients with a uterine scar after CD [46, 47]. This pilot study is the first data set on the efficacy and safety of the application of the osmotic dilator in this subgroup of patients. The osmotic dilator is easy to apply and can be effortlessly inserted by a physician. Our patients had no complaints whatsoever, neither during insertion, dilation nor extraction of Dilapan-S®. As it stays intracervically for at least 8 h (up to 12 h) the patients avoid frequent vaginal examinations that are generally regarded as very unpleasant. In addition, pharmacological means are not licensed in patients with a uterine scar. The osmotic dilator, however, is officially approved, providing physicians with an additional appeal to support TOLAC even in patients with an unfavorable cervix. We observed no significant differences in fetal and or maternal outcomes when compared with other groups, but in the clinic we noticed less uterine hyperstimulation and/or pathological CTG pattern in the group using Dilapan-S®.

We can conclude that the osmotic dilator is a viable option for cervical ripening in women who have had a previous CD. It is as effective in the mode of delivery and actual time from onset of labor to delivery as prostaglandins. In this special subgroup of patients we should be careful with the administration of drugs that are known for a higher risk of uterine hyperstimulation and pathological FHT. There is a good reason prostaglandins are not labeled for the usage in women with a uterine scar after CD. With the osmotic dilator we accept the slower mechanism of action and the subsequent well-controllable titration of oxytocin to support the patient in her wish for TOLAC.

Right now our clinic is conducting a prospective observational study on mechanical ripening in patients with an unfavorable cervix and a previous CD. This pilot study constitutes the foundation of this investigation. We hope that eventually more women will be provided with the opportunity for VBAC and that the overall cesarean rate can be lowered.

Additionally, patient's satisfactory rate appears to be much higher in the group where cervical ripening was performed using the osmotic dilator. To collect more data, we will use a questionnaire on patient's satisfaction in our future investigations.

Author's statement

Conflict of interest: Authors state no conflict of interest.

Material and methods: Informed consent: Informed consent has been obtained from all individuals included in this study.

Ethical approval: The research related to human subject use has complied with all the relevant national regulations, and institutional policies, and is in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committee.

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