Cases reports from Brazil about the use of pessary AM INGAMED in pregnant women with short cervix after universal screening

Salvador AD, Dutra JP, Laranjeira CLS, Silva CHM, Geo MS Mater Dei Hospital - High Risk Pregnancy Unit, Belo Horizonte, Brazil

Objective

The objective of this study was to evaluate the maternal and neonatal outcomes by describing all cases of pessary use in the prevention of preterm labor from January 2016 to April 2018 in a private quaternary hospital.

Methods

A prospective cohort of patients attended at the Obstetric High Risk Unit of a private hospital in Brazil using Pessary AM-Ingamed (Photo 1). The pessary Am Ingamed is the only pessary for preterm labor prevention that can be used in Brazil, according to ANVISA (Brazilian Health Agency for the Use of Medicines and Medical Materials). Nineteen pregnant women were submitted to the insertion of pessary after transvaginal ultrasonography that diagnosed a short uterine cervix with a measurement inferior to 25 mm. The insertion of the device was performed immediately after the ultrasonography.

Results

The mean age of the pregnant women was 35 years, 16 pregnancies were singletons, two were twins and one gestation was triplet. Twelve women were nulliparous, eight patients had previous history of uterine curettage for spontaneous abortion in the first trimester and one patient had a previous extreme preterm delivery at 22 weeks with a neonatal fetal death. The pessaries were inserted between 19 and 30 weeks of gestation. The infectious screening was negative in all pregnant women at the time of insertion of the pessary. One patient presented urinary retention by compression of the urethra, soon after the insertion of the pessary, a condition that was resolved with repositioning of the device, and in one patient the pessary had to be repositioned twice. All patients reported increased volume of vaginal secretion, and no vaginal ulcer occurred. One patient presented urinary tract infection resolved after antibiotic therapy without complications. All women used 200 mg of vaginally progesterone until the 36th week of gestation. During pregnancy, the high-risk obstetric team routinely evaluated all patients within a two weeks interval. The mean gestational age of removal of the pessary was 36 weeks. Of these patients, 9 had delivery after 37 weeks, 4 vaginal and 3 cesarean sections (CS). Eight had deliveries before 37 weeks by CS, two being due to chronic fetal distress with restricted fetal growth, one due to severe preeclampsia, one due to acute fetal distress, two after preterm labor, one after maternal cholestasis and one had an elective CS at 33 weeks because of a monoamniotic twin pregnancy. There is another two waiting for delivery. In only 6 births the newborn required hospitalization in an Intermediate Neonatal Intensive Care Unit (NICU).

Conclusion

The cases described in this series demonstrate a good maternal and neonatal outcome and positive experience with the use of the pessary AM INGAMED. In this group of women, the pessary AM INGAMED proved to be effective in preventing preterm birth in pregnant women with uterine cervix length less than 25 mm between 19 and 29 weeks of gestation (2 of them after 26 weeks, because of cervical lenth of 15mm). The results of our study do not coincide with the results of another open-label, randomized trial comparing the placement of pessary with expectant control (control) in women with a single pregnancy, in which another pessary model was used. The associated use of vaginal progesterone may be a cause of error in the analysis due to its protective effect on preterm delivery, but the results, recorded in the current literature, showed a reduction of only 50% in the risk of delivery before the 34th week with the use of progesterone alone. It is also important to emphasize that all patients tolerated well the pessary use.