Early and supervised use of the Epi-No® device in the prevention of high-grade perineal trauma and urinary incontinence 6 months after childbirth

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Hypothesis / aims of study

For a successful vaginal birth, the vaginal opening must slowly stretch, as when the baby descends rapidly, the tissues can tear [1]. Thus, several interventions have been used during the gestational period to prepare for childbirth, including perineal massage and the use of vaginal dilators [1]. EPI-NO® is a device that aims to stretch perineal structures gradually and slowly in the prenatal period to prevent a rapid traumatic laceration during childbirth [1,2,3]. We hypothesized that supervised use of EPI-NO® by a specialist physiotherapist, may avoid inadequate device manipulation and positioning bias and result in adequate muscle stretching during vaginal delivery. This study aimed to assess the efficacy of early and supervised use of EPI-NO® device in the prevention of perineal trauma and UI 6 months after delivery in primigravid women.

Study design, materials and methods

A cluster clinical trial was conducted in a low-risk maternity hospital, to verify the effect of supervised and early use of the EPI-NO® device in the prevention of perineal trauma and UI 6 months after delivery in primigravid women. The study was approved by research ethics committee (no.2.219.051) (ClinicalTrials.gov NCT04955418). **Study group (SG):** primigravid women aged 18–40 years (30th and 32nd gestational weeks). The study protocol has been disseminated to all local primary care units through detailed information folders. **Control group**: low-risk pregnant women originated from the same primary care units, who had free access to the same maternity hospital for childbirth between, and who were not previously exposed to the study protocol. CG were recruited after delivery, through a screening face to-face interview while they were still hospitalized; were invited to participate in the study, which included an evaluation 6 months after delivery and attended the evaluation criteria: primigravid women, a single fetus, aged 18 and 40 years, no instrumentalized delivery, between 37 and 42 weeks without complications. Exclusion criteria: previous perineal massage or pelvic muscle training, UI before pregnancy, The ICIQ-UI SF was applied in both groups: at baseline and 6 months after delivery in SG. The same questionnaire was applied to the CG 6 months after delivery. Pregnant women in the SG underwent 10 sessions (twice a week for 5 weeks) with the EPI-NO® from the 34th gestational week onwards. SG was evaluated before the intervention (30th and 32nd week) and 6 months after delivery. CG was evaluated at baseline and 6 months after delivery. Evaluations were performed for both groups by a blinded researcher: a structured questionnaire, physical examination, and answers to ICIQ-SF.

Study protocol: The pregnant in the supine position, back raised, flexed, and abducted lower limbs (30º to 45º), and feet supported on the stretcher. The EPI-NO® was protected with a condom, lubricated, and inserted into the vagina introitus. at a depth that allowed visualization of 2 cm of the balloon. The deflated probe was minimally inflated until it was felt in the vaginal canal. The first 5 min were devoted for pelvic floor perception(10 contractions and perineal relaxation to tone and maintain muscle strength, followed by 15 min to stretch the perineum by gradually inflating the device (participant's tolerance).The participant was instructed not to contract the perineal, gluteal, adductor muscles, or perform Valsalva maneuver. After 20 min, the participant relax so that the inflated device could be gently withdrawn from the vaginal cavity. Perineal lacerations were systematically reported by the assistant obstetrician and classified.

Results and interpretation

Table 1 . Classification of obstetric perineal trauma between groups.

Variables	SG	CG	Total
No laceration	11 (29.7%)	7 (21.9%)	18
1st-degree laceration	20 (54.1%)	4 (12.5%)	24
2nd degree laceration	4 (10.8%)	17 (53.1%)	21
3rd degree laceration	0	1 (3.1%)	1
Episiotomy	2 (5.4%)	3 (9.4%)	5
Total	37	32	69

Chi-square test p=0.0004
SG= study group

Table 2 Multivariate logistic regression model of risk factors or protection for deep perineal trauma.

Variables that remained in the model	*p-value*	Odds Ratio (95%CI)
Use of Epi-No®	0.00006784	0.0324 (0.0060 – 0.1751)
Time of expulsion stage	0.0003759	1.0658 (1.0290 – 1.1040)

** Maternal obesity, baby size and weight excluded from the model due to low reproductive capacity*

Table 3 Pad usage, continence status and ICIQ-SF 6 months after delivery

Variables	SG	CG	p-value
Use a pad for urine leakage	1 (2.7%)	6 (18.75%)	0.07 Z
No UI	21 (56.75%)	17 (53.12%)	0.65 Z
Stress UI	14 (37.83%)	11 (34.37%)	0.65 Z
Urgency UI	0	1 (3.12%)	0.65 Z
Mixed UI	2 (5.40%)	3 (9.37%)	0.65 Z
ICIQ-SF	0 (0-0)	0 (0-11)	0.002 W
ICIQ-SF (question 5)	0 (0-0)	0 (0-6)	0.016 W

W = Mann-Whitney U test; Z = Chi-square test

Conclusions

Our study demonstrated that supervised use of EPI-NO® was associated with a less deep perineal trauma, a significantly higher maximum perineal strength, a significant lower median value of the ICIQ-UI SF postpartum, and a better quality of life in primigravid women. Furthermore, the proportion of women with an intact perineum or spontaneous minor (first-degree) laceration was significantly higher in the SG in comparison to controls. Supervised use of the EPI-NO® device as of 34 weeks of pregnancy was associated with less deep perineal trauma, a better quality of life, and a significantly lower ICIQ-UI SF postpartum.

References

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