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DOES THE EPI-NO® PREVENT LEVATOR TRAUMA? A 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). Prevention of levator trauma may reduce the future prevalence of this condition. 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 shown to be associated with a shortened 2nd stage, reduced use of analgesics and reduced episiotomy rates (*1*). This study was designed to evaluate the effect of Epi-No use on pelvic floor integrity. The null hypothesis was: "Antepartum use of the Epi-No device does not prevent levator trauma".

Study design, materials and methods

This is a prospective randomised controlled trial. 200 nulliparous women carrying a singleton pregnancy at a mean gestation of 35.8 weeks (range 33-37) were recruited from the antenatal clinic at two tertiary hospitals between July 2007 and July 2009. All were invited for a 2nd assessment at least 3 months postpartum. All participants underwent an interview and 4D translabial ultrasound, after voiding, in the supine position as previously described (*2*) at both antepartum and postpartum appointments. Participants were randomised into the Control or Epi-No group after antepartum assessment according to a pre-generated computer list. Women in the intervention group were instructed in the use of device from 37 weeks till delivery. Ultrasound analysis was performed on a PC using the software 4D sonoview v5, blinded to all other data including group allocation. Hiatal dimensions were determined as previously described (*2*). The primary outcome parameters were levator avulsion 'macrotrauma') and traumatic overdistension ('microtrauma'). Avulsion was diagnosed on tomographic ultrasound imaging using volumes acquired on contraction as previously described (*3*). Levator microtrauma was defined as ≥20% peripartum increase in hiatal area on Valsalva. Delivery data were collected from the hospital database. Modified intention to treat (ITT) and treatment received analysis were performed. Multivariable logistic regression was performed to control for confounders. A P <0.05 was considered statistically significant.

Results

Of the 200 participants 96 were randomised to the Control group and 104 to the Epi-No group. There was no significant difference in demographic variables including ethnicity, antepartum body mass index (BMI), history of pregnancy and family history of caesarean section (CS). Delivery data of the study population by group allocation are shown in Table 1. There were no significant differences in obstetric variables between groups. 146 women (73%) returned for a postpartum assessment 5.6 (2.3-22.1) months postpartum. One woman had a 2nd delivery before returning for assessment and was excluded from all further analysis, leaving 145 (64 in Control group, and 81 in EpiNo group). An assessment for irreversible overdistension was possible in 126 (53 in Control group, and 73 in EpiNo group) women. Two women were excluded from this analysis due to a second pregnancy at follow-up, two due to missing volume data, two due to poor Valsalva manoeuvre and 13 due to avulsion.

There were 13 avulsions (3 bilateral, 10 unilateral), with the risk halved in the Epi-No group (6%) compared to the control group (13%) (P=0.19). 31 women were diagnosed with irreversible levator overdistension (microtrauma), 14 (26%) in the control and 17 (23%) in the Epi-No group (P=0.69) (Table 2). Similar findings were obtained after adjustment for known confounders such as antepartum BMI, intrapartum use of epidural, length of 2nd stage and forceps delivery. Compliance may affect results, with the prevalence of microtrauma reducing from 38% to 26% and to 17% for women who did not use the device, used it ≤20 times and > 20 times, respectively. 11 women in the Control group used the Epi-No before birth and 8 women in the Epi-No group did not use the birth trainer. To account for these crossovers, a treatment received analysis was performed, revealing largely similar findings compared to the ITT analysis (see Table 3).

	Control (N=96)	Epi-No (N=104)	P value
Maternal age	29.3 (±5.5)	28.9 (5.8)	0.62
Delivery mode**			0.97
Caesarean	23 (27%)	24 (23%)	
Prelabour	6	1	
1st stage	13	16	
2nd stage	4	7	
Normal vaginal delivery	52 (54%)	58 (56%)	
Vacuum	17 (18%)	17 (16%)	
Forceps	4 (4.0%)	5 (5.0%)	
Use of intrapartum epidural	47 (49%)	49 (57%)	0.74
Length of 2nd stage/min*	59 (36-88)	60 (28-104)	0.87
Neonatal birth weight/gm	3424 (±459)	3464 (±453)	0.53
Apgar score ≥7 at 1 minute	86 (91%)	94 (91%)	0.96
Apgar score ≥7 at 5 minute	94 (98%)	103 (99%)	0.51

Episiotomy (vaginal delivery only)	21/73 (29%)	26/80 (33%)	0.62
Any perineal tear (vaginal delivery only)	32/73 (44%)	29/80 (36%)	0.34
Major perineal tear (vaginal delivery only)	4/73 (5%)	2 /80(3%)	0.34

*Table 1 Demographic and delivery data (N=200).T-test or X2 test; *Kruskal Wallis test.*

	Control (N=64)	Epi-No (N=81)	Relative risk	P value
Avulsion (N=13/145)	8/64 (13%)	5/81 (6%)	0.49 (CI 0.17-1.44)	0.19
Microtrauma (N=31/126)	14/53 (26%)	17/73 (23%)	0.88 (CI 0.48-1.63)	0.69
Any trauma (N=44/139)	22/61 (36%)	22/78 (28%)	0.78(CI 0.48-1.27)	0.32

Table 2: Incidence of levator by group allocation (modified intention to treat analysis (ITT)). Denominators differ due to missing data (see text).

	No antepartum use (N=61)	Antepartum use (N=84)	Relative risk	P value
Avulsion (N=13/145)	7/61 (12%)	6/84 (7%)	0.62 (CI 0.22-1.76)	0.37
Microtrauma (N=31/126)	16/53 (30%)	15/73 (21%)	0.68 (CI 0.37-1.25)	0.22
Any trauma (N=44/139)	23/60 (38%)	21/79 (27%)	0.69 (CI 0.43-1.13)	0.14

Table 3 Incidence of levator trauma in the control and intervention group (Treatment received analysis). Denominators differ due to missing data (see text).

Interpretation of results

In this randomised controlled pilot study we found a weak trend towards a lower incidence of levator avulsion and irreversible overdistension in women allocated to antenatal Epi-No use. While the intention to treat analysis showed a halving of avulsion risk in the treatment arm, the unexpectedly low prevalence of avulsion in our population has resulted in this pilot study having insufficient power to test the null hypothesis. Based on these findings an intention to treat study would need a sample size of 660 women to show a reduction in the incidence of levator avulsion by 50% with full compliance. We are in the process of continuing recruitment until this target is reached.

Concluding message

The Epi-No Birth Trainer may have a potential role in the prevention of levator trauma. However, studies with a larger sample size are needed to test this hypothesis.

References

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Australian Trials Registry** **ACTRN 12609000592246**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**SWAHS HREC no. 07-022**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**