Synthetic osmotic dilator prior to induction of labor
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Objective
The aim of this data collection is to monitor post market clinical practice of the application of synthetic osmotic dilator for cervical ripening prior to induction of labor. The main focus was the rate of Caesarean sections. Additionally, we were aiming to confirm safety and tolerability of synthetic osmotic dilators in routine clinical practice as well as to provide clinical recommendations concerning number of dilators and duration of insertion.

Methods
This is an interim analysis of a 2-year prospective observational international multicenter data collection involved 6 study sites in 5 countries. Demographic and procedural details and post-delivery complications for women undergoing induction of labor when synthetic osmotic dilators were used were recorded on a standardised form and entered into an electronic data capture system for analysis.

Results
Between the 1 May 2015 and 11 November 2015 214 women were enrolled. The average age was 30 years, 63.5% were nulliparous, 23.4% had a previous vaginal delivery and 13.1% had previous cesarean section. One to five synthetic osmotic dilators were used for cervical ripening prior to induction of labor. One third of women (30%) received four dilators. The average cesarean section rate was 30.4% and differs from 20% to 33% in relation to each study site. 11.2% of women delivered spontaneously vaginally without application of any further induction method after dilators’ extraction. The average increase of Bishop score was +3.7. No uterine hyperstimulation and no fetal pathology was reported based on CTG during cervical ripening. 10.3% of patients experienced uterine contractions while the dilator was inserted. Non-serious complications or discomfort during cervical ripening were reported in 8.3% of women. Maternal infectious complications were observed in 5 cases (2.3%). There was no association with maternal infection and the use of osmotic dilators reported. No neonatal infectious complication was reported.

Conclusion
We were able to show that the application of osmotic dilators is a safe and efficient method of cervical ripening. No serious adverse outcome for mother and newborn was reported. The synthetic osmotic dilator has the capability to reach a high vaginal delivery rate. In addition it has the potential to prevent unnecessary cesarean sections in high risk patients. It is cost effective as the application of the osmotic dilator can be an outpatient procedure in low risk patients.