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Original work

Is the Epi-no® device a tool for the prevention of perineal injuries of obstetric origin?

Is the Epi-no® trainer a device to prevent perineal trauma?

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Summary

Introduction: pelvic floor physiotherapy prior to childbirth is a tool for the prevention of perineal injuries of obstetric origin.

Objective: to study the usefulness of pelvic floor physiotherapy, such as perineal massage and exercises with the Epi-no® device, in injuries of obstetric origin.

Material and methods: a single-centre, national, prospective, observational, comparative, prospective study was carried out in three arms of 332 patients: group A (129): control group patients; group B (103): patients performing perineal massage exercises; group C (100): patients performing exercises with the Epi-no® device.

Results: it was shown that the higher the number of Epi-no® achieved, the lower the rate of episiotomies and the higher the rate of intact perineums, $p < 0.001$ for both. The Epi-no® group had shorter expulsion time compared to the massage and control groups ($p = 0.043$). Patients in the Epi-no® group had a lower rate of instrumental deliveries (28%) compared to the massage group (35.9%) and control group (50.4%) ($p = 0.002$). Lower rates of episiotomy were found in the Epi-no® group (37%) versus the massage group (55.3%) and control group (69%), ($p < 0.001$). A higher rate of intact perineum was also demonstrated in the Epi-no® group (32%) versus the massage group (8.7%) and control group (2.3%), $p < 0.001$. No statistically significant differences in weight, head circumference, Apgar test or foetal pH were demonstrated between the different groups.

Conclusion: The use of instrumental devices to help train the pelvic muscles, such as the Epi-no®, is considered to be highly effective in preparation for childbirth. Moreover, its effects are satisfactorily complemented by therapies such as perineal massage. Exercises with the Epi-no® device have benefits on perineal injuries such as episiotomy and tears compared to the control group and the perineal massage group.

Key words:

Episiotomy. Device Epi-no®. Perineal injuries. Perineal massage. Pelvic floor physiotherapy.

Abstract

Introduction: Pelvic floor antenatal physiotherapy is a technique to prevent perineal trauma during childbirth.

Objective: To study the efficacy of the perineal massage and Epi-no® device to prevent perineal trauma.

Material and methods: We performed a comparative single-center, national, prospective, observational study of 332patients: group A (129): control group; group B (103): perineal massage group; group C (100): Epi-no® device group.

Results: The study showed a significant reduction in the rate of episiotomies in the Epi-no® group (37%) compared to massage group (55.3%) and control group (69%). Higher rate of intact perineum was also shown in the Epi-no® group (32%), compared to massage group (8.7%) and control group (2.3%), $p < 0.001$. Patients from Epi-no® group had a significant reduction in the duration of the second stage of labour than patients from perineal massage group and control group. We also found that Epi-no® group had lower rates of instrumental deliveries (28%), compared to massage group (35.9%) and control group (50.4%) ($p = 0.002$). No statistically significant differences in fetal outcomes as fetal APGAR scores and fetal pH, between groups were demonstrated.

Conclusion: The Epi-no® device is beneficial in decreasing perineal damage during vaginal delivery. Training with Epi-no® device decreases episiotomy rates and increases intact perineum outcomes.

Key words:

Episiotomy. Epi-no® device. Perineum trauma. Perineal massage. Antenatal physiotherapy.

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INTRODUCTION

Pelvic floor injuries of obstetric origin are considered by many gynaecologists to be inevitable sequelae for some women who have suffered traumatic births. A high percentage of patients will experience some form of perineal injury during childbirth that will require repair, and some of these will leave sequelae in the patient in the short and long term.

The family model in our country has changed, women have fewer children, they enter the world of work at an earlier age, many of them are more physically active than in the past and they have a longer life expectancy. For all these reasons, there is a great need to inform pregnant women about the importance of the pelvic floor during pregnancy and childbirth and its prevention. Many professionals propose pelvic floor physiotherapy prior to childbirth as a tool for the prevention of perineal and pelvic floor injuries during childbirth, such as episiotomies and tears.

The main objective of this study was to examine the usefulness of pelvic floor physiotherapy prior to childbirth, such as perineal massage and exercises with the Epi-no® positive dis- positive, in relation to obstetric injuries.

MATERIAL AND METHODS

A single-centre, national, prospective, observational, comparative, prospective study of three arms of 332 patients was conducted from October 2013 to August 2015. The project was conducted after approval by the Ethics Committee of the Hospital Universitario Puerta de Hierro de Majadahonda.

- Group A (129): control group patients.
- Group B (103): patients performing perineal massage exercises.
- Group C (100): patients exercising with the Epi-no® device.

All patients signed the informed consent to participate in the study and decided in which branch of the study they wanted to participate (control group, peri- ineal massage group and exercise group with the Epi-no® device).

The physiotherapist explained to the patients who entered the peri- neal massage branch how to perform it in a first session, offering two more sessions prior to delivery to consolidate knowledge and correct errors in the performance of the massage. It was recommended that the massages should begin around week 33 and be performed daily for 10 minutes a day.

Patients in the Epi-no® group were shown how to use the Epi-no® device and how to perform the exercises by a gynaecologist or the physiotherapist at week 36. Those patients with questions about the exercises returned to the clinic as often as needed. It was recommended to start the exercises in week 36 and to perform them daily for 10-20 minutes a day. The size of the balloon was

gradually increasing from one preparation session to the next. A measurement chart was enclosed with the device. After each exercise session, the patient measured the diameter of the inflated balloon by aligning it on the left side of the chart with the solid line (0 cm). The horizontal arrows shown in figure 1 indicate the widest point of the balloon. Thus, in contrast to previous studies where the balloon circumference was studied (1-3), the patient found it easier to measure. At the time of data collection, the maximum number achieved by the patient during the exercises was analysed.

Four on-call teams composed of two attending gynaecologists and one trainee resident were selected. The study was single-blinded, explaining to the patient that she was not to give information about the branch of the study she was in.

During hospital admission, data were collected on the variables analysed (Table I).

The inclusion and exclusion criteria for the patients in the study were as follows:

Patients included in the present study had to meet the following *inclusion criteria:*

- Primiparous at term (from 36.6 weeks).
- Pregnant with previous caesarean section due to abnormal presentation or induction failure (no labour).
- Autonomous patient who agrees to participate in the study and signs the informed consent form.
- Vaginal delivery assisted by the different groups of gynaecologists (attending gynaecologists ± resident) who participated in the study.
- Live and viable newborn.

Table I. Variables to be analysed

1. Maternal age
2. Mother's height
3. Gestational age
4. EPI-NO: - Number of Epi-not reached
5. Perineal massages: – Frequency (never, < 1 time/week, > 1 time/week, 1 time/day, > 1 time/day) – Starting week – Sessions
6. Length of perineal tendon body
7. Childbirth: – Expulsion time – Induced or spontaneous childbirth – Euthocic or instrumental birth – Episiotomy – Perineal tear and grade
8. Newborn: – Weight – Head circumference – APGAR test – Fetal pH

The *exclusion criteria* were as follows:
- Pregnant with previous vaginal delivery.
- Pregnant with previous caesarean section in labour.
- Non-viable newborn with severe congenital malformations or intrauterine growth restriction (IUGR).
- Patients not attended at delivery by the participating on-call teams.
- Twin gestation.

RESULTS

A descriptive study of the study population was carried out, analysing the variables collected and comparing them between the different study groups.

There were no statistically significant differences in age, maternal height and gestational age in the three groups (Table II).

Statistically significant differences were observed in the length of the perineal raphe, with the mean of the Epi-no® group being shorter (3.3 cm) than the control group and the perineal massage group (3.5 cm both), with a p-value of 3.5 cm for the Epi-no® group and 3.5 cm for the control group.

= 0.040 and p = 0.007 respectively (Tables III and IV).

Within the perineal massage group, the patients who underwent perineal

The average number of perineal massage sessions per week was 4.9, with an average duration of 5.3 weeks during gestation, and the average number of perineal massage sessions was 25.5 during the entire gestation (Table V).

Table II. Patient characteristics

		Group A	Group B	Group C	p-value
Age	n	129	103	100	0,229
	Media	33,1	33,8	32,9	
	Medium	33,0	34,0	32,5	
	Typ. dev.	4,5	3,5	3,93	
	Minimum	20	24	23	
	Maximum	44	43	41	
Mother's height	n	129	103	100	0,503
	Media	165,7	165,8	166,5	
	Medium	165,0	167,0	167,5	
	Typ. dev.	5,7	5,7	5,6	
	Minimum	150	150	152	
	Maximum	188	180	180	
Gestational age	n	129	103	100	0,861
	Media	39,4	39,4	39,4	
	Medium	39,0	40,0	40,0	
	Typ. dev.	1,1	1,1	1,0	
	Minimum	37	37	37	
	Maximum	41	41	41	

Within the Epi-no® group, the patients reached a mean balloon diameter of 8.1 cm, i.e. a balloon diameter of 8.1 cm, i.e. an average balloon diameter of 8.1 cm.

Table III. Length of the perineal raphe

		Group A	Group B	Group C	p-value*
Length of the perineal raphe	n	129	103	100	*0,006*
	Media	3,5	3,5	3,3	
	Medium	3,5	3,5	3,4	
	Typ. dev.	0,5	0,4	0,5	
	Minimum	2,0	2,5	2,0	
	Maximum	4,5	4,2	4,2	

Table IV. Perineal raphe length II (Bonferroni test)

Length of the perineal raphe	p-value
Group A - Group B	1,000
Group A - Group C	*0,045*
Group B - Group C	*0,007*

Table V. Perineal massage

	n	Media	Medium	Typ. dev.	Minimum	Maximum
Frequency (times/wk)	103	4,9	4,0	1,7	2,0	7,0
Weeks (n.º of wk)	103	5,3	5,0	1,5	2,0	10,0
Number of massages	103	25,5	21,0	12,5	9,0	70,0

Table VI. Epi-no®

	n	Media	Medium	Typ. dev.	Minimum	Maximum
No. Epi-no® reached	100	8,1	8,0	0,8	6,0	9,5

No. Epi-no® achieved				
	n	Media	Typ. dev.	p-value*
Tear				
No	65	8,1	0,9	0,469
Yes	35	8,2	0,7	
Episiotomy				
No	63	8,4	0,7	*< 0,001*
Yes	37	7,6	0,7	
Perineum intact				
No	68	7,9	0,7	*< 0,001*

Yes	32	8,6	0,8	

balloon diameter of 25.44 cm. The higher the number of Epi-no® achieved (larger the Epi-no® diameter), the lower the rate of episiotomy and the higher the rate of intact perineum, with p < 0.001 for both (Table VI).

Statistically significant differences were found in the expulsion time. The Epi-no® group had the shortest duration with a mean of 65.9 minutes, with a statistically significant difference between this group and the control group (p = 0.043). No differences were found between the perineal massage and control groups (p = 0-061) and the Epi-no® and perineal massage groups (p > 0.999) (Table VII).

The study analysed the rate of instrumental deliveries and eutocic deliveries. The Epi-no® group had 72% euthocic deliveries, the massage group 64.1% and the control group 49.6%, with a p=0.002. Likewise, we found 28% instrumental deliveries in the Epi-no® group, 35.9% in the perineal massage group and 50.4% in the control group, with a p=0.002 (Table VIII). In reference to episiotomy and perineal tears, a lower rate of episiotomy was found in the Epi-no® group (37%) compared to the massage group (55.3%) and control group (69%), these differences being statistically significant (p < 0.001) (Table IX). A higher rate of intact perineums was also demonstrated in the Epi-no® group (32%), compared to the Epi-no® control group (32%) and the Epi-no® control group (32%), with a statistically significant difference (p < 0.001).

Table VII. Expulsion time

		Group A	Group B	Group C	p-value
Expulsion time (minutes)	n	129	103	100	*0,019*
	Media	79,8	66,0	65,9	
	Medium	66,0	60,0	60,0	
	Typ. dev.	46,7	43,4	38,6	
	Minimum	10,0	10,0	10,0	
	Maximum	200,0	160,0	180,0	

Expulsion time (minutes)	p-value
Group A - Group B	0,061
Group A - Group C	*0,043*
Group B - Group C	> 0,999

Table VIII. Type of delivery: euthocico *vs.* instruments

	Group A		Group B		Group C		p-value
	n	%	n	%	n	%	
Euthocic birth							
No	65	50,4	37	35,9	28	28,0	*0,002*
Yes	64	49,6	66	64,1	72	72,0	
Instrumental delivery							

The difference between the massage group (8.7%) and the control group (2.3%) was p < 0.001 (Table X).

The analysis of perineal tears is difficult to interpret, because there is a higher rate of first degree tears in the Epi-no® group compared to the control group, due to the lower rate of episiotomies and the higher number of intact perineums (Table XI). If we perform an overall analysis, the results would be as follows:

- Epi-no® *Group:*
  - Episiotomies: 37%.
  - Perineal tear: 35.5%:
    - 1.er grade tears: 58.8%.
    - Tear 2.º grade: 41.2%.
    - Tear 3.er grade: 0%.
  - Full perineum: 32%.
- *In the massage group there are 55.3% of episiotomies:*
  - Episiotomies: 55.3%.
  - Perineal tear: 48.5%:
    - 1.er grade tears: 68%.
    - Tear 2.º grade: 24%.
    - Tear 3.er grade: 8%.
  - Full perineum: 8.7%.

Table IX. Episiotomy

	Group A		Group B		Group C		p-value
	n	%	n	%	n	%	
Episiotomy							
No	40	31,0	46	44,7	63	63,0	*< 0,001*
Yes	89	69,0	57	55,3	37	37,0	

Table X. Perineses intact

	Group A		Group B		Group C		p-value
	n	%	n	%	n	%	
Perineum intact							
No	126	97,7	94	91,3	68	68,0	*< 0,001*
Yes	3	2,3	9	8,7	32	32,0	

Table XI. Perineal tears

	Group A		Group B		Group C		p-value
	n	%	n	%	n	%	
Tear							
No	67	51,9	53	51,5	65	65,0	*< 0,082*
Yes	62	48,1	50	48,5	35	35,5	
Grade of tear							
1	21	33,9	34	68,0	20	57,1	*0,002*
2	37	59,7	12	24,0	14	40,0	
3 (A+C)	4	6,5	3	6,0	0	0,0	

No	64	49,6	66	64,1	72	72,0	*0,002*
Yes	65	50,4	37	35,9	28	28,0	

– *Control group:*
  - Episiotomies: 69%.
  - Perineal tear: 48.1%:
    - 1.er grade tears: 33.9%.
    - Tear 2.º grade: 59.7%.
    - Tear 3.er grade: 6.5%.
  - Full perineum: 2.3%.

In the analysis of these data, we have patients who may have had an episiotomy and some type of tear; therefore, the percentages do not add up to 100%. The Epi-no® group had a total of 104.5%, the perineal massage group 112.3% and the control group 119.4%.

No statistically significant differences were found in weight, head circumference, Apgar test or pH. between the different groups.

After the descriptive analysis of the sample, different logistic regression analyses were carried out to obtain the relationship between the different variables comparing the different groups. The most important results found were the following:

We found that the longer the length of the perineal raphe, the lower the risk of patients having an episiotomy (OR = 0.436, 95% CI 0.256-0.741), irrespective of the group to which the patient belonged, with no association found with perineal tears.

The greater the head circumference of the baby, the greater the risk of instrumental delivery (OR = 1.497, 95% CI 1.236-1.812), and the greater the birth weight, the greater the risk of episiotomy (OR = 1.001, 95% CI 1.000-1.002). This result was significant, but caution should be exercised as it is close to 1, which would indicate that the risk is equal for all. No statistically significant relationship was found between head circumference and tear rate.

Finally, a multivariate analysis was performed to look at the risk of tearing, episiotomy, and intact perineum rate. between the different groups adjusting for confounding variables (birth weight, head circumference, instrumental delivery, spontaneous or induced delivery, perineal raphe length and maternal age).

Patients in the control group had 1.755 times the risk of having a tear as those in the Epi-no® group and patients in the perineal massage group had 1.767 times the risk as those in the Epi-no® group (OR = 1.755; 95% CI: 0.993-3.101 and OR = 1.767);
95% CI 0.978-3.192, respectively) (Table XII).

Patients in the control group had 3.831 times the risk of episiotomy as the Epi-no® group and patients in the perineal massage group had 2.497 times the risk as the Epi-no® group (OR = 3.831, 95% CI: 1955-7.394 and OR = 2.497, 95% CI: 1.286-4.847, respectively; OR = 3.831, 95% CI: 1955-7.394 and OR = 2.497, 95% CI: 1.286-4.847, respectively).
tively) (Table XIII).

Patients in the control group had a higher risk of perineal injury than those in the Epi-no® group (OR = 27.606; 95% CI: 7.039-108.273; p = 0.000) and those in the Epi-no® group had a higher risk of perineal injury than those in the control group (OR = 27.606; 95% CI: 7.039-108.273; p = 0.000).
patients in the massage group were 6.562 times more likely to suffer a perineal injury than those in the Epi-no® group (OR = 6.562: 95% CI: 2.550-16.885) (Table XIV).

DISCUSSION

There are multiple risk factors involved in short- and long-term pelvic floor complications. Undoubtedly, vaginal delivery is the most important risk factor among premenopausal women with pelvic floor pathology (4).

All women during vaginal delivery experience some stretching of the pelvic floor tissues, and approximately 80-85% of women suffer some form of perineal injury during vaginal delivery (tearing, laceration or episiotomy), with approximately 70% of these requiring stitches. During the second stage of labour, the foetal head exerts a force on the pelvic floor of the vagina.

Table XII. Multivariate analysis: risk of perineal tearing in the different groups adjusting for confounding variables

	B	E.T.	Wald	gl	Sig.	OR	95.0% CI for OR	
							Inferior	Top
Group			4,657	2	0,097			
Group A	0,562	0,290	3,747	1	0,053	1,755	0,993	3,101
Group B	0,569	0,302	3,562	1	0,059	1,767	0,978	3,192
Weight RN grams	0,000	0,000	0,045	1	0,832	1,000	0,999	1,001
Head circumference	0,190	0,117	2,652	1	0,103	1,210	0,962	1,521
Spontaneous/induced labour	-0,525	0,250	4,420	1	0,036	0,592	0,363	0,965
Instrumental delivery	-0,334	0,249	1,798	1	0,180	0,716	0,440	1,167

Perineal raphe length	0,948	0,263	4,391	1	0,037	1,729	1,034	2,892
Maternal age	-0,019	0,029	0,445	1	0,505	0,981	0,928	1,038
Constant	-7,620	3,622	4,427	1	0,035	0,000		

Table XIII. Multivariate analysis: risk of episiotomy in the different groups adjusting for confounding variables

	B	E.T.	Wald	gl	Sig.	OR	95.0% CI for OR	
							Inferior	Top
Group			16,368	2	0,000			
Group A	1,343	0,335	16,029	1	0,000	3,831	1,985	7,394
Group B	0,915	0,338	7,310	1	0,007	2,497	1,286	4,847
Weight RN grams	0,001	0,000	1,279	1	0,258	1,001	1,000	1,001
Head circumference	0,057	0,133	0,183	1	0,669	1,058	0,816	1,373
Spontaneous/induced labour	0,700	0,297	5,557	1	0,018	2,014	1,125	3,605
Instrumental delivery	2,156	0,305	50,056	1	0,000	8,634	4,752	15,688
Perineal raphe length	-0,896	0,299	8,964	1	0,003	0,408	0,227	0,734
Maternal age	0,030	0,033	0,798	1	0,372	1,030	0,965	1,099
Constant	-3,304	4,106	0,647	1	0,421	0,037		

Table XIV. Multivariate analysis: confidence of having an *intact perineum* in the different groups adjusting for confounding variables

	B	E.T.	Wald	gl	Sig.	OR	95.0% CI for OR	
							Inferior	Top
Group			29,639	2	0,000			
Group A	3,318	0,697	22,645	1	0,000	27,606	7,039	108,273
Group B	1,881	0,482	15,221	1	0,000	6,562	2,550	16,885
Weight RN grams	0,001	0,001	2,657	1	0,103	1,001	1,000	1,003
Head circumference	0,457	0,227	4,065	1	0,044	1,579	1,013	2,461
Spontaneous/induced labour	0,552	0,448	1,519	1	0,218	1,736	0,722	4,175
Instrumental delivery	3,376	1,047	10,401	1	0,001	29,266	3,760	227,779
Perineal raphe length	-0,321	0,418	0,591	1	0,442	0,725	0,319	1,646
Maternal age	0,077	0,053	2,114	1	0,146	1,080	0,974	1,199
Constant	-21,153	7,186	8,666	1	0,003	0,000		

16 Newtons (N), being 54 N during contraction and 120 N during maternal pushing. Instrumental vacuum extraction increases the force on the pelvic floor to 113 N and forceps to 200 N (5). Ashton-Miller and DeLancey report that 1 in 10 primiparas will suffer substantial damage to the levator ani during labour, with short and long-term consequences such as urinary and faecal incontinence, pelvic organ prolapse or sexual dysfunction (5). Within vaginal delivery, the risk factors with the greatest impact include: forceps deliveries, very prolonged second stage of labour, fetal weight, and the risk factors of fetal failure (6).

> 4,000 g (6) and head circumference > 35.5 cm (7,8).

The use of instrumental devices to assist pelvic muscle training, such as the Epi-no®, is considered to be highly effective in preparation for childbirth. Moreover, its effects are satisfactorily complemented by therapies such as perineal massage.

Perineal massage during pregnancy is a safe, well-accepted and tolerated technique aimed at increasing flexibility and reducing internal tension of the perineal musculature. The timing, frequency and duration are not well established. Many professionals recommend starting around week 33 and performing them for 10 minutes daily, although some authors have shown the same effectiveness if performed 2-3 times a week (9). According to a 2013 Cochrane review, perineal massage in nulliparous women reduces the likelihood of perineal trauma, especially reducing the number of episiotomies and perineal pain.

Thus, it is advisable that women receive information on the likely benefit of perineal massage and how to practice it (9). In learning correct perineal massage, a professional should be involved in guiding and correcting the patient or the patient should be given the opportunity to learn how to use perineal massage

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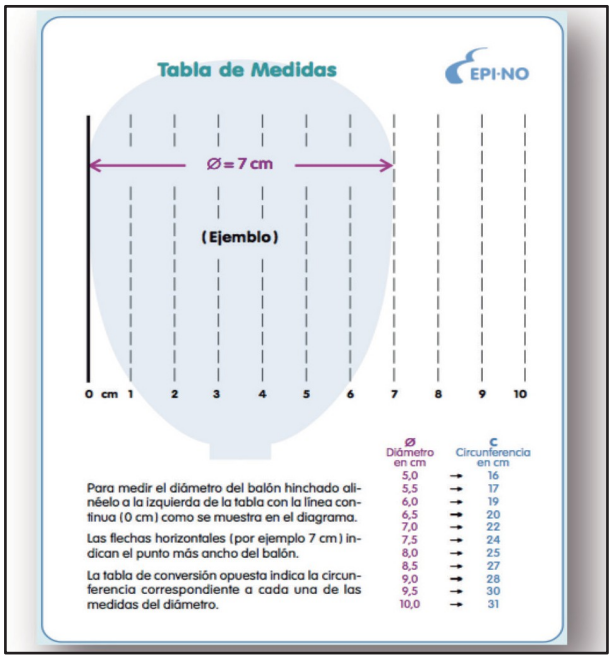

Figure 1. Table of measurements.
A table of measurements in cm, from 0-10 cm, is shown. At the bottom left of the figure, you can see the head circumference of a newborn baby to which the diameter of the balloon corresponds. www.Epi-no®.es

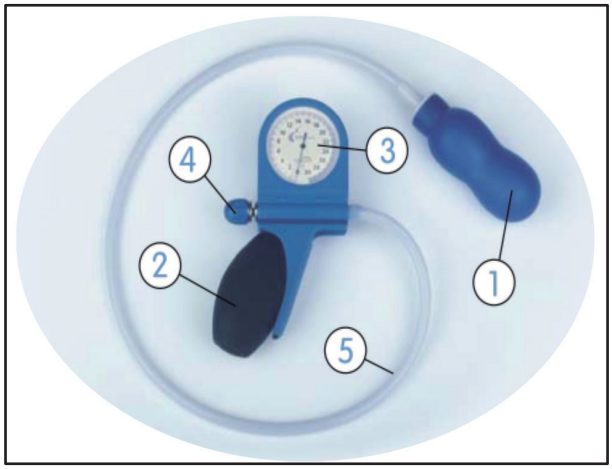

Figure 2. Epi-no® Delphine Plues.
The figure shows the different parts of which it is made up. www.Epi-no®.es

to their partner, as is done in the present study. This is because verbal or visual information, without practical teaching, may introduce reproducibility problems in the studies because there may be variations in massage technique, frequency and who performs the massage.

The *Epi-no® device* is a silicone balloon "1", a knob "2" with a built-in pressure display *(bio-feedback)* or pressure gauge "3", an exhaust valve "4", connected by a flexible plastic tube "5" (Fig. 2).

There are few studies in the literature evaluating its efficacy. Hillebrenner et al (1) conducted a single-blind study in which they studied the rate of episiotomies, perineal tears, length of expulsion and newborn Apgar test in 45 primiparous women who used the device compared with a control group. The results were 82% episiotomies in the control group and 47% in the Epi-no® group; 8% grade I and II tears in the control group and 4% in the Epi-no® group; 9% intact perineum in the control group and 47% in the Epi-no® group. It was also observed that patients who reached a larger balloon diameter and who had more sessions obtained better results, but this was not statistically significant. No significant differences were obtained in grade I and II tears. The newborns in the Epi-no® group also had expulsion periods 25 minutes shorter on average than the control group, as well as a better Apgar test score.

Kovacs et al (2) analysed the same variables as the previous study in 48 nulliparous women who used the device for a period of two consecutive weeks and 248 nulliparous women in the control group. The Epi-no® group had a higher number of intact perineums and lower rates of tears and episiotomies, although the latter was not statistically significant. No improvement was demonstrated in the length of second stage of labour, the rate of unscheduled deliveries or the Apgar test score.

Ruckhäberle et al (3) recruited 107 patients in the Epi-no® group and 105 in the control group. They obtained the following results: 37.4% intact perineum in the Epi-no® group versus 25.7% in the control group; 41.1% episiotomy in the Epi-no® group versus 50.5% in the control group; 20.6% grade I and II tears in the Epi-no® group versus 24.8% in the control group; 5.6% grade III and IV tears in the Epi-no® group versus 4.8% in the control group. This group found no correlation between balloon circumference achieved, number of sessions and intact perineum. There were no statistically significant differences in the length of the dilation and expulsion period or in the rate of vaginal infections.

Shek et al. (10) conducted a prospective, randomised study on levator ani injury and positive Epi-no® using pre- and post-delivery 4D translabial ultrasound. They found no statistically significant differences in the rate of levator ani avulsions, episiotomies, tears, length of third stage of labour and Apgar test scores.

Kok et al (11) conducted a study on the results of Epi-no® in Asian nulliparous women in a hospital setting where episiotomy was almost routinely performed in primiparas. Thirty-one patients were enrolled in the Epi-no® group and 60 in the control group.

There was a decrease in the rate of episiotomies (from 93% in the control group to 65.5%), however there were no statistically significant results in the rate of tears or intact perineums.

In our study, as in previous studies, we found a lower rate of episiotomy in the Epi-no® group (37%) compared to the mass group (55.3%) and the control group (89%), these differences being statistically significant ($p < 0.001$). We also found a higher percentage of intact perineums. Furthermore, we found a statistically significant relationship between the diameter achieved with Epi-no® and good perineal outcomes such as fewer tears, episiotomies and a higher rate of intact perineums, in contrast to certain studies such as those carried out by Hillebrenner et al (1) and Ruckhäberle et al (3).

The length of the perineal raphe (distance between the introitus and the anus) is frequently cited in the literature as a cause of traumatic vaginal delivery in primiparas when it is abnormally short, but it is not clear what the normal measurements of the perineal raphe are. This is probably due to the great difference in the different ethnicities, and even between women of the same ethnicity. Also of importance are the properties of the tissues that form it and the degree of elasticity or rigidity of these tissues. Tizk et al. were the first to publish an observational study on this subject. They defined short perineal raphe as less than 4 cm in their population group in the United Arab Emirates (12). In a study by Deering, the length of the perineal raphe was analysed and the mean was 3.9 cm. A perineal raphe of 2.5 cm or less had a significantly increased risk of severe tearing during vaginal delivery (up to 10 times greater) compared to a perineal raphe length of more than 2.5 cm. Women with short perineal raphe lengths also had an increased risk of instrumental delivery (13). Martinez Bustelo et al., professors at the University School of Physiotherapy in A Coruña, define normal perineal raphe length as between 2,5 and 3,4 cm (14).

Our results show a mean perineal raphe length of 3.3 cm in the Epi-no® group, being slightly longer in the other two groups (3.5 cm). As in previous studies, we observed a higher risk of episiotomy the shorter the length of the perineal raphe, without observing a higher rate of instrumental deliveries.

There are multiple studies in the literature that show a clear relationship between prolonged expulsive periods with higher rates of perineal injury and future pelvic floor dysfunction (15-17). In a study by Schiessl, from
1,200 patients, the average length of labour was 103 minutes in primiparas and 33 minutes in multiparas.
(18). In our series, the expulsion period was shorter in the Epi-no® and massage group, with a mean of 65.9 and 66 minutes, respectively, than in the control group, whose

The mean time was 79.8 minutes, which was statistically significant (p = 0.019).

The main modifiable factor to reduce pelvic floor injuries is instrumental delivery (19-21). These deliveries are associated with an increased risk of III and IV degree dis- garments and levator ani avulsions (22,23). Vacuum extraction has less impact on the pelvic floor than forceps (24), with lower rates of episiotomy and less injury to the levator ani (25,26).

In our population, we also found statistically significant differences in the type of delivery, with the Epi-no® group having the highest rate of euthyroid deliveries and the lowest rate of instrumental deliveries.

However, we found no statistically significant differences in the Apgar test or fetal pH between the three groups.

CONCLUSION

All pregnant women should be informed about perineal massage and exercises with the Epi-no® device. In our setting, the vast majority of midwives and physiotherapists who teach childbirth preparation classes inform patients about this technique, but few pregnant women go to a professional to receive practical instructions on how to perform it.

Exercises with the Epi-no® device have benefits on perineal injuries such as episiotomy and tears, compared to the control group and perineal massage group. In addition, patients in this group have a higher rate of intact perineums. However, we cannot affirm their benefit in the Apgar test score and foetal pH, as the differences are not statistically significant.

BIBLIOGRAPHY

1. Hillebrenner J, Wagenpfeil S, Schuchardt R, Schelling M, Schneider ATM. First clinical experiences with the new birth trainer Epi-no in primiparous women. Z Geburtsh Neonatol 2001;205:1-8.
2. Kovacs GT, Health P, Heather C. First Australian trial of the bir- th-trianing device Epi-no: a highly significantly increased chance of an intact perineum. Aust N Z K Obstet Gynaecol 2004;44(4):347-8.
3. Ruckhäberle E, Jundt K, Bäuerle M, Brisch KH, Ulm K, Dannecker C, et al. Prospective randomised multicentre trial with the birth trainer epi-no for the prevention perineal trauma. Aust N J Obstet Gynaecol 2009;49(5):478-83.
4. Lavy Y, Sand PK, Kaniel Cl, Hochner-Celnikier D. Can pelvic floor injury secondary to delivery be prevented? Int Urogynecol J 2012;23(2):165-73.
5. Ashton-Miller JA, DeLancey JO. On the biomechanics of vaginal bir- th and common sequelae. Annu Rev Biomed Eng 2009;11:163-76.
6. Perfialotis V, Vlachos D, Protopapas A, Pappa K, Vlachos G. Risk factors for severe perineal lacerations during childbirth. In J Gynecol Obstet 2014;125(1):6-14.
7. Cassadó J, Pessarrodona A, Rodriguez-Carballeira M, Hinojosa L, Manrique G, Márquez A, et al. Does episiotomy protect against

injury of the levator ani muscle in normal vaginal delivery? Neurol Urodyn 2014;33(8):1212-6. DOI 10.1002/nau.22488
8. Nyangoh Timoh K, Bessede T, Zaitouna M, Peschaud F, Chevallier JM, Fauconnier A, et al. Anatomie de muscle élévateur de l'anus et applications en gynécologie obstetrique. Gynecol Obstet Fertil 2015;43(1):84-90.
9. Beckmann MM, Garrett AJ. Antenatal perineal massage for reducing perineal trauma. Cochrane Database Syst Rev 2013;4:CD005123.
10. Sheck KL, Chantarasorn V, Langer S, Phipps H, Dietz HP. Does the Epi-no birth trainer reduce levator trauma? A randomised controlled trial. Int Urogynecol J 2011;22:1521-8.
11. Kok J, Tan KH, Koh S, Cheng PS, Lim WY, Yew ML, et al. Antenatal use of a novel vaginal birth training device by term primiparous women in Singapore. Singapore Med J 2004;45(7):318-23.
12. Rizk DE, Thomas L. Relationship between the length of perineum and position of the annus and vaginal delivery in primigravide. Int Urogynecol J 2000;11:79-83.
13. Deering SH, Carlson N, Allaire A, Satin AJ. Perineal body length and lacerations at delivery. J Reprod Med 2004;49(4):306-10.
14. Martínez Bustelo S, Ferri Morales A, Patiño Nuñez S, Viñas Diz S, Martínez Rodríguez A. Clinical interview and functional assessment of the pelvic floor. Fisioterapia 2004;26(5):266-80.
15. Van Delft K, Thakar R, Sultan A, Schwertner-Tiepelmann N, Kluivers K. Levator ani muscle avulsion during childbirth: a risk prediction model. BJOG 2014;121(9):1155-63. DOI: 10.1111/1471-0528.12676. 2014.
16. Valsky DV, Lipschuetz M, Bord A, Eldar I, Messing B, Hochner-Celnikier D, et al. Fetal head circumference and length of second stage of labor are risk factors for levator ani muscle injury, diagnosed by 3-dimensional transperineal ultrasound inprimiparous women. AJOG 2009;201(1):91e1-e7.
17. Rogers et al. Contribution of the second stage of labour to pelvic floor dysfunction: a prospective cohort comparison of nulliparous women. BJOG 2014;12(9):1145-54.
18. Schiessl B, Janni W, Jundt K, Rammel G, Peschers U, Kainer F. Obs- tetrical parameter influencing the duration of the second stage of labour. Eur J Obstet Gynecol Reprod Biol 2005;118(1):17-20.
19. Cassadó J. Four-dimensional sonographic evaluation of avulsion of levator ani according to delivery mode. Ultrasound Obstet Gynecol 2011;38:701-6.
20. Handa VL, Blomquist JL, McDermont KC, Friedman S, Munoz A. Pelvic floor disorders after vaginal birth: effect of episiotomy, perineal laceration, and operative birth. Obstet Gynecol 2012;119(2):233-9.
21. Handa VL, Blomquist JL, Knoepp LR, Hoskey KA, McDermont KC, Muñoz A. Pelvic floor disorders 5-10 years after vaginal or cesarean childbirth. Obstet Gynecol 2011;118(4):777-84.
22. Dietz H, Lanzarone V. Levator trauma after vaginal delivey. Obstet Gynecol 2005;106:707-12.
23. Kearny R, Miller JM, Ashton-Miller JA, DeLancey JO. Obstetrical factors associated with levator ani muscle injury after vaginal birth. Obstet Gynecol 2006;107(1);144-9.
24. Poen AC, Felt-Bersma RJ, Dekker GA, Devillé W, Cuesta MA, Meuwissen SG. Third degree obstetric perineal tears: risks factor and preventive role of mediolateral episiotomy. Br J Obstet Gynaecol 1997;104(5):563-6.
25. Murphy DJ, Macleod M, Bahl R, Goyder K, Howarth L, Strachan B. A randomized controlled trial of routine versus restrictive use of episiotomy at operative vaginal delivery: a multicentre pilot study. BJOG 2008;115(13):1695-702.
26. Youssef R, Ramalingam U, Macleod M, Murphy DJ. Cohort study of maternal and neonatal morbidity in relation to use of episiotomy at instrumental vaginal delivery. BJOG 2005;112: 941-5.