International observational e-registry on the use of Dilapan-S® osmotic dilator for cervical ripening prior to labor induction

Material and methods:

- Prospective observational international multicentric e-registry performed between May 2015 and April 2017.
- The main objective is to monitor clinical outcomes of the use of Dilapan-S®
  1) for cervical ripening and following procedures of induction of labor with the main focus on the duration of cervical ripening, overall duration of induced labour procedure and the rate of vaginal deliveries within 24 hours; estimated total sample size 600 women (IOL)
  2) for cervical priming prior to termination of pregnancy with regard to the number of dilators used and duration of insertion of dilators *in situ;* estimated total sample size 520 women (TOP)

Project overview:

- 21 study sites / 8 countries (UK, Germany, USA, Czech Republic, Slovakia, India, France, Russia)
- Chief investigator: Prof. Janesh Gupta, MSc, MD, FRCOG, Birmingham Women's Hospital, Birmingham, UK
- Electronic data collection, continuous remote data monitoring
- 348 patients already recruited in Jan 2016 (250 in IOL and 98 in TOP)

2015
14 sites currently recruiting
2 sites are ready to start
5 expecting EC approval

2016
Initiation of 100% of study sites
Interim data reports
Presentation of interim results

2017 +
Closing of data records
Final study reports
Publication and presentations of complete clinical results

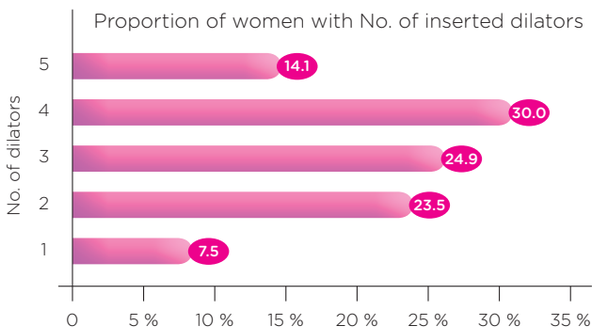
214 women from 6 study sites in 5 countries were included in the 1st interim IOL data analysis.

Country	Study site involved into the analysis		No of Patient enroled
UK	Birmingham Women's Hospital, Birmingham	*Prof. Janesh Gupta, MSc, MD, FRCOG*	40
Germany	Klinikum im Friedrichshain Vivantes, Berlin	*Ass. Prof. Lars Hellmeyer, MD*	70
Czech Republic	Masaryk University Hospital Brno	*Petr Janku, MD, PhD*	39
Slovakia	University Hospital Trnava	*Ass. Prof. Jozef Zahumensky, PhD*	37
India	UCMS Guru Teg Bahadur Hospital, New Delhi Sri Ramachandra Medical College, Chennai	*Prof. Amita Suneja, MD, FWHO* *Prof. Usha Vishwanath, MD*	28
Total	6		214

Dilapan-S®

Results:

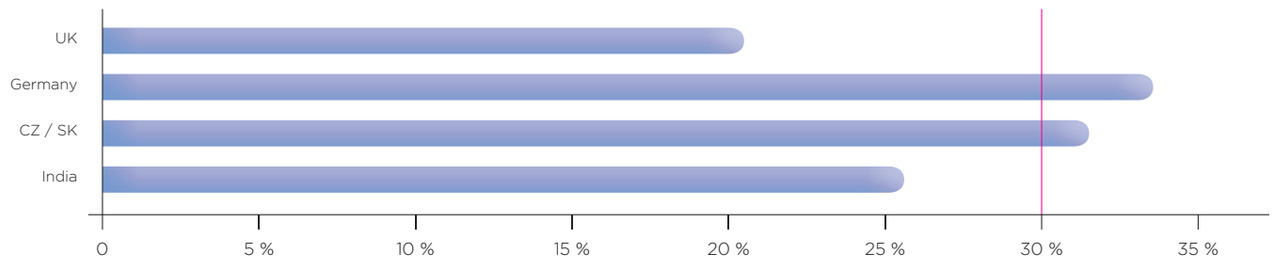
- Number of inserted dilators varied from one to five pieces.



- The average increase of Bishop score was +3,72 (measured on the 13 point scale).

All women	N	Mean	95% CI
Bishop score prior to insertion	214	2.836	2.656 to 3.017
Bishop score after extraction	214	6.552	6.299 to 6.805
Women without previous C. section	N	Mean	95% CI
Bishop score prior to insertion	186	2.887	2.694 to 3.080
Bishop score after extraction	186	6.582	6.310 to 6.853
Women with previous C. section	N	Mean	95% CI
Bishop score prior to insertion	28	2.5	1.988 to 3.012
Bishop score after extraction	28	6.357	5.617 to 7.097

- Average Caesarean section rate was 30.4% and differs from 20% to 33% in relation to each study site.



- 11.2% of women delivered vaginally with no further induction method.
- No uterine hyperstimulation and no foetal pathology was reported based on CTG during cervical ripening.
- 10.3% of patients experienced uterine contractions while the dilator was inserted.
- 8.3% of women reported complications or discomfort during preinduction.
- Maternal infectious complications were observed in 5 cases (2.3%). No association of maternal infection with the use of osmotic dilator was reported.
- No neonatal infectious complication was reported.

Conclusion:

- **Application of Dilapan-S® is a safe and efficient technique of cervical ripening.**
- **Dilapan-S® can contribute to the achievement of high vaginal delivery rate.**
- **No serious adverse outcome for mother and newborn reported.**
- **Low occurence of uterine contractions during cervical ripening.**
- **Potential to prevent unnecessary Caesarean sections in high-risk patients.**
- **The application of Dilapan-S® can be an outpatient procedure in low-risk patients and therefore cost-effective.**

References: 1. Gupta JK et al. Mechanical methods of cervical ripening. Oral presentation at All India Congress of Obstetrics & Gynaecology 2016, Agra, India 13–17 January 2016 **2.** Data on file

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Gentle. Predictable.

DIL/GOV/VIS/MARCH2016/INT004