

CERVICAL PESSARY PLUS VAGINAL PROGESTERONE IN A SINGLETON PREGNANCY WITH A SHORT CERVIX: AN ANALYSIS OF EFFICACY BASED ON THE LEARNING CURVE AND CUMULATIVE SUM ANALYSIS (LC-CUSUM) IN A QUASI-RANDOMIZED CLINICAL TRIAL

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September 11, 2020

Abstract

Objective This study aims to determine the performance of cervical pessary in singleton pregnancies with a short cervix based on the learning curve. **Design, Settings, Population, and Methods** Between 2011 and 2018, 128 singleton gestation between 18th to 24th weeks with a short cervix (<25mm) were referred to our quasi-randomized trial. All cases were treated with progesterone, and, when available, cervical pessary was also offered. Three groups were created for statistical analysis: Group 1 (n=33), treated with progesterone-only; Group 2 and Group 3, treated with cervical pessary plus progesterone. Group 2, included the first cases (n=30), defined by the learning curve and cumulative sum analysis (LC-CUSUM), while Group 3, included the subsequent (n=65). Our outcome was delivery before 34 weeks. **Main outcome measures and Results** LC-CUSUM demonstrated that 30 patients achieved learning. The preterm birth rate before 34 weeks was 27.3% in Group 1, 20% in Group 2, and 4.6% in Group 3. There was no significant difference in the Group 1/Group 2 comparison (OR 1.10, P=0.945); the Group 1/Group 3 comparison, the difference was significant (OR 0.08, P=0.003). **Conclusion** LC-CUSUM determined 30 pessaries to achieve the best pessary performance. Cervical pessary plus progesterone can reduce the preterm birth before 34 weeks in patients with a short cervix. **Funding** This study was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brazil (CAPES) - Finance Code 001 **Keywords** Preterm birth; learning curve; cervical pessary; vaginal progesterone; singleton pregnancy; short cervix; transvaginal ultrasound.

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