THE ASSESSMENT OF EFFECTIVENESS OF CERVICAL PESSARIES FOR THE PREVENTION OF PRETERM BIRTH

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Preterm births (PTB) are the cause of almost half of all deaths of newborns in the world. Of the 4 million neonatal deaths in a year, more than the fifth were due to PTB. Delivery until 37 weeks of gestation occurs in 8-12% of all pregnancies in developed countries, 80% of perinatal mortalities and 50% of childhood neurodevelopmental disorders occur in these populations of patients. The prognosis of premature infants directly depends on gestational age and birth weight. Children who survive may face the risk of significant disability, including cerebral palsy, intellectual impairment, chronic lung disease and vision and hearing loss for a lifetime. They are also at greater risk of developing hypertension, obesity, neuroendocrine disorders and development problems later in their live. Different strategies have been adopted for prevention of spontaneous PTB. Although vaginal progesterone, cervical cerclage and cervical pessary have been used in clinical practice to prevent PTB, evidence regarding the effectiveness of these interventions is still inconclusive. A meta-analysis of randomized clinical trials (RCTs) suggested that progesterone potentially reduced PTL and neonatal complications in women with twin pregnancies and a short cervix. However, a recent meta-analysis showed that progesterone could only improve some secondary outcomes, regardless of cervical length (CL). An alternative approach for the prevention of preterm birth is transvaginal placement of a round silicone cervical perforated pessary (CP) around the cervix. According to the previous literature data the prominent problems were associated with the limited number of well-trained, certified staff was involved in the pessary installation; for the majority of women involved in the prior trials, microbial factor was not excluded before CP placement and during the current pregnancy.

The aim of the study was assessment of clinical effectiveness the cervical perforated pessary (CPP) used for prevention of preterm birth.

Material and Methods. The study was performed at the National Pirogov Memorial Medical University, Vinnytsya, Ukraine. Caucasian women with prior SPL who were randomized to receive a CPP (clinical group) or without pessary (control group) was conducted at the CNE "Vinnytsia City Clinical Maternity №1, from 2014 through 2018. Eligible women were those referred to the institution for a diagnosis of cervical incompetence between 16 weeks and 18 weeks +6 days. The primary outcome will be PTL <37 weeks' gestation for any indication. Secondary outcomes will be delivery before 28, 32 and 35 weeks of gestation; tocolytic drugs, antenatal corticosteroids or MgSO4 for neuroprotection use; preterm premature rupture of membrane; chorioamnionitis; maternal side effects (including vaginal discharge, fever, vaginal infection or pain, pessary repositioning and necrosis or rupture of the cervix); maternal morbidity (urinary tract infection, endometritis); birth weight; 5 min APGAR score; perinatal death, neonatal intensive care unit (NICU) admission; days of admission to the NICU; intraventricular hemorrhage; respiratory distress syndrome; necrotizing enterocolitis; neonatal infection and a composite of poor perinatal outcomes.

Data are shown as means or as numbers and percentages. Comparisons between groups were performed with the use of the t test to test group means by assuming equal within-group variances. Statistical data were calculated and compared using the MedCalc software, developed by "MedCalc Software" (Ostend, Belgium).

Results According to the primary outcome, in Table I shows the incidence of spontaneous preterm labor at less than 37 weeks of gestation was occurred in 9 patients (14,1%) from the pessary group and 17 participants (29,3%) in the control group (RR 0,48, 95% CI, 0,23-0,99, p=0,047). In generally, in the group of participants-carriers of CP we found a significantly lower rate of spontaneous preterm birth at less than 35 weeks of gestation (p=0,029), longer gestational age at delivery (p=0,002), higher birth weight (p=0,0005), higher rate by points APGAR score on 5 minutes (p=0,02), and lower incidence of adverse composite perinatal outcome (p=0,02) compared with patients from control group. In women-carriers of CP also were established significantly lower rates of respiratory distress syndrome (p=0,02).

Outcomes	Pessary group (n = 64)	Control group (n = 58)	RR or Between-Group Difference
PTB <37 wk, n (%)	9 (14,1)	17 (29.3)	**0,48, 95% CI, 0,23-0,99, p=0,047**
PTB <35 wk, n (%)	4 (6,25)	12 (20,7)	**0,30, 95% CI, 0,10-0,88, p=0,029**
PTB <32 wk, n (%)	1 (1,6)	7 (12,1)	0,13, 95% CI, 0,02-1,02, p=0,052
PTB <28 wk, n (%)	-	3 (5,2)	-
Gestational age at delivery, mean (SD), wk	37,8 (1,8)	36,4 (3,1)	**Difference -1,4, 95% CI, -2,30 to -0,50, p=0,002**
Intrauterine growth restriction	5 (7,8)	7 (12,1)	0,65, 95% CI, 0,22-1,93, p=0,43
Preterm premature rupture of membranes <37 wk, n (%)	14 (21,9)	18 (31,0)	0,71, 95% CI, 0,39-1,29, p=0,25
Cesarean delivery, n (%)	4 (6,25)	5 (8,6)	0,72, 95% CI, 0,20-2,57, p=0,62
Spontaneous vaginal delivery	60 (93,75)	53 (91,4)	1,03, 95% CI, 0,93-1,13, p=0,62
Vaginal discharge, n (%)	49 (76,6)	34 (58,6)	**1,31, 95% CI, 1,01-1,69, p=0,04**
Pelvic discomfort, n (%)	3 (4,7)	5 (8,6)	0,54, 95% CI, 0,14-2,18, p=0,39
Chorioamnionitis, n (%)	2 (3,1)	6 (9,4)	0,30, 95% CI, 0,06-1,44, p=0,13
Endometritis, n (%)	3 (4,7)	4 (6,25)	0,68, 95% CI, 0,16-2,91, p=0,60
Birth weight, mean (SD), g	3360,0 (260,5)	3162,1 (349,0)	**Difference -197,9, 95% CI, -307,6 to -88,15, p=0,0005**
Composite perinatal outcome, n (%)	4 (6,25)	13 (22,4)	**0,28, 95% CI, 0,1-0,81, p=0,02**

Tab. I. Primary and secondary outcomes among participants in the pessary and control groups

According to the adverse events follow-up, the participants pessary clinical group had a higher rate than the control group of increased vaginal discharge (RR 1,31, 95% CI, 1,01-1,69, p=0,04), but no significant differences in pelvic discomfort (RR 0,54, 95% CI, 0,14-2,18, p=0,39), chorioamnionitis (RR 0,30, 95% CI, 0,06-1,44, p=0,13), and endometritis (RR 0,68, 95% CI, 0,16-2,91, p=0,60) were reported. In our clinical prospective trial any cases of serious injuries cervix during removal of the CP were reported.

Conclusion

The women with prior SPL use of a CPP, resulted in a lower rate of SPL. The component in the successful results of preventive strategy SPL is consideration of vaginal microbiota and role of special trained staff for installation and care cervical pessary

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