

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

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Abstract

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.