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Intrapartum care

Does the Epi-No® birth trainer prevent vaginal birth-related pelvic floor trauma? A multicentre prospective randomised controlled trial

I Kamisan Atan,[a,b] KL Shek,[a,c] S Langer,[a] R Guzman Rojas,[d,e] J Caudwell-Hall,[a] JO Daly,[f] HP Dietz[a]

[a] Sydney Medical School Nepean, The University of Sydney, Sydney, NSW, Australia [b] Universiti Kebangsaan Malaysia Medical Centre (UKMMC), Kuala Lumpur, Malaysia [c] Liverpool Clinical School, Liverpool Hospital, University of Western Sydney, Sydney, NSW, Australia [d] Facultad de Medicina, Clínica Alemana – Universidad del Desarrollo, Santiago, Chile [e] Hospital Clínico de la Universidad de Chile, Santiago, Chile [f] Royal Prince Alfred Hospital, Sydney, NSW, Australia

Correspondence: Prof. Hans Peter Dietz, Sydney Medical School Nepean, The University of Sydney, 62 Derby Street, Kingswood, 2747 NSW, Australia. Email hpdietz2@bigpond.com.au

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Objective Vaginal childbirth may result in levator ani injury secondary to overdistension during the second stage of labour. Other injuries include perineal and anal sphincter tears. Antepartum use of a birth trainer may prevent such injuries by altering the biomechanical properties of the pelvic floor. This study evaluates the effects of Epi-No® use on intrapartum pelvic floor trauma.

Design Multicentre prospective randomised controlled trial.

Setting Two tertiary obstetric units in Australia.

Population Nulliparous women carrying an uncomplicated singleton term pregnancy.

Methods Participants were assessed clinically and with 4D translabial ultrasound in the late third trimester, and again at 3–6 months postpartum. Women randomised to the intervention group were asked to use the Epi-No® device from 37 weeks of gestation until delivery.

Main outcome measures Levator ani, anal sphincter, and perineal trauma diagnosed clinically and/or with translabial ultrasound imaging.

Results Of 660 women randomised, 504 (76.4%) returned for assessment at a mean of 5 months postpartum. There was no significant difference in the incidence of levator avulsion [12 versus 15%; relative risk (RR) 0.82, 95% confidence interval (95% CI) 0.51–1.32; absolute risk reduction (ARR) 0.03, 95% CI −0.04 to 0.09; $P = 0.39$], irreversible hiatal overdistension (13 versus 15%; RR 0.86, 95% CI 0.52–1.42; ARR 0.02, 95% CI −0.05 to 0.09; $P = 0.51$), clinical anal sphincter trauma (7 versus 6%; RR 1.12, 95% CI 0.49–2.60; ARR –0.01, 95% CI −0.05 to 0.06; $P = 0.77$), and perineal tears (51 versus 53%; RR 0.96, 95% CI 0.78–1.17; ARR 0.02, 95% CI −0.08 to 0.13; $P = 0.65$). A marginally higher rate of significant defects of the external anal sphincter on ultrasound was observed in the intervention group (21 versus 14%; RR 1.44, 95% CI 0.97–2.20; ARR –0.06, 95% CI −0.13 to 0.05; $P = 0.07$).

Conclusion Antenatal use of the Epi-No® device is unlikely to be clinically beneficial in the prevention of intrapartum levator ani damage, or anal sphincter and perineal trauma.

Keywords Anal sphincter tear, Epi-No®, levator avulsion, pelvic floor trauma, perineal trauma.

Tweetable abstract No evidence of a protective effect of the Epi-No® device on intrapartum pelvic floor rauma.

Linked article This article is commented on by AM Weber, p. 1004 in this issue. To view this mini commentary visit http://dx.doi.org/10.1111/1471-0528.13923.

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Introduction

Vaginal childbirth is an established risk factor for pelvic floor injury. It may result in levator ani muscle (LAM) avulsion (macrotrauma), where the puborectalis muscle is detached from the inferior pubic ramus, or irreversible overdistension (microtrauma). The incidence of levator avulsion is reported to range between 10 and 35%,[1–4] and microtrauma may occur in 28% of women after the first vaginal birth.[5] These injuries are probably attributable to excessive stretching of the LAM during the second stage of labour.[6–8] Both forms of trauma are associated with female

pelvic organ prolapse (FPOP) and prolapse recurrence after pelvic reconstructive surgery.[3,9–11] Other vaginal birth-related injuries include perineal tears and obstetric anal sphincter injuries (OASIS). The usually quoted incidence of OASIS ranges from 0.5 to 5%, but is likely to be much higher as the diagnosis is frequently missed in the delivery suite.[12–16] These injuries may result in chronic morbidity such as FPOP, anal incontinence, perineal pain, dyspareunia, and sexual dysfunction, often involving long latency between trauma and subsequent morbidity, impairing women's quality of life (QoL).[17–20] There is an obvious need for the development of preventative strategies.

The Epi-No® (Tecsana GMBH, Muenchen, Germany) is a device with an inflatable silicone balloon coupled to a hand pump with a pressure display (Figure S1), developed as an antenatal birth trainer and to assist pelvic floor muscle training. Device development was inspired by observations of reduced perineal injuries in African mothers practising perineal stretching with gourds of increasing diameter. There is some evidence to show that antenatal use of Epi-No® may shorten the second stage of labour,[21] reduce intrapartum analgesia,[21] episiotomy rates,[21–23] and perineal tears,[24] increase the likelihood of an intact perineum,[22,24] and improve Apgar scores.[21] To date, however, there is no high-quality data assessing the effect of Epi-No® use on pelvic floor trauma.

The LAM, being a skeletal muscle, has the potential for structural modification in response to environmental changes. Studies in muscular biomechanics have shown that muscles are trainable to improve their endurance, elasticity, and strength. Intermittent muscle stretching increases muscular extensibility by increasing the muscle length mechanically through viscoelastic and plastic deformation, and through neuromuscular relaxation.[25,26] Based on these observations, prevention of pelvic floor muscle trauma can be considered feasible via gradual stretching of the LAM antenatally.

A pilot study evaluating the effects of Epi-No® on birth trauma at our unit showed a weak trend towards a lower incidence of pelvic floor trauma.[27] This current study is an extension based on power calculations performed with pilot project data. The objective of this study is to evaluate the effects of Epi-No® use on intrapartum pelvic floor trauma.

Methods

Study design and participants

This was a prospective randomised controlled trial (RCT) on women recruited at two tertiary obstetric units between July 2007 and March 2014. The inclusion criteria were: (1) uncomplicated singleton pregnancy between 33 and 35 weeks of gestation; (2) maternal age ≥18 years; (3) no previous pregnancy beyond 20 weeks of gestation; and (4) women aiming for normal vaginal delivery. All women who fitted the inclusion criteria were invited to participate.

Antenatal assessment

A first appointment was arranged between 35 and 37 weeks of gestation. Written consent was obtained after the provision and explanation of a 'patient information sheet'. Participants all underwent a standardised interview, clinical examination, including the International Continence Society (ICS) Pelvic Organ Prolapse Quantification (POP-Q),[28] and four-dimensional (4D) translabial pelvic floor ultrasound (TLUS), using either a GE Voluson 730 Expert or E8 System (GE Medical Systems, Zipf, Austria), with an 8–4 MHz curved array volume transducer, in the supine position, and after voiding. Volumes were acquired at rest, on pelvic floor muscle contraction (PFMC) and on Valsalva manoeuvres, at an acquisition angle set to the system maximum of 85°, as previously described.[29] A minimum of three ultrasound volumes on Valsalva were acquired, and the volume demonstrating the greatest degree of pelvic organ descent was used for assessment of pelvic organ descent and hiatal area on Valsalva. Levator co-activation was avoided by meticulous observation and visual biofeedback. Levator and anal sphincter integrity were assessed using volumes acquired on PFMC.

Randomisation

Participants were allocated to control or intervention (Epi-No®) groups by computer-generated block randomisation, which was concealed from assessors and provided by clerical personnel not involved in recruitment or assessment. Randomisation/group allocation was performed and revealed to assessors and participants after completion of the antenatal assessment and application of inclusion/exclusion criteria. Group allocation and breakdown of the study population for the assessment of intrapartum pelvic floor trauma is shown in Figure 1.

Epi-No® use

Women in the Epi-No® group were instructed to use the device from 37 weeks of gestation onwards, for up to two 20-minute sessions per day, comprising several 5-minute cycles. The balloon is inserted two-thirds vaginally, and inflated until it causes a stretching sensation to the level of personal comfort. Upon completion of each session, the inflated balloon is expelled by maternal effort simulating the crowning and delivery of the fetal head. Participants were encouraged to gradually increase balloon inflation over time. The diameter achieved in each session, frequency of use, and any problems encountered were recorded. Women in both groups received standard obstetric care throughout the antenatal, intrapartum, and postpartum periods. Obstetricians and midwives were blinded to group allocation.

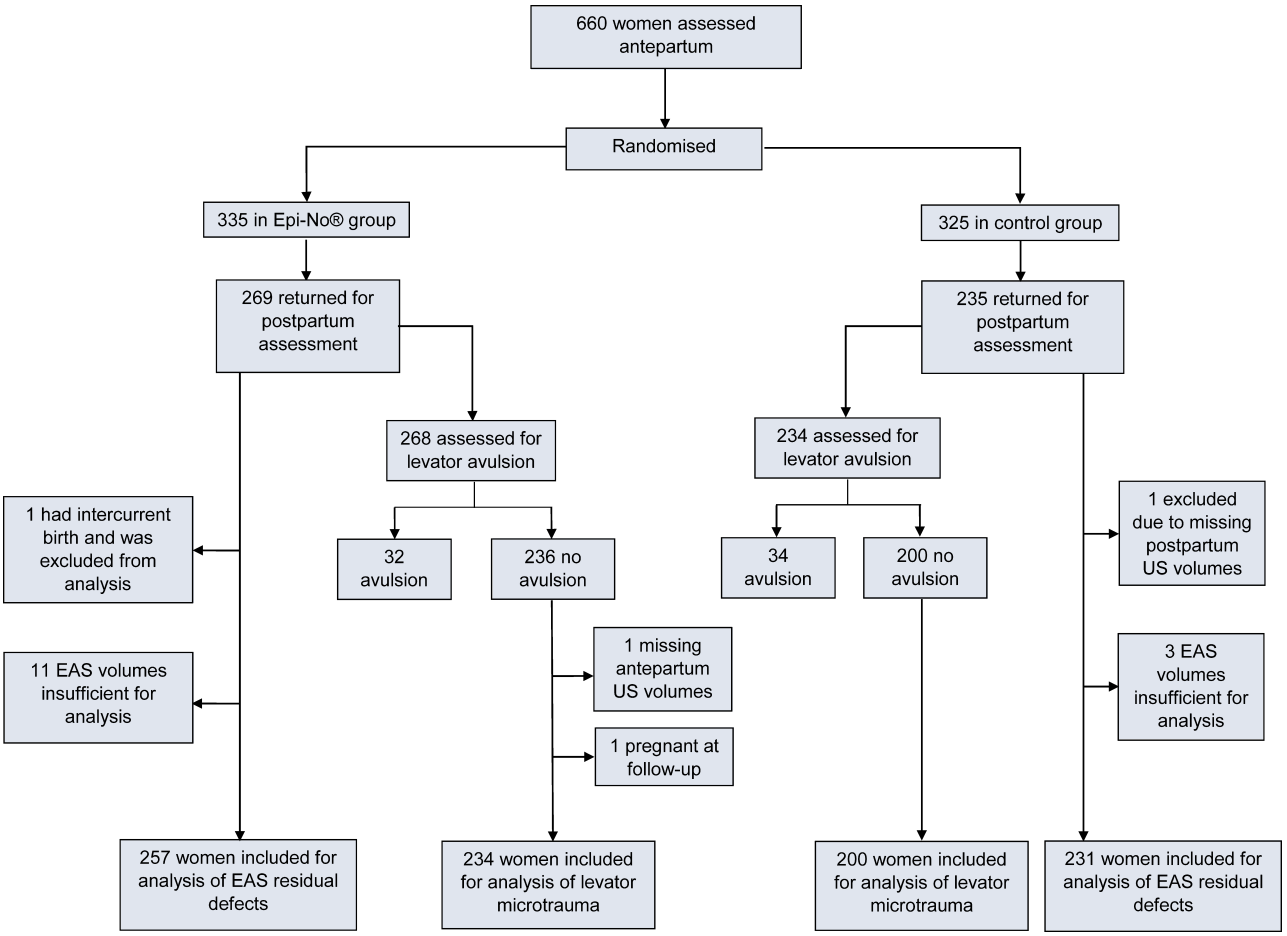

Figure 1. A flow diagram showing a breakdown of the study population for the assessment of levator avulsion, hiatal overdistension (significant microtrauma), and residual defects of the external anal sphincter.

Postpartum assessment

All participants were invited for a follow-up at 3–6 months postpartum. Written or electronic reminders were sent to non-attenders and followed-up by telephone after three failed attempts. Women who participated in the study and attended the postpartum review were offered an $A50 shopping voucher. Clinical and ultrasound assessment were repeated with the assessors blinded to group allocation, delivery, and Epi-No® use data. Archived ultrasound volume data sets were analysed at a later date using the proprietary software 4D VIEW 9.0 (GE Medical Systems), blinded against all other data, including group allocation.

Levator avulsion was diagnosed using tomographic ultrasound imaging (TUI) on volumes acquired on PFMC, with a 2.5-mm interslice interval, from 5 mm caudal to 12.5 mm cranial of the plane of minimal hiatal dimensions, incorporating the entire puborectalis muscle. The plane of minimal hiatal dimensions is identified in the midsagittal orthogonal plane, where the distance between the hyperechogenic posterior aspect of the symphysis pubis and the hyperechogenic anterior border of the LAM is minimal. Avulsion is defined as an abnormal muscle insertion observed in at least the three central slices (reference slice and the slices 2.5–5.0 mm cranial; i.e. slices 3–5 in Figure 2ii), as previously described and validated.[27,30]

'Significant levator overdistension' or 'microtrauma' is defined as a peripartum increase in hiatal area on Valsalva manoeuvre by 20% (a cut-off derived from the pilot study),[27] resulting in a hiatal area of at least 25 cm^2 (hiatal ballooning), in the absence of levator avulsion. The cut-off of 25 cm^2 for hiatal area on Valsalva constitutes the 95th centile in asymptomatic nulliparae, and is optimal for the prediction of symptoms and signs of POP using receiver operator characteristic (ROC) statistics in symptomatic patients.[31,32] Hiatal area on maximum Valsalva was measured in a rendered volume of 1–2 cm thickness containing the plane of minimal hiatal dimensions,[33] as illustrated in Figure 2(iii, iv).

The external anal sphincter (EAS) was evaluated using volumes acquired on PFMC. Using TUI, a set of eight

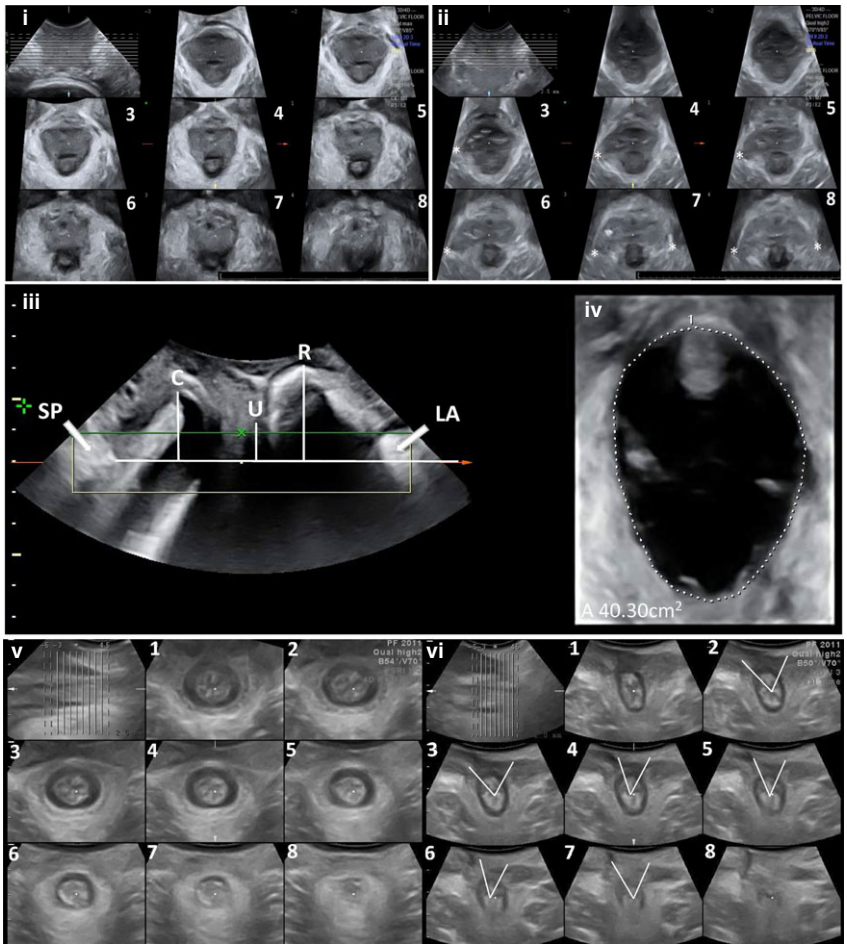

Figure 2. Tomographic ultrasound imaging (TUI): (i) normal pelvic floor; (ii) a right-sided levator avulsion, marked with *, in slices 3–8, and a left-sided partial avulsion in slices 7 and 8; (iii) measurement of pelvic organ descent against a reference line placed through the symphysis pubis (SP); C, cystocele; LA, levator ani; R, descent of the rectal ampulla; U, uterine descent; (iv) determination of levator hiatal area on maximal Valsalva in the axial plane of minimal hiatal dimensions; (v) intact/normal EAS; (vi) significant residual defect of the EAS. Angled lines show defect location and size.

slices was obtained encompassing the entire EAS by tailoring the interslice interval to the individual's EAS length, from the level of the puborectalis muscle to the subcutaneous part of EAS, as previously described.[12] A 'significant EAS defect' is defined as a gap of ≥30° in its circumference, in at least four out of six central slices (slices 2–7 in Figure 2v, vi).[34]

Maximum pelvic organ descent was defined as the maximal caudad displacement of pelvic organs, determined on maximal Valsalva and measured against the inferoposterior margin of the symphysis pubis, in the midsagittal view on TLUS (Figure 2iii).[35]

Delivery data were collected from hospital databases and/or participants' medical records, including mode of delivery, epidural use, length of first and second stage of labour, perineal tears, birthweight and Apgar scores at 1 and 5 minutes.

The primary outcome measure was sonographically defined levator ani avulsion. Secondary outcome measures were clinical perineal tears and OASIS, significant microtrauma or hiatal overdistension, and significant residual defects of the EAS. New information in the literature and technological advances made it appear prudent to include sonographic EAS trauma as one of the secondary outcomes. Our null hypothesis was 'Epi-No® use has no effect on the incidence of levator ani avulsion'.

Statistical analysis

Power calculations had been performed for the primary outcome measure using the results of the pilot phase of this trial (n = 200),[27] suggesting a 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 analyses were performed using SPSS 20 (SPSS, Chicago, IL, USA) and MINITAB 16 (Minitab State College, PA, USA). We defined 'modified ITT' as an intention-to-treat analysis performed on attenders only (instead of on all study participants), excluding those with levator avulsion for the analysis of levator microtrauma, and those with missing EAS ultrasound volumes for 'sonographic EAS trauma'. Normality was assessed using the Kolmogorov–Smirnov method. Normally and non-normally distributed continuous data were analysed using the Student's *t*–test and Mann–Whitney *U*–test, respectively. Categorical variables were analysed using chi-square tests. $P < 0.05$ was regarded as statistically significant. Differences between the two groups were expressed as relative risk (RR) and absolute risk reduction (ARR). Any effect of non-compliance was explored using Newcombe's method for simple compliance adjustment of RR reduction.[36] Subgroup analyses (modified ITT and treatment received) were undertaken for those who had achieved a vaginal delivery. There has been concern that Epi-No® use may have detrimental effects on pelvic floor structures. We therefore undertook a subgroup analysis of pelvic organ support before and after childbirth in women who delivered by prelabour and first-stage caesarean section.

Results

Six hundred and sixty women were seen between July 2007 and March 2014, at a mean gestation of 36 (SD 0.68, range 32.9–37.4) weeks. Mean maternal age at antepartum assessment was 30.5 (SD 5.24, range 18.8–45.3) years, and mean body mass index was 28.5 (SD 4.9, range 18.0–48.6) kg/m^2. They were randomised to intervention (i.e. Epi-No®; $n = 335$) and control groups ($n = 325$), see Figure 1. Demographic and delivery characteristics of study population and attenders by group allocation are presented in Table 1.

Five hundred and four women (76.4%) returned for their postpartum assessment at a mean interval of 5.1 (SD 2.4, range 2.3–22.4) months. Demographic and delivery data are shown in Table 1. Attenders were more likely to be white ($P = 0.002$), older ($P = 0.01$), and were more likely to have had intrapartum syntocinon augmentation ($P = 0.001$) and epidural pain relief ($P < 0.001$), compared with non-attenders. No significant difference was observed for delivery mode, or obstetric or neonatal outcomes (all $P > 0.1$). Thirty-nine women (16.7%) in the control group used the Epi-No® device antenatally and 19 women (7.1%) in the Epi-No® group did not, prompting simplified adjustments for non-compliance using Newcombe's method and treatment-received analysis to account for these crossovers.[36] Those who used the device did so for a median of 14 (interquartile range, IQR, 7–25; range 1–60) sessions to a median maximum balloon diameter of 7.5 (IQR 6.5–8.0, range 3–12) cm.

Two women were excluded from further analysis, for missing postpartum ultrasound volumes in one and for an intercurrent birth in another, leaving 502 participants (234 and 268 in the control and Epi-No® groups, respectively) for assessment of levator avulsion. Evaluations of significant microtrauma were possible in 434 women and analysis of EAS integrity was performed for 488 women (Figure 1).

In the delivery suite, perineal tears and OASIS were diagnosed in 249/497 (50.1%) and 31/497 (6.2%) women, respectively, and there were no significant differences between control and treatment groups for either outcome ($P = 0.61$ and 0.41, respectively). At the postpartum sonographic assessment, levator avulsion was diagnosed in 13.1% ($n = 66$; bilateral in 21), and significant microtrauma was diagnosed in 13.8% ($n = 60$). There was no significant difference in the rate of avulsion (RR 0.82, 95% CI 0.51 to 1.32; ARR 0.03, 95% CI –0.04 to 0.09; $P = 0.39$) and microtrauma (RR 0.86, 95% CI 0.52–1.41; ARR 0.02, 95% CI –0.05 to 0.09; $P = 0.51$) between the two groups; hence the null hypothesis could not be disproven. Significant sonographic defects of the EAS were seen in 17.6% of the women ($n = 86/488$), and such trauma had remained clinically undiagnosed in 84% ($n = 72/86$). A marginally higher rate of sonographic EAS defects was observed in the intervention group (21 versus 14%, respectively; RR 1.44, 95% CI 0.95–2.20; ARR –0.06, 95% CI –0.13 to 0.05; $P = 0.07$; Table 2). Very similar findings were obtained in a treatment-received analysis and in subgroup analysis of women delivered vaginally (Table S1). Simplified adjustments accounting for non-compliance (16.7 and 7.1% in the control and Epi-No® groups, respectively) using Newcombe's method had no effect on our results and conclusions.[36] Adjusted RRs (95% CIs) for levator avulsion, significant levator microtrauma, and sonographic EAS defects were 0.23 (–0.40 to 0.57; $P = 0.38$), 0.19 (–0.51 to 0.56; $P = 0.50$), and –0.62 (–1.73 to 0.04; $P = 0.08$), respectively.

A subgroup analysis (modified ITT) assessing the effect of 'frequency of use' in the Epi-No® group showed no significant difference ($P = 0.62$) in the rate of levator avulsion between those who did not use the device (2/18), those who used it ≤20 times (23/171), and those who used it >20 times (7/77). There was a non-significant decrease in microtrauma in these subgroups from 22 to 12 to 9% ($P = 0.30$; Table S2). Upon treatment-received analysis, frequency of use was not associated with levator avulsion ($P = 0.36$) or microtrauma ($P = 0.15$) (Table S3).

No adverse effects of the device on pelvic organ support was observed in a subgroup analysis on women who had prelabour and first-stage caesarean section (Table S4).

Table 1. Demographic and delivery data of the study population (n = 660) and attenders (n = 504)

	Study population (n = 660)			Attenders (n = 504)		
	Control (n = 325)	Epi-No® (n = 335)	P	Control (n = 235)	Epi-No® (n = 269)	P
Maternal age (years)*	30.55 (5.11)	30.50 (5.36)	–	30.78 (4.97)	30.92 (5.32)	–
Antepartum body mass index (kg/m^2)*	28.67 (4.90)	28.57 (4.96)	–	28.62 (4.96)	28.47 (4.81)	–
Gestational age at antepartum visit (weeks)*	36.00 (0.68)	35.95 (0.69)	–	36.02 (0.69)	35.93 (0.71)	–
Family history of caesarean section (%)**	62/324 (19%)	76/333 (23%)	–	48 (21%)	61 (23%)	–
History of previous pregnancy (%)**	87 (27%)	79 (24%)	–	64 (27%)	61 (23%)	–
White women (%)**	241/324 (74%)	264/333 (79%)	–	184 (79%)	216 (81%)	–
Gestational age at delivery (weeks)*	40.09 (1.20)	39.99 (1.27)	0.28	40.07 (1.20)	39.98 (1.28)	0.38
Delivery mode						
Caesarean	76 (23%)	78 (23%)		54 (23%)	62 (26%)	0.99
Prelabour	21	15		14	12	
First stage	37	53		26	41	
Second stage	18	10	0.93	14	9	
Normal vaginal delivery	180 (55%)	178 (53%)		133 (57%)	149 (55%)	
Ventouse	47 (14%)	50 (15%)		32 (14%)	38 (14%)	
Forceps	19 (6%)	23 (7%)		16 (7%)	20 (7%)	
Syntocinon use**	148 (46%)	152 (45%)	0.10	111 (47%)	129 (48%)	0.72
Use of intrapartum epidural (%)**	135 (42%)	147 (44%)	0.54	102 (43%)	118 (44%)	0.92
Length of second stage (minutes)***	60 (80–109)	56 (79–105)	0.43	62 (29–116.25)	57 (27.75–110.25)	0.44
Neonatal birthweight (gram, SD)*	3460	3434	0.44	3444 (394)	3443 (431)	0.97
Apgar score ≥7 at 1 minute (%)**	275/303 (91%)	277/306 (91%)	0.66	201/217 (93%)	221/248 (89%)	0.19
Apgar score ≥7 at 5 minutes (%)**	297/304 (98%)	304/307 (99%)	0.28	215/218 (99%)	247/249 (99%)	0.55
Follow-up interval (months)***	–	–	–	4.37 (3.7–5.6)	4.50 (3.75–5.6)	0.38
Breast feeding**	–	–	–	177 (75%)	217 (81%)	0.15
Episiotomy,*****	66/246 (27%)	67/251 (26.7%)	0.36	46/181 (25%)	56/207 (27%)	0.71
Any perineal tear,*****	123/246 (50%)	126/251 (50%)	0.61	96/180 (53%)	104/204 (51%)	0.65
Major perineal tear,*****	13/246 (5%)	18/251 (7%)	0.41	11/181 (6%)	14/207 (7%)	0.77

Data are presented as: *mean (standard deviation), **n (%), or ***median (interquartile range). Denominators differ because of missing data. Analysed using *Student's t–test, **chi–square test, and ***Mann–Whitney U–test. ****Vaginal delivery only.

Discussion

Main findings

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. It is the first RCT testing an intervention that is potentially preventive of major maternal birth trauma, defined as not just clinical perineal and anal sphincter trauma, but also (usually clinically occult) levator ani and clinically undiagnosed anal sphincter damage.

These forms of maternal birth trauma are common sequelae of vaginal childbirth and frequently lead to symptoms of pelvic floor dysfunction such as female pelvic organ prolapse, anal incontinence, and sexual dysfunction, affecting QoL and use of healthcare services. During the second stage of labour, the LAM, particularly the puborectalis muscle, is required to stretch substantially, lengthening by 25–250% of its original length.[6–8] In a minority, this leads to avulsion of the muscle from its insertion on the inferior ramus of the os pubis;[37] however, stretching of a skeletal muscle fibre to more than 1.5 times its original length may also result in substantial ultrastructural damage.[38] Levator injury of either type, alone or in combination, may result in a more distensible and less contractile pelvic floor muscle.[11,39] In the current study 19% (n = 34/180) and 14% (n = 25/179) of vaginally parous women in the control group sustained levator avulsion and hiatal overdistension or 'significant microtrauma', respectively, which is comparable with previously reported prevalence figures for avulsion.[1,3,27] The incidence of levator injury was not significantly different between the groups, hence

Table 2. Incidence of pelvic floor trauma in control and Epi–No® groups by (A) modified intention to treat analysis and (B) treatment received analysis (chi–square test)

	(A) Modified intention-to-treat analysis			(B) Treatment-received analysis		
	Control group (*n* = 234)	Epi–No® group (*n* = 268)	RR (95% CI) ARR (95% CI)	No antepartum Epi-No® use (*n* = 212)	Antepartum Epi-No® use (*n* = 288)	RR (95% CI) ARR (95% CI)
Levator avulsion (*n* = 66)	34/234 (15%)	32/268 (12%)	0.82 (0.51 to 1.32) 0.03 (−0.04 to 0.09) *P* = 0.39	31/212 (15%)	35/288 (12%)	0.83 (0.52 to 1.34) 0.03 (−0.04 to 0.09) *P* = 0.42
Significant levator microtrauma (*n* = 60)	30/200 (15%)	30/234 (13%)	0.86 (0.52 to 1.41) 0.02 (−0.05 to 0.09) *P* = 0.51	24/181 (13%)	36/251 (14%)	1.08 (0.65 to 1.81) 0.02 (−0.05 to 0.09) *P* = 0.75
Significant residual EAS defect (*n* = 86)	33/231 (14%)	53/257 (21%)	1.44 (0.95 to 2.20) −0.06 (−0.13 to 0.05) *P* = 0.07	26/210 (12%)	60/276 (22%)	1.76 (1.13 to 2.77) −0.06 (−0.13 to 0.01) *P* = 0.007

Data presented as *n* (%) and differences between groups expressed as relative risk (RR) and absolute risk reduction (ARR). Denominators differ because of missing data/ultrasound volumes (see text).

we were unable to reject the null hypothesis. This was also the case for all secondary outcome measures such as significant microtrauma, significant residual anal sphincter trauma, and clinical perineal tears or OASIS.

Three previous smaller case–control studies have claimed a positive effect of Epi-No® on episiotomy rate, perineal tears, duration of second stage and neonatal APGAR scores.[21,23,24] In clear contradiction of those studies, this large RCT found no significant difference between the Epi-No® and control groups for any of those parameters. This may be a result of differences in study design or ethnic composition, but it is equally possible that the results reported by the non-randomised studies were influenced by unrecognised confounding factors. Our results were in contrast with a smaller randomised trial that has observed a significant increase in the rate of intact perineum.[22] This discrepancy may be attributed to a slightly less effective Epi-No® use achieved in our study: i.e. mean maximum balloon diameter of 7.3 (SD 1.5, range 3–12) cm versus 7.7 cm. Similarly, however, the smaller RCT did not find any significant effect of Epi-No® use on episiotomy rate, major perineal tears, duration of second stage, and neonatal Apgar scores.[22]

In this study, we observed a 6.2% incidence of clinical major perineal tears and 17.6% sonographically diagnosed OASIS. This is comparable with the 0.5–6.6% and 15–35% incidence of clinically and sonographically diagnosed OASIS reported by previous studies.[12,15,16,40] The discrepancy between clinical and sonographic OASIS prevalence may result from clinical under-diagnosis or truly 'occult' tears.[12,14,15] Andrew et al. reported that diagnoses of OASIS were being missed by midwives, senior house officers, and specialist registrars in 87, 67, and 14% of deliveries, respectively.[14] Previous studies have claimed a 1.2–13.4% overall prevalence of occult anal sphincter injury.[12,14,16] The marginally increased risk of sonographically diagnosed EAS defect in the intervention group (21 versus 14%; RR 1.44, 95% CI 0.95 to 2.20; *P* = 0.07) observed in our study may be a spurious finding, as we are not aware of any pathophysiological mechanism that could explain such an association. At any rate, as the EpiNo® does not seem to convey any benefit, potential negative effects may be a moot point.

Strengths and limitations

Our study can claim several major strengths. It is likely to be sufficiently large to detect a clinically significant effect size. Furthermore, demographic data suggest that our population is largely representative of Australian primiparae. Most importantly, we did not only assess clinical perineal trauma but also sonographic evidence of pelvic floor and anal sphincter trauma. Levator trauma, the main etiological factor in FPOP,[41] is commonly occult and requires imaging for diagnosis. The clinical detection of anal sphincter tears in the delivery suite is feasible, but the diagnosis often seems to be missed.[12,15] Hence, unbiased and comprehensive detection of maternal birth trauma requires postnatal imaging.[42]

There are also factors that limit the interpretation of our results. Our participants were largely white, which implies that conclusions cannot necessarily be extrapolated to other populations as LAM morphology and biometry seems to vary from one ethnicity to another.[43,44] This may suggest further studies on the effect of Epi-No® in other populations.

Secondly, most of our patients did not use the device as frequently as instructed. Manufacturer recommendations specify at least one daily 20-minute session, comprising four 5-minute cycles, aiming to reach a balloon diameter of 8.5–10.0 cm. In our study, the mean maximum balloon size achieved was 7.3 cm, and only 19.6% of women using the Epi-No® device reached a maximum balloon size of ≥8.5 cm; however, the balloon diameter measured by participants at the end of each session may not reflect true vaginal dilatation, as the balloon may undergo deformation during removal. Unfortunately, we have no data on session duration, but evaluating the effect of frequency of use as part of the treatment-received analysis did not even show trends. Frequency of use may indeed be a confounding factor for any effect on investigated outcomes, but if so the effect size may be so small as to be clinically irrelevant.

Interpretations

This large prospective RCT, in contrast to previous studies in the literature, has failed to provide evidence for a clinically beneficial effect of antepartum use of the Epi-No® birth trainer on the LAM, external anal sphincter and perineum. The absolute risk reduction of levator avulsion and microtrauma of 3% (95% CI –4 to 9%) and 2% (95% CI –5 to 9%) is likely to be clinically irrelevant, even if real. The null hypothesis: 'Epi-No® use has no effect on the incidence of levator ani avulsion', could not be refuted.

Conclusion

Our study has shown that antenatal use of the Epi-No® device is unlikely to be clinically beneficial in the prevention of intrapartum pelvic floor trauma in primiparae, in a largely white population. This applies to levator avulsion, hiatal overdistension, sonographic anal sphincter trauma, and clinical perineal tears. Further research directed towards intrapartum modification of biomechanical properties of the levator ani may help develop a preventative strategy for vaginal birth-related pelvic floor trauma.

Disclosure of interests

Full disclosure of interests available to view online as supporting information.

Contribution to authorship

IKA, RG, SL, JC, JOD, and KS were involved in participant recruitment and data acquisition. IKA and KS assessed imaging analysis reliability series and wrote the first draft. HPD was responsible for study conception and design, drafting the article, and revising it critically for important intellectual content. IKA and HPD performed the statistical analysis and data interpretation. All authors critically revised the first draft and approved the final version.

Details of ethics approval

This study was approved by the Sydney West and Sydney South Area Health Service Human Research Ethics Committees (SWAHS HREC 07-022 and SSAHS HREC X09-0384) on 30 April 2007, and was registered with the Australian New Zealand Clinical Trial Registry (ANZCTR ACTRN12609000592246). The full trial protocol can be accessed at http://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=308224).

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Figure S1. The Epi-No® birth trainer.

Table S1. Subgroup analysis of those who achieved a vaginal delivery.

Table S2. Modified intention-to-treat analysis using chi-square test (three degrees of freedom) showing incidence of pelvic floor trauma in the Epi-No® group (n = 266) relative to frequency of use.

Table S3. Treatment-received analysis showing incidence of pelvic floor trauma in women who used the Epi-No® device (n = 288) relative to frequency of use (chi-square test).

Table S4. Peripartum change (δ) in hiatal area and pelvic organ position on maximal Valsalva in women delivered by prelabour/first-stage caesarean section (n = 93), by allocated group. ■

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