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Objective:

The purpose of this study is to evaluate efficacy and safety of use of the synthetic osmotic dilator Dilapan-S® for cervical ripening prior to labor induction according to defined criteria and to compare results in females with/without caesarean section in their medical history.

Material and methods:

The study was designed as an observational, prospective, multicentre, data collection, performed between 15. May 2013 and 31. October 2013. The 96 females with singleton pregnancy after 36 week of gestation with cephalic presentation of the baby and Bishop score < 4 were included in the data analysis. 35 patients (36.5 %) had a Caesarean section reported in their medical history, while the group of females without previous Caesarean section involved 61 women (63.5 %). Assessment of the primary objective and success of cervical ripening procedure was based on the Bishop (cervical) 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®. We evaluated answers about satisfaction from patient's questionnaire.



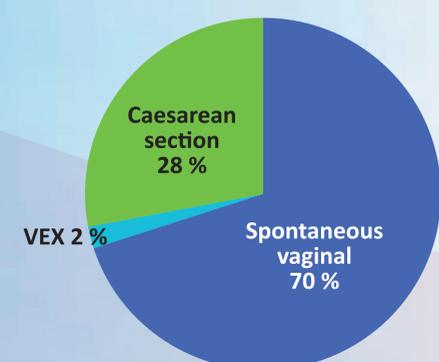
Fig. 1: Dilapan-S® osmotic cervical dilator before and after anisotropic swelling

Results 1:

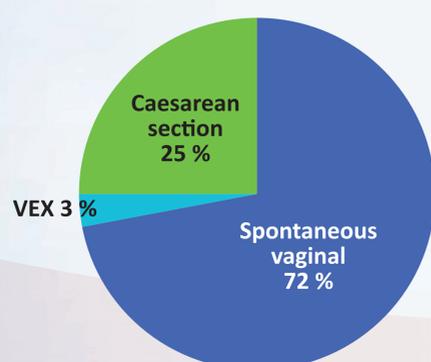
The evaluation of efficacy of the medical device Dilapan-S® in labor pre-induction showed that the application was effective regarding of the Bishop score progression with the increase from a mean of 2.81 to 6.13, which was confirmed as statistically significant. Successful pre-induction (Bishop score 5 and more) was achieved in 86.5 % of women. In our study 68 females (71.6 %) delivered vaginally, 27 females (28.4 %) delivered by Caesarean section. When comparing the subgroup of women with a Caesarean section in their medical history and the subgroup of women without previous CS, there was no significant difference in the ratio of completed vaginal births.

Mode of delivery	All females		Females with previous SC		Females without previous SC	
	n	%	n	%	n	%
Vaginal	68	71.6 %	22	64.7 %	46	75.4 %
Caesarean section	27	28.4 %	12	35.3 %	15	24.6 %

Tab. 1: Comparison of delivery mode in women with/without Caesarean section in previous history



Graph. 1: Mode of delivery in all women (n=95)

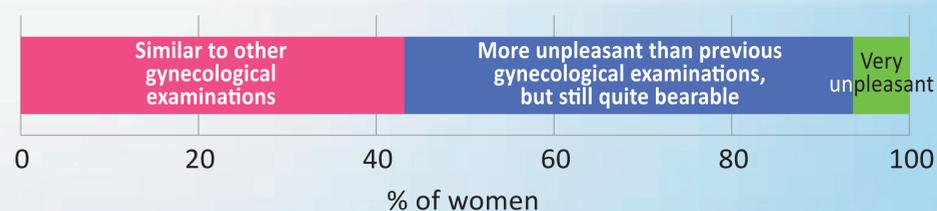


Graph. 2: Mode of delivery in women without SC in previous history (n=61)

Results 2:

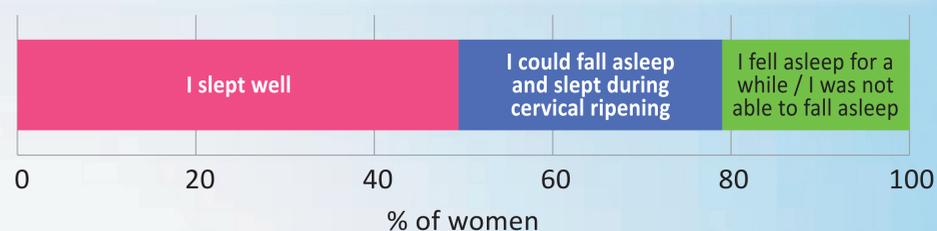
In most cases inserted dilators of Dilapan-S were in situ overnight. The average number of dilators inserted were 3 (range: 2–5). The patients questionnaire was completed by all 96 mothers. 89 women (93.7 %) evaluated the procedure of insertion of Dilapan-S® as similar to other gynecological examinations or more unpleasant but still quiet tolerable. Patient's soreness assessment of Dilapan-S® insertion resulted in a mean pain score of 3.2 (0–10 points scale). 79 % of all women were able to sleep without any problems or with only minor difficulties. Uterine contractions during cervical ripening phase were assessed as none, mild or moderate in 90 % of all women.

93,7 % women evaluated Dilapan-S insertion as fully acceptable



Graph. 3: Women satisfaction / insertion assessment

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



Graph. 4: Women satisfaction / opportunity to sleep during cervical ripening process

Results 3:

Uterine hypertonus during pre-induction was not recorded. Signs of fetal hypoxia did not occur on CTG trace during pre-induction. A pH value of 7.10 and less from umbilical artery was found in 1 newborn (1.0 %). Apgar score at 5th minute less than 7 was found in 1 newborn (1.0 %). One case of postpartum metritis was reported after vaginal delivery in the subgroup with CS in previous history. Postpartum infectious complications in newborns were not reported. The extraction of Dilapan-S® was assessed by physician as easy in 100 %. Rupture of membranes associated with insertion of Dilapan-S® was not reported in any of the participating females.

Conclusion:

Dilapan-S® administered for cervical ripening prior to labor induction was effective concerning the increase of the Bishop score in females regardless of Caesarean section in their medical history. 71,6 % of all females delivered vaginally. The majority (93,7 %) of all women evaluated the insertion of Dilapan-S® as fully acceptable. 79 % of all females were able to sleep without any or only minor problems. Use of Dilapan-S® was not associated with occurrence of excessive uterine contractions, infections or other complications in all 96 cases.