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Use of the osmotic dilator Dilapan-S for cervical ripening prior to inducion of labor in women with/without Caesarean section in medical history

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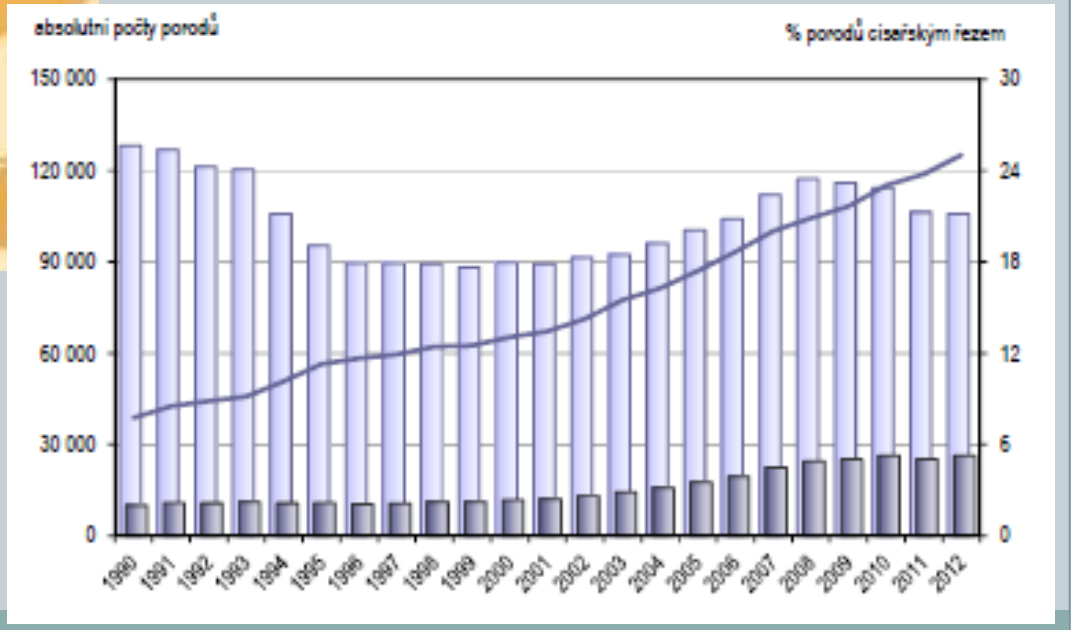
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Czech Republic



C/S rate > 25%



Mechanical methods for induction of labour (Review)

Jozwiak M, Bloemenkamp KWM, Kelly AJ, Mol BWJ, Irion O, Boulvain M

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2012, Issue 3

http://www.thecochranelibrary.com

- advantages of mechanical methods (storage, price, availability)
- efficacy comparable to pharmacological methods
- low risk of uterine hyperstimulation and fetal distress
- lower risk of side effects
- the risk of infectious complications has not been proven

THE COCHRANE COLLABORATION®

Dilapan-S: Mode of Action

Rigid gel rod that increases in volume by absorbing fluids from cervical canal

Mechanical pressure, osmotic gradient reversal and increased cell wall permeability result to the

- Reversible cell dehydration and cervical tissue softening (short-term)
- Release of endogenous prostaglandins causing collagen reorganization and tissue restructuring (mid/long-term)

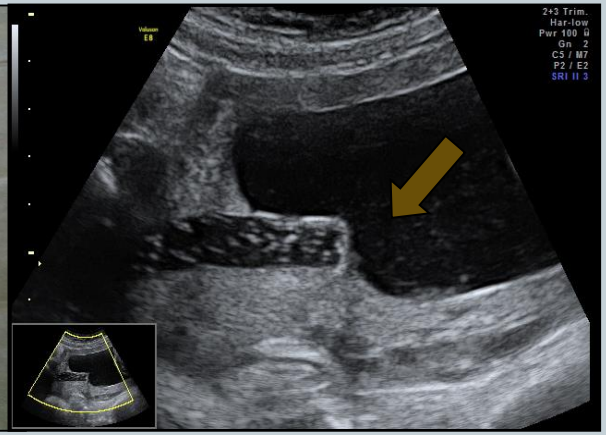


Aim of the Study

To evaluate efficacy and safety of use of the synthetic osmotic dilator Dilapan-S for cervical ripening prior to labor induction and to compare the results in women with/without Caesarean section in medical history.







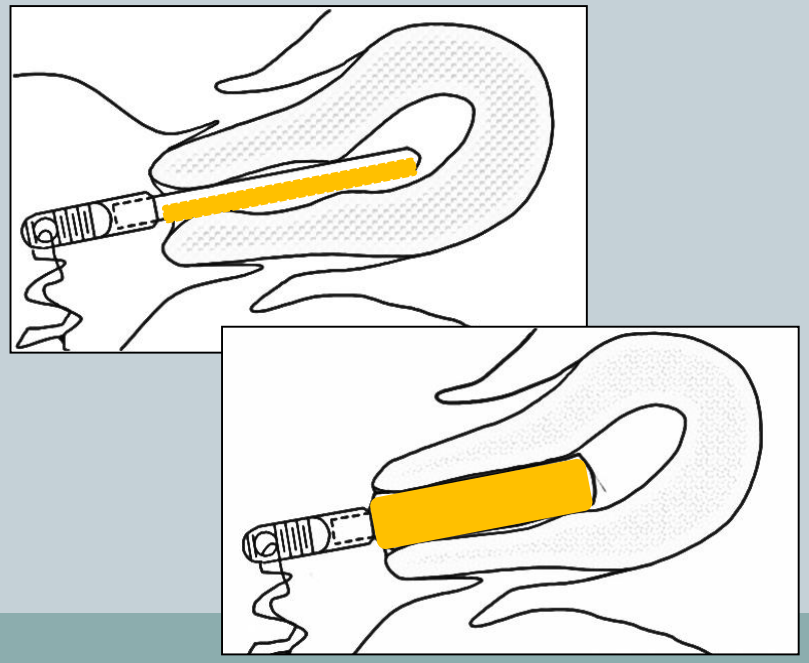
Materials and Methods

- **Prospective, observational, multicenter study**
- 125 patients undergoing induction of labor with the use of osmotic cervical dilators Dilapan-S for cervical ripening
- 64 patients (51.2 %) with previous Caesarean section in their medical history

Inclusion criteria:

- singleton pregnancy
- > 36th week of gestation
- cephalic presentation
- cervix score ≤ 4 *

* Burnett modification of Bishop score with scale 0-10 points was used.



Primary endpoints

- **efficacy of pre-induction**
  (achieving cervix score of 5 or more)
- **mode of delivery**
  (vaginal delivery rate)
- **perinatal outcomes**
  (pH of a. umbilicalis < 7.10, Apgar score at 5th minute < 7)
- **separate evaluation of both subgroups of patients: with and without history of Caesarean section**

Secondary endpoints

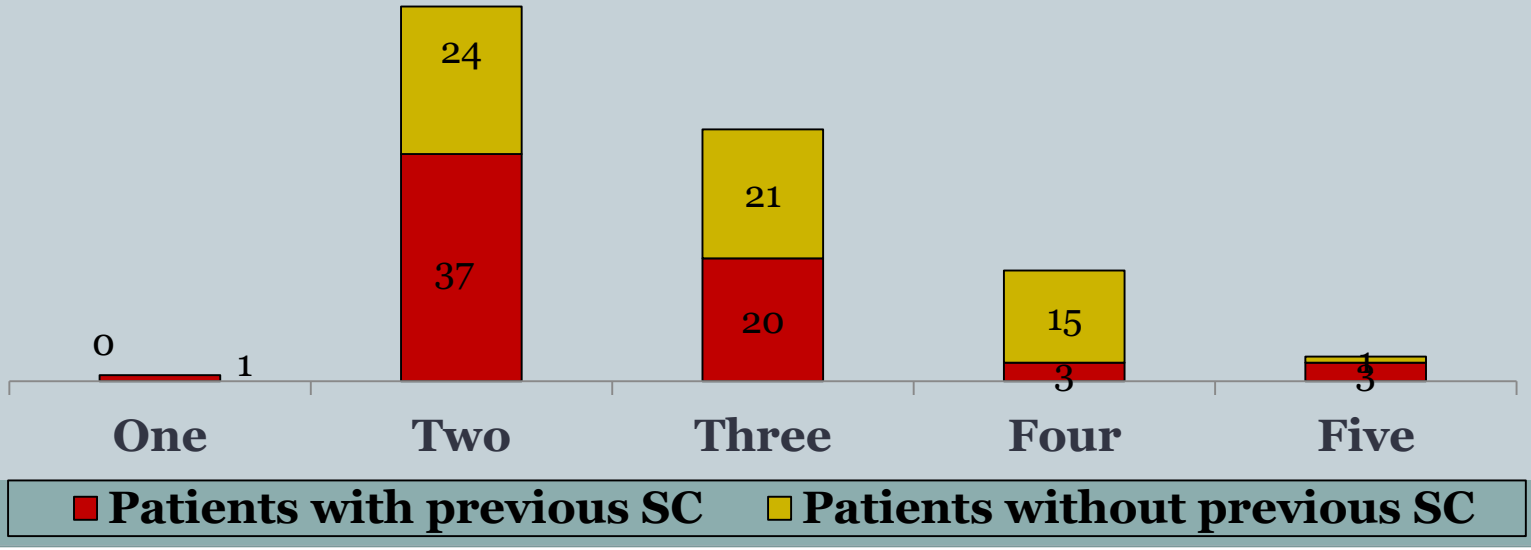
- **incidence of contraction activity and uterine hyperstimulation during pre-induction**
  (> 5 contractions per 10 min.)
- **signs of intrauterine fetal distress**
  (cardiotocography)
- **incidence of infectious complications in mothers and in newborns**
- **patients questionnaire**
  (acceptance of Dilapan-S insertion, ability to relax / ability to sleep during pre-induction)

Indication for induction of labor

Indications	All patients		Patients with previous SC		Patients without previous SC	
	n	%	n	%	n	%
Post-term pregnancy	58	35.0 %	36	37.9 %	22	31.0 %
Previous SC	30	18.0 %	30	31.6 %	0	-
Hypertensive disease /Preeclampsia	16	9.7 %	10	10.5 %	6	8.5 %
Gestational diabetes	16	9.7 %	8	8.4 %	8	11.3 %
Fetal macrosomia	13	7.8 %	3	3.2%	10	14.1 %
IUGR	13	7.8 %	2	2.1 %	11	15.5 %
Elective SC (mother‘s request)	3	1.8 %	2	2.1 %	1	1.4 %
Premature rupture of membranes	2	1.2 %	0	-	2	2.8 %
Rh immunization and rising antibody titre	1	0.6 %	0	-	1	1.4 %
Others	14	8.4 %	4	4.2 %	10	14.0 %

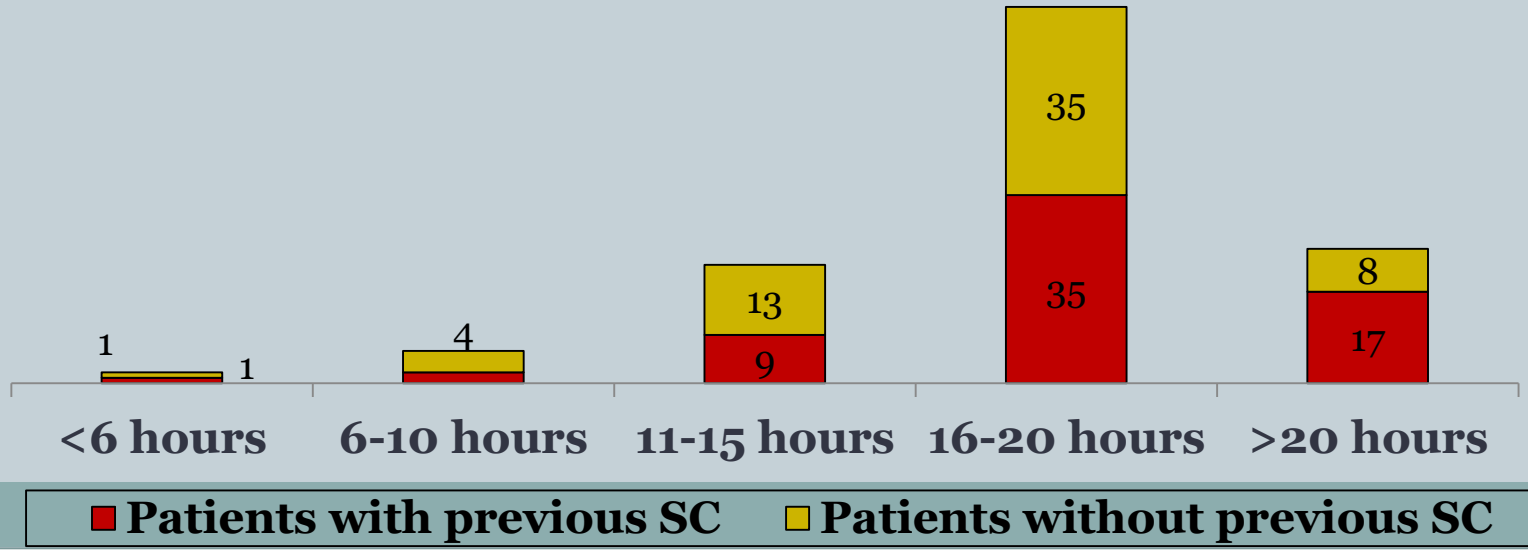
Number of inserted osmotic dilators

	n	Mean	Median	Min	Max
All patients	125	2.70	**3**	1	5
Patients with previous SC	64	2.53	**2**	1	5
Patients without previous SC	61	2.89	**3**	2	5

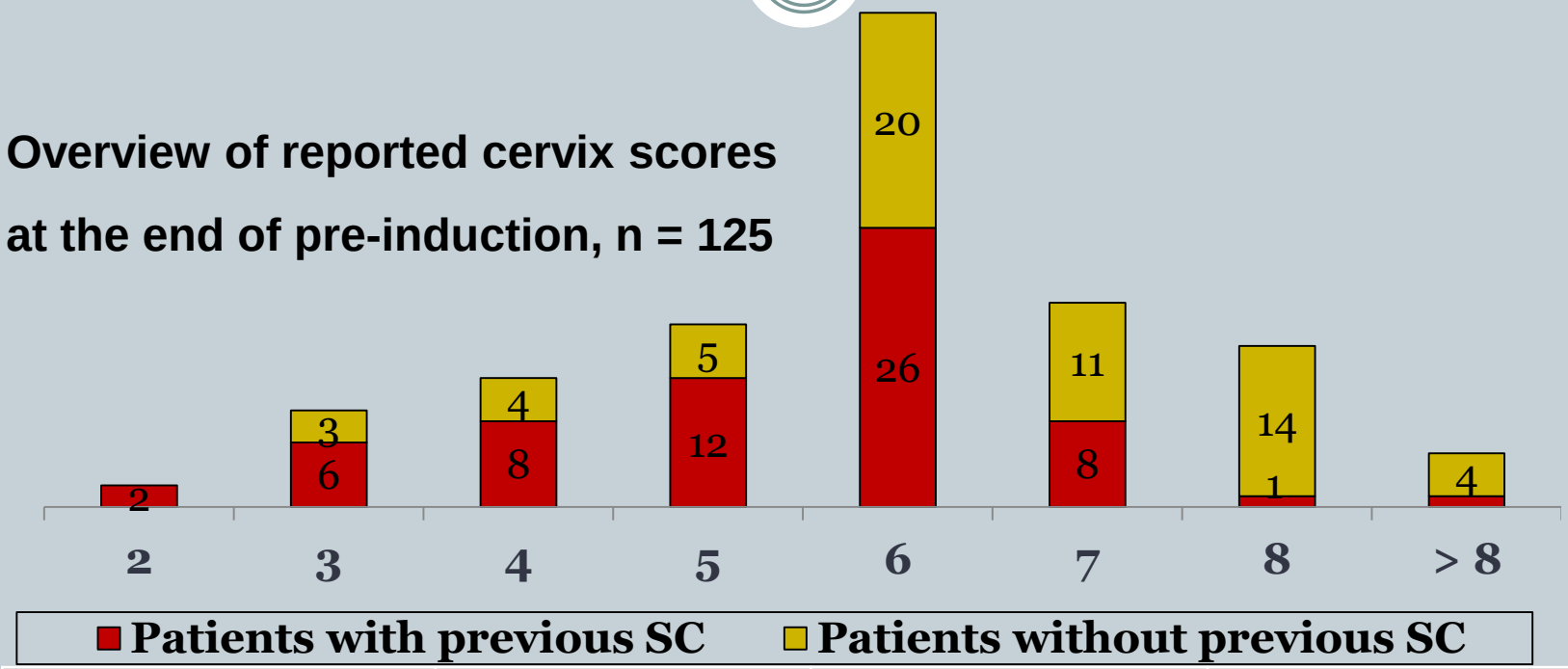


Duration of pre-induction

	n	Mean *(hours)*	Median *(hours)*	Min *(hours)*	Max *(hours)*
All patients	125	17.36	**18,0**	2	24
Patients with previous SC	64	18.02	**18,5**	2	24
Patients without previous SC	61	16.67	**18,0**	5	24



Results I - Efficacy: *Improvement of Cervix Score*



	All patients		Patients with previous SC		Patients without previous SC	
	n	%	n	%	n	%
CS ≥ 5 at the end of pre-induction	102	81.6 %	48	75.0 %	54	88.5 %

Results II: *Mode of Delivery*

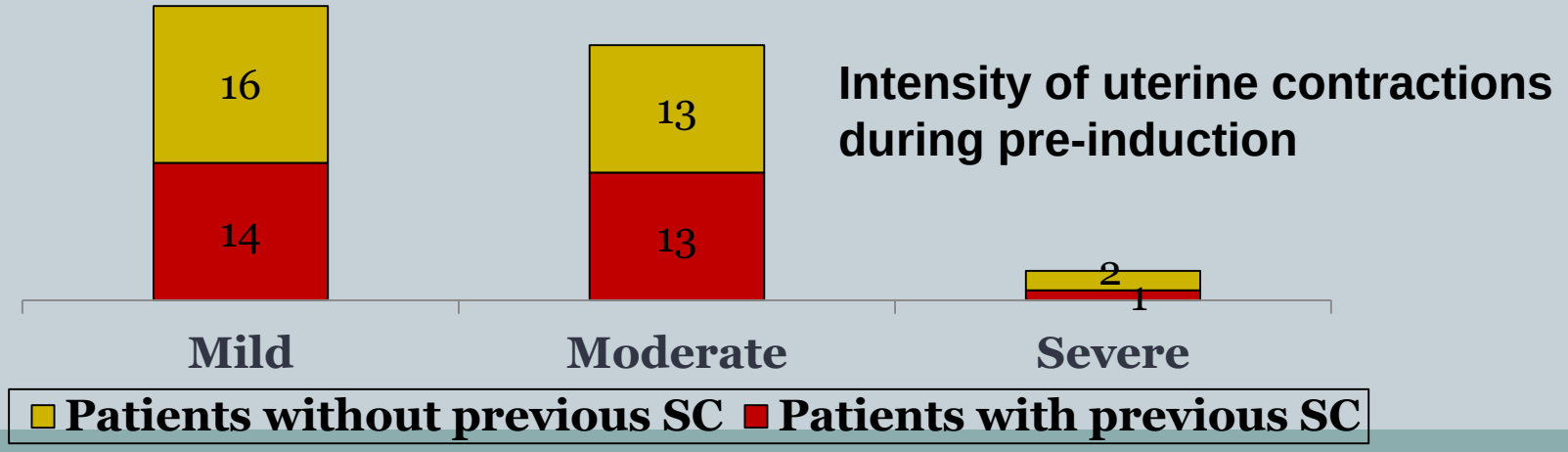
Delivery mode	All patients		Patients with previous SC		Patients without previous SC	
	n	%	n	%	N	%
Vaginal	83	**66.1 %**	37	**57.1 %**	46	**75.4 %**
Caesarean section	42	33.9 %	27	42.9 %	15	24.6 %

A statistically significant difference between sub-groups of patients with/without SC in medical history was not observed ($p\text{-value}_{min} \leq 0{,}117$).



Results III - safety: *Complications during pre-induction*

- No case of signs of fetal hypoxia at CTG trace during pre-induction
- Contraction activity during pre-induction was reported in 42 patients (34 %)
- Uterine hyperstimulation was not recorded



Results IV – Safety: *Intra- and postpartum complications*

- **Apgar score < 7 at 5th min** in 1 newborn (1.0 %) of mother with previous Cesarean section
- **pH < 7.10** was reported in 2 newborns of mothers with previous Cesarean section

- **postpartum endomyometritis** 1 mother without SC in history (3rd day after vaginal delivery), ATB therapy, no relation to the use of Dilapan-S was found

- postpartum **infectious complications in newborns** were not reported

Results Va: *Patients' satisfaction*

Dilapan insertion evaluated as acceptable by 93.6% of women

Answer	All patients		Patients with previous SC		Patients without previous SC	
	n	%	n	%	n	%
a: similar to other gynecological examinations	56	**44.8 %**	29	45.3 %	27	44.3 %
b: more unpleasant than previous gynecological examinations, but still quite bearable	61	**48.8 %**	32	50.0 %	29	47.5 %
c: very unpleasant, associated with significantly negative feelings	8	6.4 %	3	4.7 %	5	8.2 %

Results Vb: *Patients' satisfaction*

89.6 % of women were able to relax during cervical ripening

Answer	All patients		Pacients with previous SC		Pacients without previous SC	
	n	%	n	%	N	%
a: very good, I had no problems which prevented me from rest	73	**58.4 %**	35	54.7 %	38	62.3 %
b: quite well, sometimes problems occured	39	**31.2 %**	22	34.4 %	17	27.9 %
c: I rather could not relax due to the problems accompanied with cervical ripening	12	9.6 %	7	10.9 %	5	8.2 %
d: I could not relax at all due to the problems during cervical ripening	1	0.8 %	-	-	1	1.6 %

Results Vc: *Patients' satisfaction*

79.2% of women stated ability to sleep during cervical ripening

Answer	All pacients n = 95		Pacients with previous SC		Pacients without previous SC	
	n	%	n	%	n	%
a: I slept well, I had no problems which prevented me from sleep	61	**48.8%**	32	50.0 %	29	47.5 %
b: I could fall asleep and I slept during this delivery phase despite occassional problems	38	**30.4%**	20	31.3 %	18	29.5 %
c: I fell asleep for awhile, but in general I could not sleep much	18	14.4 %	10	15.6 %	8	13.1 %
d: I was not able to fall asleep	8	6.4 %	2	3.1 %	6	9.8 %

Conclusions

- Osmotic cervical dilator Dilapan-S is highly effective and safe in cervical ripening
- The advantage is the low incidence of adverse contractile activity during pre-induction minimising the risk of uterine hypestimulation
- It can be effectively used even in patients with a history of previous Caesarean section
- Infectious complications related to the use of Dilapan/S in mothers and newborns in our sample were not recorded
- High patients´satisfaction rate incl. ability to relax and sleep during cervical ripening

Thank you for your attention.



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