

## International observational E-registry on the use of Dilapan-S® for cervical ripening prior to labor induction

International study from 7 countries (11 study sites), monitoring clinical outcomes of the use of synthetic osmotic dilator Dilapan-S® for cervical ripening prior to induction of labor.

**Study** Chief investigator: Prof. Janesh Gupta, MSC, MD, FRCOG, Birmingham Women’s Hospital, Birmingham, UK

**Main Focus on**

- Duration of cervical ripening
- Overall duration of induced labor procedure
- Vaginal delivery rate

543 subjects enrolled / 444 eligible for analysis



**Mean Age** 29.3 years

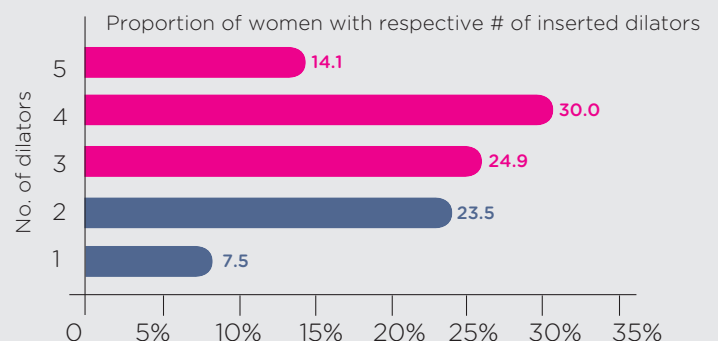
**Mean Gestational Age** 39.4 weeks

45% of indications represented relative contraindications for usage of prostaglandins

**Mean number of dilators used** 3.8 pieces

### Major indications for labor inductions

- |                                  |     |
|----------------------------------|-----|
| 1. Post-term pregnancy           | 31% |
| 2. IUGR                          | 12% |
| 3. Pre-eclampsia                 | 11% |
| 4. Gestational Diabetes Mellitus | 10% |
| 5. Previous C-Section            | 6%  |



## Efficacy

**Mean gain of Bishop score**  
+3.6

**Cervical Ripening achieved in**  
94.4%

**Rate of vaginal delivery**  
70%

\*Vaginal delivery rate varied between 51-83%, depending on study center



## Patient Satisfaction

- Mild discomfort **3.4%**
- Mild uterine contractions **25%**
- Fully acceptable insertion **95%**

## Safety

- Infectious complications of mother or baby related to usage of dilators: **0%**
- Suspected fetal pathology based on CTG: **0.2%**
- Apgar score (5 min) <7: **0.7%**

## Significantly better outcomes when Dilapan-S<sup>®</sup> left in situ up to 12 hours

	< 12 hrs	> 12 hrs
Number of subjects	188	256
Mean number of dilators	4	3.6
Mean vaginal delivery rate	76.6%	64.8%
Mean vaginal delivery within 36 hrs	66%	48.4%
Mean insertion - delivery time	24.3 hrs	39.1 hrs



## Conclusion

- The use of Dilapan-S<sup>®</sup> leads to high vaginal delivery rate.
- Significantly better outcomes when Dilapan-S<sup>®</sup> left in situ up to 12 hours verses longer duration.
- Use of Dilapan-S<sup>®</sup> does not lead to serious maternal or neonatal adverse effects.

**References:** 1. Gupta JK: Recent advances in induction of labour. Oral presentations at EBCOG 2018. 18 March 2018 2. Data on file