Prospective, observational, multicentre data collection on the use of the osmotic dilator Dilapan-S® in labor pre-induction in women with/ without Caesarean section in medical history

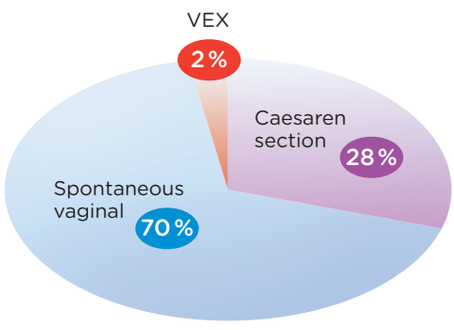
Material and methods:

- The study was performed between May 2013 and October 2013 at 6 clinical centres.
- 96 women with singleton pregnancy after 36 week of gestation with head longitudinal position of the baby and Bishop score < 4 were included in the data analysis.
- 35 patients (36.5 %) had Caesarean section reported in their medical history.
- Assessment of the primary objective and success of cervical ripening procedure was based on the Bishop score. Safety data collection was focused on fetal hypoxia, uterine hypertonus, clinical signs of infection and other potential adverse effects related to the use of Dilapan-S®. In addition, patients' satisfaction was evaluated by personal patient questionnaire.

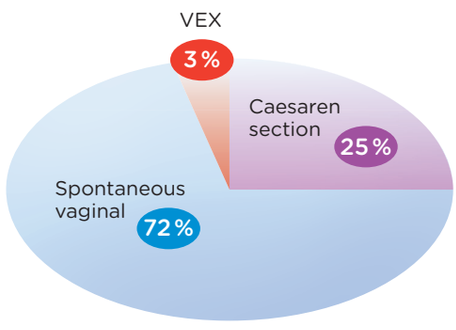
Results:

- Average number of inserted dilators was 2 (range from 2 to 5).
- Bishop score increase (measured on the 10 point scale) was +3,23 points (from 2.81 to 6.13). By 3.7 in group of women without previous C. section and by 2.7 in group of women with previous C. section, resp. (p-value) ≤ 0.003.
- Successful preinduction rate (Bishop score > 5): 86.5 %

	All women		Women with previous C. section		Women without previous C. section	
	n	%	n	%	n	%
Bishop score ≥ 5	83	86.5 %	29	82.7 %	54	88.5 %



Mode of delivery in all women (n = 95)

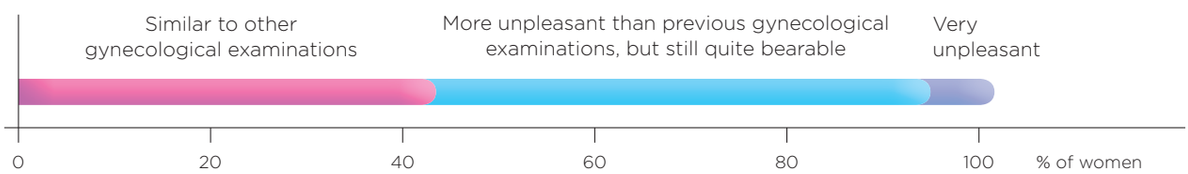


Mode of delivery in women without C. section in previous history (n = 61)

Dilapan-S®

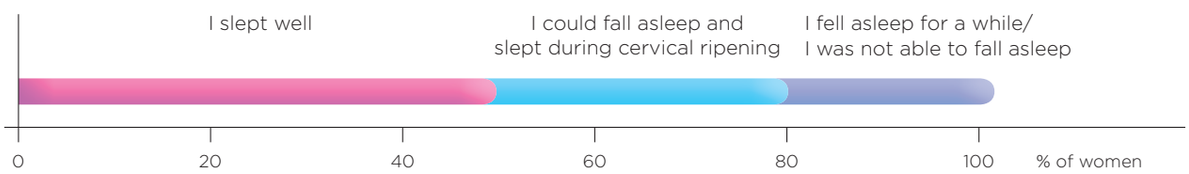
- Vaginal delivery rate: 71.6 % (75.4 % in women without previous C. section and 64.7 % in women with previous C. section, respectively)
- The mean time of Dilapan-S® insertion was 16.99 hours (mainly overnight).
- Dilapan-S® extraction was assessed by physicians as easy in 100 %.
- No fetal hypoxia at CTG trace during preinduction.
- Uterine contractions measured by CTG occured in 30 females (31.3 %).
- No uterine hyperactivity (> 5 contractions/10 minutes).
- Rupture of membranes associated with insertion of Dilapan-S® was not reported.
- No infectious complications related to Dilapan-S® use in mothers and newborns were reported.

93.7 % women evaluated Dilapan-S® insertion as fully acceptable



Women satisfaction / insertion assessment

Dilapan-S® allows 4 from 5 women to sleep during cervical ripening process



Women satisfaction / opportunity to sleep during cervical ripening

Conclusion:

- **High efficacy and safety, even in women with previous C. section, were confirmed.**
- **Low incidence of the uterine activity promotes patient excellent satisfaction.**
- **The use of higher number of dilators improved clinical outcomes in terms of gain in Bishop score as well as in terms of achieving of vaginal births. Higher number of inserted dilators was not accompanied by more pain during insertion and did not affect ability to rest or sleep during preinduction.**
- **Achieving shorter preinduction time was not among the objectives of this study, but from the presented impact of the number of dilators on Bishop score can be assumed that higher number of dilators could potentially lead to shortening of the preinduction time.**

References: 1. Hruban L et al: Effectiveness and safety of the osmotic dilator Dilapan-S® for cervical ripening in females with/without C. section in medical history. Poster presentation. XXIV. European Congress of Perinatal Medicine, June 104, Florence, Italy **2.** Zahumensky J et al: The impact of the number of pieces of osmotic dilator Dilapan-S® used for cervical ripening on the course and outcome of labor. Poster presentation, 13rd World Congress in Fetal Medicine, June-July 2014, Nice, France **3.** Vlk R et al: Efficacy and safety of the osmotic dilator Dilapan-S® for cervical ripening in women with/without C. section. Poster presentation. 13rd World Congress in Fetal Medicine, June-July 2014, Nice, France

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Gentle. Predictable.

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