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DOES THE EPI-NO PREVENT PELVIC FLOOR TRAUMA? A MULTICENTRE RANDOMISED CONTROLLED TRIAL.

Hypothesis / aims of study

In 10-30% of women, vaginal birth results in levator ani tears which are associated with female pelvic organ prolapse (FPOP) and recurrence after prolapse surgery. In addition, it is now clear that tears to the external anal sphincter, a major etiological factor in the pathogenesis of fecal incontinence, are much more common than previously realised. Prevention of such trauma may reduce the future prevalence of these conditions. The Epi-No® Birth Trainer is an inflatable balloon device designed to allow women to gradually stretch the vagina and perineum from 37 weeks' gestation onwards. It has been claimed to shorten the 2nd stage of labour, reduce analgesics use and episiotomy rates [1]. This study was designed to evaluate the effect of Epi-No use on pelvic floor and anal sphincter integrity. The null hypothesis was: "Antepartum use of the Epi-No device does not prevent levator trauma".

Study design, materials and methods

This was a multicentre prospective randomized controlled trial conducted between July 2007 and March 2014. All primigravidae with an uncomplicated singleton pregnancy aiming for a vaginal delivery were identified in late pregnancy and invited to participate. Participants were assessed at a mean gestation of 36.0 weeks (SD 0.7, range, 32.9-37.4) and 3 months post-partum. They underwent a standardized interview and clinical examination including ICS POP-Q assessment and 4D translabial ultrasound, supine and after voiding as previously described [2]. Participants were randomized into the Control or Epi-No group after their antepartum assessment according to a computer- generated randomisation list. Those in the Epi-No group were asked to use the device from 37 weeks of gestation until the start of labour or rupture of membranes, according to the manufacturer's instructions, at least twice a day for at least 10 minutes per session. Ultrasound volume data were analysed at a later date, using proprietary software (4D View version 9.0), blinded to all clinical data including group allocation. The primary outcome measure was levator avulsion as diagnosed by tomographic translabial ultrasound [2]. Secondary outcome measures were significant obstetric anal sphincter defects on ultrasound [3], significant hiatal overdistension or ''microtrauma' (defined as >20% peripartum increase in hiatal area on Valsalva, resulting in hiatal area of >25cm2 in the absence of levator avulsion) and perineal trauma as diagnosed in Labour Ward. Delivery data were collected from the hospital database. Power calculations had been performed using the results of the pilot phase of this trial (n=200), providing a required sample size of 660 for 80% power to show statistical significance at an alpha error level of 5%, assuming a reduction in levator avulsion rate from 13% to 6.5% in the intervention arm. Modified intention to treat (ITT) and treatment received analysis were performed using SPSS v 20.0 and Minitab v 16. A $P<0.05$ was considered statistically significant.

Results

Of 660 partipants, 325 were randomized to the Control group and 335 to the Epi-No group. The randmisation process was effective in that there were no significant differences as regards demographic parameters (such as ethnicity, antepartum Body Mass Index (BMI), previous pregnancy less than 20 weeks and family history of caesarean section (CS) between the two groups. 38 women in the control group used the Epi-No device antenatally and 17 in the Epi-No group did not use the birth trainer; hence we also performed a treatment received analysis to account for these cross-overs. Those who did use the EpiNo did so on average 16.7 (SD 12.3, range 1-60) times. Delivery characteristics of the study population by group allocation are shown in Table 1, and there were no significant differences in obstetric outcomes such as delivery mode, length of second stage and perineal trauma. 503(76%) women returned for a second assessment at a mean of 5.1 months postpartum (SD 2.5, range, 2.3-24.3). Three women were in their second pregnancy by then and were excluded from further analysis. We were unable to retrieve US volumes in 3 women, leaving a total of 499 women for analysis of the primary outcome measure. Assessment of external anal sphincter (EAS) defects was not possible in 11 women due to either missing or suboptimal sphincter imaging, leaving 488 to be included in the assessment of EAS.

	Control (N=325)	**Epi-No (N=335)**	**P value**
Delivery mode Caesarean Normal vaginal delivery Ventouse Forceps	 75 (23%) 180 (55%) 47 (14%) 19(6%)	 77 (23%) 178 (53%) 50 (15%) 24(7%)	0.37
Syntocinon use	147 (45%)	151 (45%)	0.32
Use of intrapartum epidural	135 (42%)	147 (44%)	0.71
Length of 2nd stage (median, IQR)*	49 (16-104)	44 (12.5-98)	0.31
Neonatal birth weight (gram, SD)	3464 (413)	3434 (423)	0.37
Apgar score ≥7 at 1 minute	271 (83%)	275 (82%)	0.78
Apgar score ≥7 at 5 minute	293 (90%)	301 (90%)	0.33
Episiotomy (vaginal delivery)	66/246 (27%)	68/252 (27%)	0.99
Any perineal tear (vaginal delivery)	121/244 (50%)	126/249 (51%)	0.82

Major perineal tear (vaginal delivery)	13/244 (5%)	18/249 (7%)	0.39

Table 1 : Delivery data for control and Epi-No groups (N=660). Denominators for some measures differ due to missing data. T-Test or X2 test; * Kruskal Wallis test.

A levator avulsion was diagnosed in 64 (12.8%) women, with no significant difference between control and intervention groups: 33(14%) vs 31(11%) (P=0.40). Sixty women (12%) were diagnosed with significant overdistension (microtrauma), and again there was no difference between the groups. Significant residual defects of the external anal sphincter were seen in 90/ 488 women (25%), and there was a marginally higher rate in the intervention group (34/230 vs 56/ 258, OR 1.6 [1.00-2.56]; P= 0.05), see Table 2. Largely similar finding were observed in a 'treatment received' analysis (see Table 3).

	Control group (N=233)	Epi-No group (N=266)	Relative risk (95% CI)	P value
Levator avulsion	33/233 (14%)	31/266 (12%)	0.80 (0.47-1.35)	0.4
Significant microtrauma	30/233 (13%)	30/256 (12%)	0.86 (0.50-1.48)	0.58
Significant EAS defect	34/230 (15%)	56/258 (22%)	1.60 (1.00-2.56)	0.05
Any trauma	83/230 (36%)	97/258 (38%)	1.07 (0.74-1.54)	0.73

Table 2 : Pelvic floor trauma in control and Epi-No groups (intention to treat analysis). Denominators differ due to missing / suboptimal EAS imaging.

	No Epi-No use (N=211)	Epi-No use (N=285)	Relative risk (95% CI)	P value
Levator avulsion	29 (14%)	35 (12%)	0.88 (0.52-1.49)	0.63
Significant microtrauma	24 (11%)	36 (13%)	1.13 (0.65-1.95)	0.67
Significant EAS defect	27/209 (13%)	63/276 (23%)	1.99 (1.22-3.26)	0.05
Any trauma	69/209 (33%)	111/276 (39%)	1.37 (0.94-1.99)	0.1

Table 3 : Pelvic floor trauma in control and Epi-No groups (treatment received analysis). Denominators differ due to missing / suboptimal EAS imaging.

Interpretation of results

This large multicentre randomised controlled trial has failed to find any evidence for a protective effect of the antenatal use of a vaginal balloon device, the Epi-No, on pelvic floor structures in primiparae giving birth to a term singleton after uncomplicated pregnancies. This is true for levator avulsion, levator hiatal overdistension and clinical perineal trauma. We did identify a marginal negative effect of EpiNo use on significant residual EAS defects diagnosed on average 5 months after childbirth, but this finding may be spurious,

Concluding message

We have been unable to confirm a protective effect of the EpiNo device for pelvic floor structures during vaginal childbirth.

References

1. Aust NZ J Obstet Gynaecol 44:347-348
2. Int Urogynecol J 22:1221-1232
3. Ultrasound Obstet Gynecol 42 (4):461-466

Disclosures

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