

The first Australian trial of the birth training device EPI-NO

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Background

The EPI-NO Birth Trainer aims to gradually stretch the vagina and perineum with gentle dilation with volumes similar to the foetal head. A previous study in Germany suggested that using the EPI-NO device significantly decreased the the incidence of perineal tears and episiotomies, and significantly shortened the second stage of labour. It also suggested that 1 and 5 minute Apgars were superior in babies delivered by women who had previously used the EPI-NO device. (Schuchardt et al. 2000)

This Study

The purpose of the project was to assess whether the EPI-NO Birth Trainer improved:

- birth outcomes with regard to lower requirement for instrumental delivery
- the episiotomy rate, with regard to vaginal tears
- the duration of the second stage of labour
- the comparison of Apgar scores at 1 and 5 minutes

The perineum was considered "intact" if no suturing was required.

Method

Forty-eight primagravid women were enrolled prospectively to use the EPI-NO Birth Trainer and all 248 primagravid women who delivered in the Birralee Unit during the same time period were used as controls. The subjects were asked to do preparation with the birth trainer for 15 minutes a day for 14 days consecutively between 37 weeks and term.

The women were asked to insert the EPI-NO (fig. 2) birth training device into the vagina, pump up the balloon, until it becomes firm and until it produces discomfort. Once the balloon was inflated the woman was asked to control gliding the device using her vaginal muscles in order to simulate childbirth. This could be assisted in the beginning by gently guiding the balloon out by hand. After several attempts this should be restarted with the balloon deflated and then pumped up again with the exercise repeating as described above (fig. 1). After use, the balloon was washed with soap and water and used again the following day. The birth weight of babies was compared to comparable.

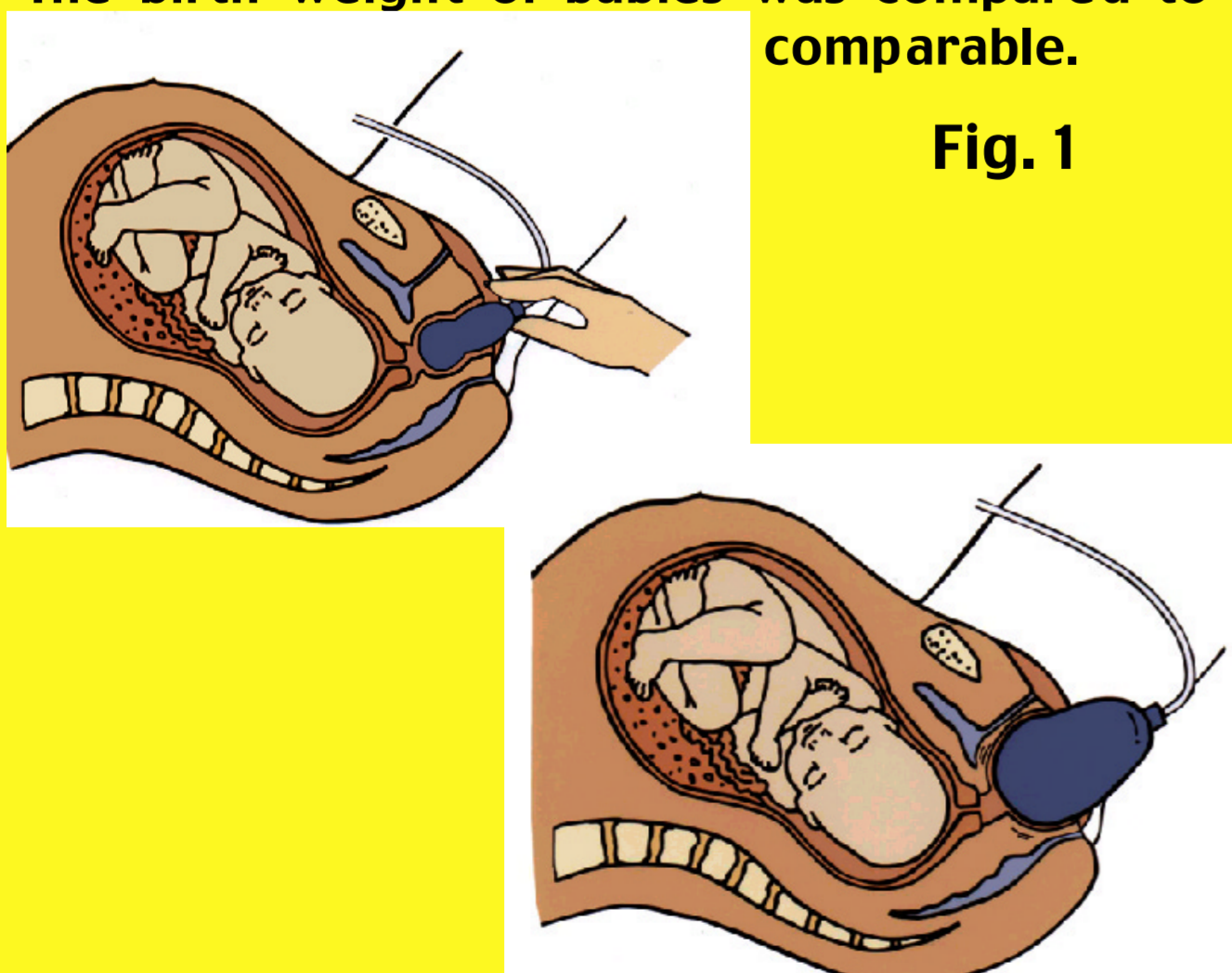


Fig. 1



Fig. 2

Results

Of the 48 women, 9 underwent Caesarean delivery and therefore the effect of the EPI-NO device on the perineum could not be evaluated.

For the remaining 39 women, the average birth weight for the subjects was 3477 gm (S.D.484g) and for the 248 controls 3324g (S.D.423g)

Mode of delivery

	Subjects	percent	Controls	percent
Normal Vaginal	27	69	194	78
Vacuum	8	21	27	11
Forceps	4	10	27	11
Caesarean	9	19		

Effect on the perineum

	EPI-NO	percent	Controls	percent
Intact	18	46	41	17
Episiotomy	10	26	85	34
Vaginal Tear	11	28	122	49

Intact: $p < 0.0001$, Episiotomy $p = 0.29$ NS, tears $p = 0.0145$

Apgar Scores

	Apgar at 1 minute		Apgar at 5 minutes	
	EPI-NO	Controls	EPI-NO	Controls
Mean	7.6	7.9	9.2	9.1
S.D.	1.5	1.3	1.7	0.8

Duration of second stage (minutes)

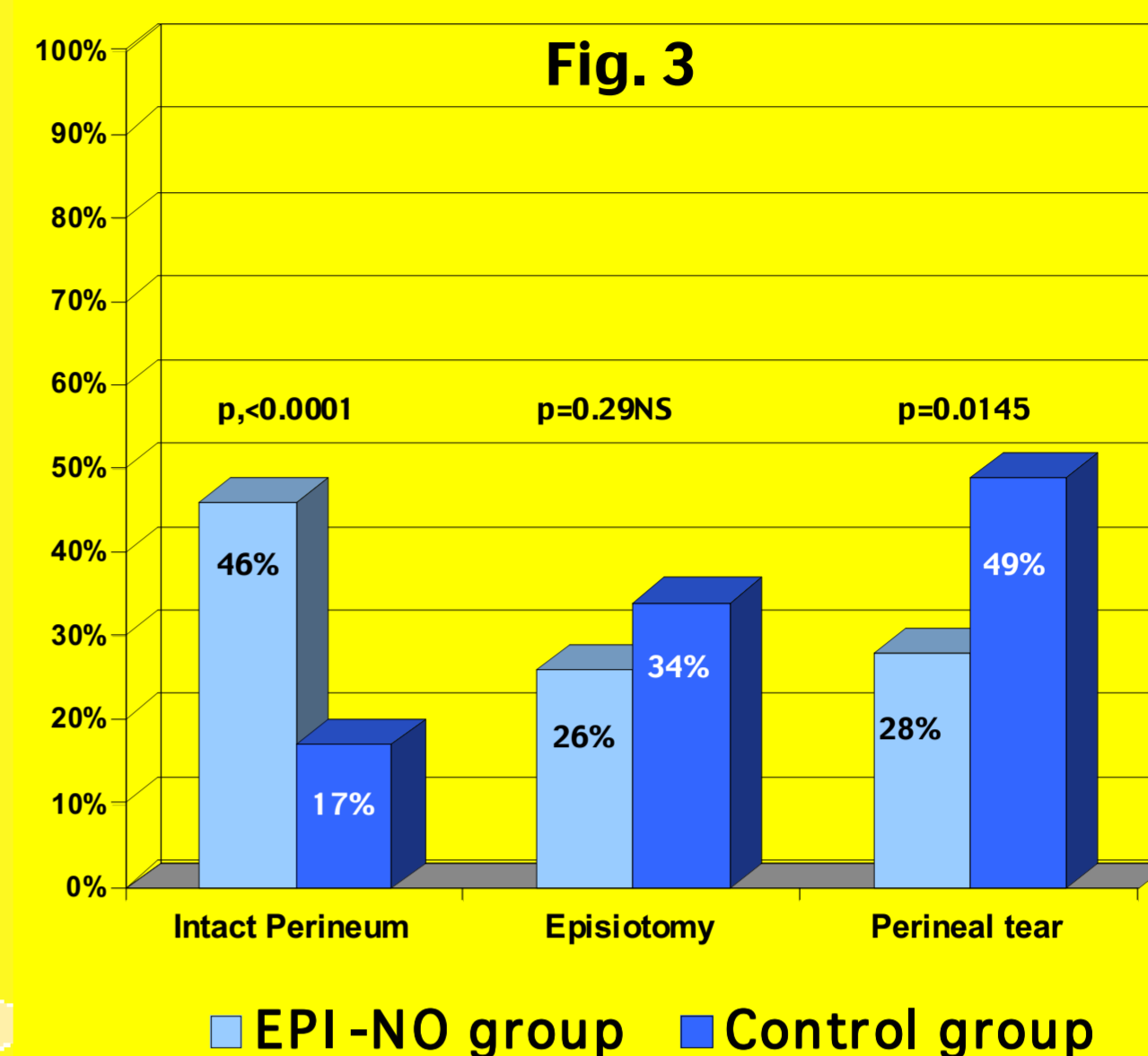
	EPI-NO	Controls
Mean	61	81
S.D. *	52	58

The study indicated that EPI-NO training significantly increased the rate of intact perineums, and significantly reduced the rate of vaginal tears. In 46% of normal vaginal deliveries for the EPI-NO group, delivery was achieved with an "intact perineum" whereas in the control group only 17% were delivered without episiotomy or vaginal tears. The vaginal tear rate was reduced from 49% in the control group to 28% in the study group. An episiotomy rate of 26% was achieved in the EPI-NO group, compared to 34% in the control group (fig. 3). The length of second stage of labour averaged 61 minutes for the EPI-NO group and 81 minutes for the control group (fig 4).

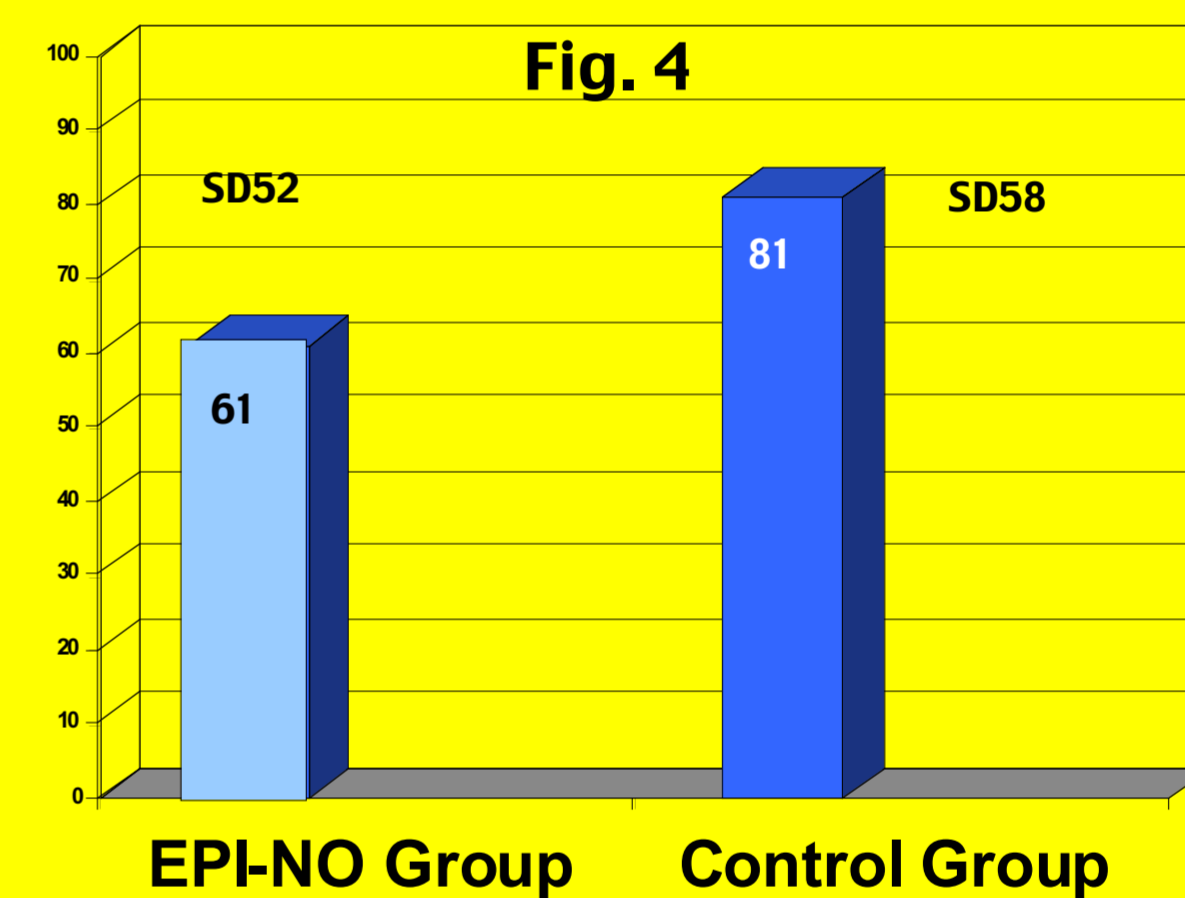
In comparing the Apgar scores, no significance was revealed between the EPI-NO and Control groups.

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Effect on the perineum (primigravidae)



Duration of second stage in minutes



The project was approved by the Research & Ethics Committee of Box Hill Hospital, Eastern Health and all women gave written consent.

Comparison to German Trial

The German EPI-NO Trial (Schuchardt et al. 2000) measured Anxiety, Analgesic Use, Length of Second Stage Labour, Perineal Outcomes and Apgar Scores after 1 and 5 minutes. The Trial found that... "with daily EPI-NO training it is possible to reduce the anxiety of birth significantly. By reducing anxiety of birth it is also possible to shorten the second stage of labour as well as the analgesics requirements. By a slower, more gentle pre-expansion of vulva and vagina regulated by the woman herself, it has been possible to reduce injuries to the vulva as well as the vagina significantly."

Effect on the perineum (Primigravidae)

	Australian Trial		German Trial	
	EPI-NO	Controls	EPI-NO	Controls
Intact	46%	17%	47%	9%
Episiotomy	26%	34%	49%	82%
Vaginal Tear	28%	49%	4%	8%

Duration of second stage (minutes)

	Australian Trial		German Trial	
	EPI-NO	Controls	EPI-NO	Controls
Mean	61 *	81 *	29	54

$p = 0.01$

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