South African National Essential Medicine List
Adult Hospital Level Medication Review Process
Component: Obstetrics

EVIDENCE SUMMARY:
Date: 12 March 2019

Summary prepared by Dr E Bera.
Affiliation: Department of Obstetrics & Gynaecology, University of the Witwatersrand; Adult Hospital Level Committee Member (2017-2020)
Conflicts of interest: None declared

Intervention: Foley catheter bulb for induction of labour

Recent study published in the Obstetrics and Gynaecology, 2018 was appraised - investigating whether cervical ripening using foley catheter with misoprostol vs misoprostol alone, would shorten shortened induction-to-delivery time. This randomised study[1] was done at a New York hospital between 2015 & 2016. The objective was to determine if, among women undergoing induction of labour (IOL), the addition of a Foley catheter to misoprostol may shorten the induction-to-delivery interval.

Women at ≥37 weeks gestation, with a singleton fetus, cephalic presentation, and a Bishop score of <7, were offered participation in the study. Exclusion criteria included ruptured membranes, uterine contractions, previous caesarean delivery, multiple pregnancy, or any contra-indication to vaginal delivery.

Randomisation was by computer generated assignment. Neither health care workers nor participants were blinded to allocation. Women randomised to the misoprostol-only arm received 25 mcg vaginal misoprostol 4-hourly for a maximum of 24 hours, whereas women randomised to the Foley-misoprostol arm, in addition to misoprostol, had a Foley catheter inserted through the internal cervical os, and the bulb was inflated with 60 mL of sodium chloride. The catheter was taped to the patient's inner thigh under gentle traction.

The primary endpoint was time from the onset of induction to delivery. Secondary endpoints included CD rate, uterine tachysystole, blood loss at delivery, chorio-amnionitis, and neonatal outcomes.

Two hundred women were randomised, 100 in each arm. There were by-and-large no significant differences in the characteristics of the 2 groups. The primary endpoint, median time from the onset of induction to delivery, was significantly shorter in the Foley-misoprostol arm (15 vs 19 hours, p=0.001). This time difference was significant for both intention-to-treat & per-protocol analyses. There were no significant differences in the secondary endpoints between the 2 groups, except for a higher rate of meconium stained amniotic fluid in the misoprostol-only arm.

Brief Comments
The shorter induction-to-delivery time appears to be driven by the shorter time to reach the active phase of labour, since time from active phase to delivery was not significantly different. This suggests that the addition of the Foley catheter speeds up cervical ripening.

[1] Al-Ibraheemi Z, Brustman L, Bimson BE, Porat N, Rosenn B. Misoprostol With Foley Bulb Compared With Misoprostol Alone for Cervical Ripening: A Randomized Controlled Trial. Obstet Gynecol. 2018 Jan;131(1):23-29.

The shorter induction-to-delivery time was shorter for both nulliparous & multiparous women. Although the study was adequately powered for time interval, it may have been underpowered for less common endpoints such as chorio-amnionitis, or some neonatal outcomes. Nevertheless, their results could be generalised to our setting since the Bishop score is a universal tool to assess favourability of the cervix, and our methods for IOL are not dissimilar to those in the USA.

A minor caveat – it would have been informative to compare patient satisfaction in each arm, if anything, to ascertain acceptability of the Foley catheter for routine use.