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Original Work

Is the Epi-no® trainer a device for preventing perineal trauma of obstetric origin?

Is the Epi-no® trainer a device for preventing perineal trauma?

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Abstract

Introduction: Pelvic floor antenatal physiotherapy is a technique for preventing 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-centre, national, prospective, observational study of 332 patients: 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 the massage group (55.3%) and the 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 the perineal massage group and the control group. We also found that the Epi-no® group had lower rates of instrumental deliveries (28%), compared to the massage group (35.9%) and the control group (50.4%) ($p = 0.002$). No statistically significant differences in foetal outcomes such as foetal APGAR scores and foetal pH were demonstrated between groups.

Conclusion: The Epi-no® trainer device is beneficial in decreasing perineal damage during vaginal delivery. Training with the 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

Obstetric pelvic floor injuries are considered by many gynaecologists to be unavoidable sequelae for some women who have suffered traumatic births.

A high percentage of patients will experience some type of perineal injuries during childbirth that will require repair, and some of them will leave the patient with short- and long-term sequelae.

The family model in our country has changed: women are having fewer children; they join the world of work early; many of them do more physical activity than in the past and 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 about prevention. Many professionals propose pelvic floor physiotherapy prior to childbirth, as a tool for preventing perineal and pelvic floor injuries during childbirth such as episiotomies and tears.

We carried out this work with the main objective of studying the usefulness of pelvic floor physiotherapy prior to childbirth, such as perineal massage and exercises using the Epi-no® device, in preventing obstetric injuries.

MATERIAL AND METHODS

A national single-centre, prospective, comparative observational study of three cohorts of 332 patients was carried out from October 2013 to August 2015. The project was carried out after being approved by the Ethics Committee of the Puerta de Hierro University Hospital in Majadahonda.

- Group A (129): control group patients.
- Group B (103): patients who performed perineal massage exercises.
- Group C (100): patients who performed exercises using the Epi-no® device.

All patients signed the informed consent form for taking part in the study and decided on the study cohort in which they wanted to take part (control group, perineal massage group, and exercise group using the Epi-no® device).

In the first session the physiotherapist explained to the patients included in the perineal massage group how to do this, offering two more sessions prior to childbirth to consolidate knowledge and correct errors in its performance. It was recommended that they start with daily 10-minute massages at around week 33.

At 36 weeks a gynaecologist or physiotherapist taught patients in the Epi-no® device group how to use the Epi-no® device and how to do the exercises. Those patients with doubts about the exercises returned to the consultation as many times as they needed. It was recommended that they start the exercises in week 36, performing them daily for 10-20 minutes a day. The size of the balloon was gradually increased from one preparation session to the next. A measurement chart was attached to the device. After each exercise session the patient measured the diameter of the inflated balloon by aligning it to the left of the table with the solid line (0 cm). The horizontal arrows shown in Figure 1 indicate the widest point reached by the balloon. In this way, unlike other studies carried out previously in which the circumference of the balloon was studied (1-3), the patients found it easier to take the measurement. When it came to collecting the data, the maximum number reached by the patient during the exercises was analysed.

Four on-call teams were selected, consisting of two attending gynaecologists and one resident in training. This was a single-blind study, and it was explained to the patient that she should not provide information on the study cohort in which she was taking part.

On admission to hospital, data were collected on the variables that were to be analysed (Table I).

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

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

- Primiparous at term (from week 36.6).
- Pregnant woman with a previous caesarean section due to abnormal presentation or induction failure (without labour).
- Autonomous patients who agreed to take part in the study and who signed the informed consent form.
- Vaginal delivery assisted by the various on-call groups (attending gynaecologists ± resident) who took part in the study.
- Newborn alive and viable.

Table I. Variables to be analysed

1.	Maternal age
2.	Mother's height
3.	Gestational age
4.	EPI-NO: – Epi-no number reached
5.	Perineal massages: – Frequency (never, < once/week, > once/week, once/day, > once/day) – Start week – Sessions
6.	Length of the perineal tendon body
7.	Childbirth: – Expulsion time – Induced or spontaneous labour – Eutocic or instrumental delivery – Episiotomy – Perineal tear and degree
8.	Newborn: – Weight – Head circumference – APGAR test – Foetal pH

The *exclusion criteria* were as follows:

- Pregnant woman with previous vaginal delivery.
- Pregnant woman with previous caesarean section with labour.
- Non-viable newborn with severe congenital malformations or intrauterine growth restriction (IUGR).
- Patients not attended by the participating on-call teams when giving birth.
- 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 between the three groups (Table II).

Statistically significant differences were observed in the length of the perineal raphe, the mean of the Epi-no® group (3.3 cm) being less than both the control group and the perineal massage group (3.5 cm in each case), with a p-value = 0.040 and p = 0.007 respectively (Tables III and IV).

The patients in the perineal massage group performed an average of 4.9 perineal massages per week, with a mean duration of 5.3 weeks during pregnancy and an average number of perineal massage sessions of 25.5 during pregnancy (Table V).

Table II. Patient characteristics

		Group A	Group B	Group C	P-Value
Age	n	129	103	100	0.229
	Average	33.1	33.8	32.9	
	Median	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
	Average	165.7	165.8	166.5	
	Median	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
	Average	39.4	39.4	39.4	
	Median	39.0	40.0	40.0	
	Typ. Dev.	1.1	1.1	1.0	
	Minimum	37	37	37	
	Maximum	41	41	41	

The patients in the Epi-no® group reached an average balloon diameter of 8.1 cm, i.e. a balloon circumference of 25.44 cm. The greater the Epi-no® number reached (greater diameter of the Epi-no®), the lower the rate of episiotomies and the higher the rate of intact perineums, with a $p < 0.001$ for both (Table VI).

Table III. Perineal raphe length

		Group A	Group B	Group C	p-value*
Perineal raphe length	n	129	103	100	*0.006*
	Average	3.5	3.5	3.3	
	Median	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)

Perineal raphe length	P-Value
Group A - Group B	1.000
Group A - Group C	*0.045*
Group B - Group C	*0.007*

Table V. Perineal massages

	n	Average	Median	Typ. Dev.	Minimum	Maximum
Frequency (times/week)	103	4.9	4.0	1.7	2.0	7.0
Weeks (number of weeks)	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	Aver.	Med.	Typ. Dev.	Minimum	Maximum
Epi-no® No. reached	100	8.1	8.0	0.8	6.0	9.5
Epi-no® number reached						
	n		Average	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		
Intact perineum						
No	68		7.9	0.7		*< 0.001*
Yes	32		8.6	0.8		

Statistically significant differences were found in the expulsion time. The Epi-no® group was the one with the shortest duration, at an average 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).

In the context of the study, the rate of instrumental deliveries and eutocic deliveries was analysed. 72% of eutocic deliveries were found in the Epi-no® group, 64.1% in the massage group, and 49.6% in the control group, with a p=0.002. Similarly, we found 28% of 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).

With regard 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 the 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 massage group (8.7%) and the control group (2.3%), with p < 0.001 (Table X).

Table VII. Expulsion time

		Group A	Group B	Group C	P-Value
Expulsion time (minutes)	n	129	103	100	*0.019*
	Average	79.8	66.0	65.9	
	Median	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: eutocic vs. instrumental

	Group A		Group B		Group C		P-Value
	n	%	n	%	n	%	
Eutocic delivery							
No	65	50.4	37	35.9	28	28.0	*0.002*
Yes	64	49.6	66	64.1	72	72.0	
Instrumental delivery							
No	64	49.6	66	64.1	72	72.0	*0.002*
Yes	65	50.4	37	35.9	28	28.0	

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 a greater number of intact perineums (Table XI). If we perform a joint analysis, the results would be as follows:

- *Epi-no® group:*
  - Episiotomies: 37%.
  - Perineal tear: 35.5%:
    - 1st degree tears: 58.8%.
    - 2nd degree tear: 41.2%.
    - 3rd degree tear: 0%.
  - Intact perineums: 32%.
- *In the massage group, there are 55.3% episiotomies:*
  - Episiotomies: 55.3%.
  - Perineal tear: 48.5%:
    - 1st degree tears: 68%.
    - 2nd degree tear: 24%.
    - 3rd degree tear: 8%.
  - Intact perineums: 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. Intact perineums

	Group A		Group B		Group C		P-Value
	n	%	n	%	n	%	
Intact perineum							
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	
Tear Degree							
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	

– *Control group:*
  - Episiotomies: 69%.
  - Perineal tear: 48.1%:
    - 1st degree tears: 33.9%
    - 2nd degree tears: 59.7%
    - 3rd degree tears: 6.5%
  - Intact perineums: 2.3%.

In the analysis of these data, we find patients who may have an episiotomy and some type of tear; therefore, the sums of the percentages are not 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 score, or foetal pH between the different groups.

Following a descriptive analysis of the sample, various logistic regression analyses were performed to obtain the relationship between the different variables by comparing the different groups. The most outstanding results found were the following:

It was found that the greater the perineal raphe length, the lower the risk of patients having an episiotomy (OR = 0.436; 95% CI: 0.256-0.741), regardless of the group to which the patient belonged, there being no relationship with perineal tears.

The greater the head circumference of the newborn, the greater the risk of instrumental delivery (OR = 1.497; 95% CI: 1.236-1.812). It was also shown that the greater the weight of the newborn, the greater the risk of having an episiotomy (OR = 1.001; 95% CI: 1.000-1.002). This result was significant, but caution should be exercised since it is close to 1, a value that would indicate that the risk is the same for everyone. No statistically significant relationship was found between head circumference and tear rate.

Finally, a multivariate analysis was performed to determine the risk of tearing, episiotomy, and complete perineum rate among the different groups, adjusting for confounding variables (e.g. weight, head circumference, instrumental delivery, spontaneous or induced delivery, perineal raphe length, and maternal age).

Patients in the control group had a 1.755 times greater risk of having a tear than those in the Epi-no® group and patients in the perineal massage group a 1.767 times greater risk than 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 a 3.831 times greater risk of episiotomy than the Epi-no® group, and patients in the perineal massage group had a 2.497 times greater risk than those in the Epi-no® group (OR = 3.831; 95% CI: 1955-7.394 and OR = 2.497; 95% CI: 1.286-4.847, respectively) (Table XIII).

Patients in the control group had a greater risk of suffering a perineal injury than those in the Epi-no® group (OR = 27.606; 95% CI: 7.039-108.273; p = 0.000), and patients in the massage group had a 6.562 times greater risk of suffering 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. There is no doubt that vaginal delivery is the most important risk factor among premenopausal women with pelvic floor pathology (4).

During a vaginal birth, all women suffer some stretching of the pelvic floor tissues, and approximately 80-85% of women suffer some type of perineal injury during vaginal delivery (tearing, dilaceration, or episiotomy), and approximately 70% of them require suturing. During the expulsion period, the foetal head exerts a force of 16 Newtons (N) on the pelvic floor, being 54 N during contraction and 120 N in maternal pushing. Instrumental vacuum deliveries increase the force on the pelvic floor to

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

	B	E.T.	Wald	Gl	Gis.	OR	95.0% CI for OR	
							Lower	Higher
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
Newborn weight in 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	0.548	0.263	4.351	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	Gis.	OR	95.0% CI for OR	
							Lower	Higher
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
Newborn weight in 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 in achieving an *intact perineum* in the different groups by adjusting for confounding variables

	B	E.T.	Wald	Gl	Gis.	OR	95.0% CI for OR	
							Lower	Higher
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
Newborn weight in 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		

113 N and forceps to 200 N (5). Ashton-Miller and DeLancey point out that 1 in 10 primiparous women will suffer substantial damage to the levator ani during childbirth, and its short- and long-term consequences, such as urinary and faecal incontinence, pelvic organ prolapse, or sexual dysfunction (5). Within vaginal delivery, among the risk factors with the greatest impact are: forceps deliveries, very long expulsion periods, foetal weight > 4,000 g (6), and head circumference >35.5 cm (7,8).

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. In addition, its effects are satisfactory complements to therapies such as perineal massage.

Perineal massage during pregnancy is a safe, well-accepted, and tolerated technique for increasing flexibility and reducing the internal tension of the perineal muscles. Neither the time of onset nor the frequency and duration of use are well established. Many professionals recommend starting it around week 33 and performing it for 10 minutes daily, although certain authors have shown the same effectiveness if it is performed 2–3 times a week (9). According to a 2013 review by La Cochrane, perineal massage in nulliparous women reduces the likelihood of perineal trauma, especially in reducing the number of episiotomies and perineal pain.

It is therefore advisable that women receive information about the probable benefit of perineal massage and how to practise it (9). In order to learn how to perform a correct perineal massage, a professional should be involved to guide and correct the patient or her partner, as is done in the present study. This is because

verbal or visual information, without practical teaching, can introduce reproducibility problems in the study because there may be variations in the massage technique, frequency, and who is performing it.

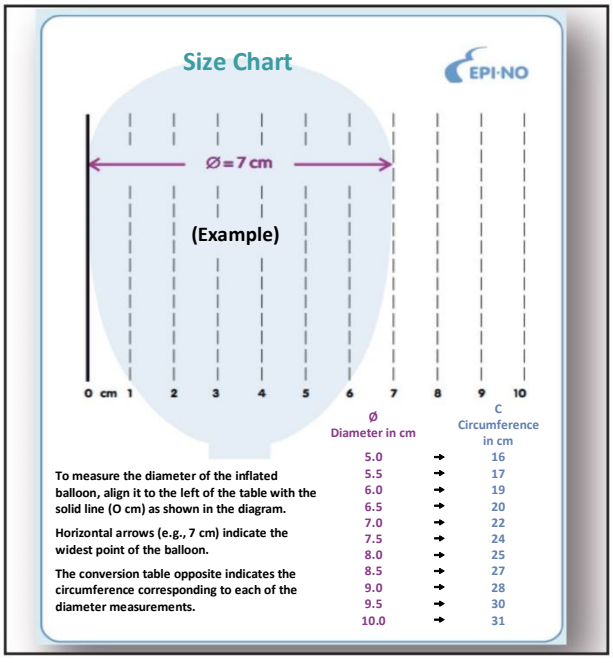

Figure 1. Measurement chart.
A table of measurements in cm, from 0-10 cm, is shown. At the bottom left of the figure, you can see the head circumference of a newborn to which the diameter of the balloon corresponds. www.Epi-no®.es

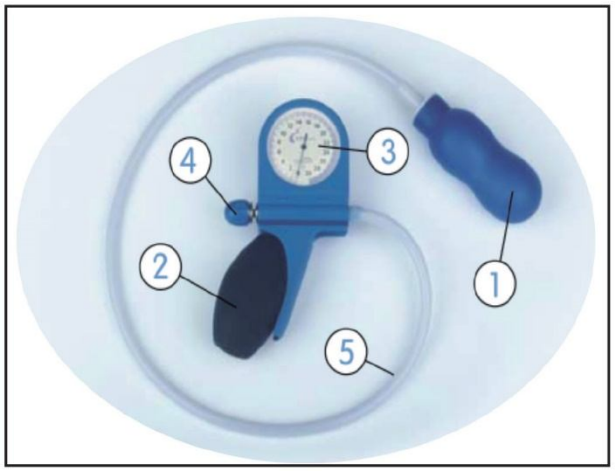

Figure 2. Epi-no® Delphine Plues.
This picture shows its various component parts. www.Epi-no®.es

The *Epi-no® device* is a silicone balloon "1", a knob "2" with an integrated pressure display *(biofeedback)* or pressure gauge "3", an exhaust valve "4", connected by a plastic hose "5" (Fig. 2).

There are few studies in the literature that evaluate its efficacy. Hillebrenner et al. (1) conducted a single-blind study in which they studied the rate of episiotomies, perineum tears, duration of expulsion, and Apgar test on the newborn in 45 primiparous women who used the device, comparing it with a control group. They obtained 82% episiotomies in the control group and 47% in the Epi-no® group; 8% first- and second-degree tears in the control group and 4% in the Epi-no® group; 9% intact perineums in the control group and 47% in the Epi-no® group. In addition, it was observed that patients who reached a larger balloon diameter and who performed a greater number of sessions obtained better results, but these results were not statistically significant. No significant differences were obtained in first- and second-degree tears. They also had expulsion periods on average 25 minutes less than the control group, in addition to a better score in the Apgar test on newborns in the Epi-no® group.

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 obtained a greater number of intact perineums and a lower number of tear and episiotomy rates, although the latter data were not statistically significant. No improvements were shown in the duration of expulsion, instrumental delivery rate, or Apgar test score.

Ruckhäberle et al. (3) recruited 107 patients in the Epi-no® group and 105 in the control group. The following results were obtained: 37.4% intact perineums in the Epi-no® group, compared to 25.7% in the control group; 41.1% episiotomies in the Epi-no® group and 50.5% in the control group; 20.6% first- and second-degree tears in the Epi-no® group compared to 24.8% in the control group; 5.6% third- and fourth-degree tears in the Epi-no® group vs. 4.8% in the control group. This group found no correlation between the circumference of the balloon reached, nor the number of sessions and intact perineums. They did not obtain statistically significant differences in the duration of the dilation or expulsion period, nor in the rate of vaginal infections.

Shek et al. (10) conducted a prospective randomised study on levator ani trauma and the Epi-no® device using translabial 4D ultrasound before and after delivery. They found no statistically significant differences in the rate of levator ani avulsions, episiotomies, tears, expulsion period duration, and Apgar test scores.

Kok et al. (11) conducted a study on the Epi-no® results in nulliparous Asian women, in a hospital setting, where episiotomy was performed routinely in primiparous women. A total of 31 patients were recruited in the

Epi-no® group and 60 in the control group.

A reduction in the rate of episiotomies was obtained (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 well as in certain results from previous studies, we found a lower rate of episiotomy in the Epi-no® group (37%) compared to the massage 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. In addition, we found a statistically significant relationship between the diameter achieved with the Epi-no® device and good perineal results such as fewer tears and episiotomies and a higher rate of intact perineums, in contrast with certain studies such as those conducted by Hillebrenner et al. (1) and Ruckhäberle et al. (3).

In the literature, the length of the perineal raphe (the distance between the introitus and the anus) is frequently cited as a cause of traumatic vaginal delivery in primiparous women, when it is abnormally short; but without making it clear what the normal measurements are. This is probably due to the great difference in different ethnicities, and even between women of the same ethnicity. The properties of the tissues that form it and their degree of elasticity or rigidity are also of relevant importance.

Tizk et al. were the first to publish an observational study on the subject. They defined a short perineal raphe as one measuring less than 4 cm, in their population group in the United Arab Emirates (12). In a study carried out by Deering, the length of the perineal raphe was analysed, with the mean being 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 raphes also had a higher risk of instrumental delivery (13). Martinez Bustelo et al., professors at the University School of Physiotherapy of A Coruña, define the length of the normal perineal raphe as between 2.5 and 3.4 cm (14).

Our results show a mean perineal raphe of 3.3 cm in the Epi-no® group, while the other two groups were somewhat higher (3.5 cm). As in previous studies, the lower the length of the perineal raphe the greater the risk, no higher rate of instrumental deliveries being observed.

There are multiple studies in the literature that observe a clear relationship between prolonged expulsion periods and higher rates of perineum injuries and future pelvic floor dysfunctions (15-17). In a study conducted by Shiessl on 1,200 patients the mean expulsion duration was 103 minutes in primiparous women and 33 minutes in multiparous women (18). In our study, the expulsion period was shorter in the Epi-no® and massage groups, with a mean of 65.9 and 66 minutes respectively, than in the control group where the mean was 79.8 minutes, this being statistically significant ($p = 0.019$).

The main modifiable factor for reducing pelvic floor injuries is instrumental delivery (19-21). These births are associated with an increased risk of third- and fourth-degree tears and levator ani avulsions (22,23). The suction or vacuum method has fewer consequences for the pelvic floor than the use of forceps (24), with lower rates of episiotomies and less levator ani trauma (25,26).

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

However, we did not find statistically significant differences in the Apgar test results nor in foetal 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 provide childbirth preparation classes inform patients of this technique, but few pregnant women go to a professional to receive practical instruction in how to perform it.

Exercises with the Epi-no® device have benefits in terms of perineum 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 its benefit for Apgar test scores and for foetal pH since the differences are not statistically significant.

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