

Evaluation of the Perineal Massage Effectiveness by Using a Vulvar Gel (Palomacare®) Containing *Centella asiatica* Phytosome during Pregnancy and Labor

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Abstract

Objective: To assess the beneficial effects in delivery and postpartum of perineal massage during pregnancy and labor in primiparous women.

Methods: Observational, multicenter, open, prospective pilot study with control group. Women with a first pregnancy were included who were assigned in a non-randomized way to one of the two study groups: intervention group (A) with daily perineal massage using Palomacare® Gel vulvar from the 35th week of pregnancy and during labor and control group (B) with usual clinical practice without performing perineal massage.

The following variables were evaluated at the time of delivery: need for episiotomy, presence and characteristics of tears, volume of bleeding caused by them and time of expulsion of the newborn from complete dilation. In the postpartum visit, the appearance of the episiotomy or lesions, the degree of pain and the degree of satisfaction with the appearance and evolution of the vulvo-perineal wound were assessed.

Results: 40 women (20 per group) between 23 and 45 years were evaluated. There were no significant differences between groups in the number of episiotomies and in the time of delivery of the newborn. In group A, there was a tendency towards a lower number of tears (35% vs 25%) and a significant lower volume of bleeding: 65% vs. 40% of patients without bleeding or with minimal bleeding in groups A and B, respectively ($p < 0.02$). At the postpartum visit, the appearance and healing of the episiotomy was rated excellent in 85% of patients in group A vs. 35% in group B ($p < 0.0001$). Pain was mild in 75% vs. 30% of patients in group A and B, respectively ($p < 0.0001$). 95% of patients in group A were satisfied or very satisfied with the postpartum evolution of the wound compared to 25% in group B ($p < 0.0001$).

Conclusion: The application of a daily perineal massage from the 35th week of pregnancy and during labor using Palomacare® Vulvar Gel shows beneficial effects on the delivery and postpartum of primiparous women. These results should be validated in a larger study.

Keywords: Perineal massage; Episiotomy; Vulvar Gel; Primiparous

Introduction

Perineal trauma is one of the most frequent complications in the second stage of labour, either as perineal (spontaneous) muscular tear or by performing episiotomy (iatrogenic). The incidence of women who suffer some type of perineal trauma during delivery, ranges between 30% and 85% and is more pronounced in primiparous women [1-3]. It is associated with an increase in morbidity as it increases the risk of bleeding, perineal pain and postpartum urinary incontinence, as well as anal incontinence and sexual dysfunction. Women's fear of going through perineal trauma has led to an increase in the demand for cesarean section to avoid risks [4].

Episiotomy is an obstetric practice consisting of a surgical incision in the perineal region, indicated in situations of signs of fetal distress, insufficient progression of labor and threat of third-degree laceration. The usual justification for professionals is that it contributes to the prevention of severe perineal trauma, uterine prolapse and urinary incontinence.

However, the preventive use of episiotomy to avoid muscular tears is not advised by WHO since it does not present any scientific evidence that supports its benefit, but it does have sequelae for women, mainly the increase in the infection rate, the risk of severe injury to the perineum, greater blood loss, discomfort and longer recovery time in the postpartum period, with repercussions on the establishment of the breastfeeding process [5,6].

Different techniques, like physical exercise, perineal massage in advanced stages of pregnancy or during labor, the modified Ritgen maneuver and the application of hot gauze during labor, have been analyzed to prevent perineal trauma by reducing the number of episiotomy and lacerations [7-10].

In one study, it has been observed that perineal massage starting at week 35 of pregnancy and performed 3 - 4 times per week for 4 minutes or once for 10 minutes per week, increases elasticity and reduces the risk of perineal trauma from episiotomy or spontaneous muscular tears [7]. Likewise, perineal massage during labor, delivery with a lubricating gel has shown a reduction in stress, pain and the probability of suffering perineal trauma due to the distension of the muscles of the perineum surrounding the vaginal introitus [11].

However, there is very little experience in the combined use of both techniques, intrapartum perineal massage and perineal massage from the 35th week of gestation. Therefore, it is intended to carry out a pilot study with the objective of evaluating the beneficial effects in delivery and postpartum of perineal massage performed with Palomacare® Vulvar gel during pregnancy from week 35 and in labor in primiparous women [12].

Methods

Design and patients

Prospective, open pilot study with a control group carried out in the obstetric consultations of the General Hospital of Catalonia and of the Sagrada Familia Clinic of Barcelona under conditions of usual clinical practice (PERIMAPART study: PERIneal MAssage PART). Participants were recruited between February 2019 and April 2019. Women who attended a routine control visit of week 35 of their first pregnancy were included. After granting their informed oral consent, they were assigned in a non-randomized manner to one of the two study groups:

- Group A or intervention, in which the perineal massage was performed with Palomacare® Vulvar Gel.
- Group B or control, without perineal massage.

Study procedure

The study was conducted in accordance with the principles of the Declaration of Helsinki. The perineal massage of women in group A was carried out as follows:

- By the patient herself from week 35, after explanation of the technique by the midwife/gynecologist. A daily application was performed preferably at night.
- By the midwife/gynecologist during labor (with sterile glove), from the dilation of 5 - 6 cm to the full dilation. It could be repetitive.

The massage technique is detailed below: with an approximate amount of 1 ml (approximately the length of the last phalanx of the index finger) of Palomacare® Vulvar Gel, a circular movement was performed with the index and middle fingers on the vulvar fork and the perineum, following the direction of the vaginal introit, for about a minute. Palomacare® Moisturizing and repairing vulvar gel is a medical device marketed by Procure Health Iberia S.L. (Benifaió Valencia, Spain) whose active ingredients are: niosomes with hyaluronic acid, beta-glucan niosomes, *Centella asiatica* phytosomes, BioEcolia® (alpha-oligoglycan; prebiotic), and Aloe vera [13,14]. The vaginal gel needed for the study was provided free of charge to all participating women.

The patients were visited three times, approximately at 35 weeks of pregnancy (visit 1), at birth (visit 2) and between 10 - 15 days after delivery (visit 3).

Evaluation criteria

During visit 2 the presence and type of episiotomy, the presence and characteristics of the tear (grade I, II or III), the volume of bleeding specifically produced by the episiotomy and/or the tears assessed with a Likert-type scale from 0: no bleeding (no episiotomy or tear) to 4: very severe bleeding (vaginal disinsertion that requires transfusion), and the time of expulsion of the newborn valued in three categories: rapid (< 30 minutes), moderate (30 - 60 minutes) and slow (> 60 minutes) were evaluated. During the visit 3, the evaluation of the episiotomy or lesions by the midwife/doctor was performed with a Likert scale from 1: excellent appearance and scarring of the episiotomy to 4: dehiscence of the episiotomy or lesions. Likewise, the patient assessed the pain using an analog visual scale from 0: no pain to 10: maximum pain imaginable (1 - 2 mild pain, 3 - 7 moderate pain and 8 - 10 severe pain) [12] and also her degree of satisfaction over the appearance and evolution of the vulva-perineal wound with a scale from 1: very dissatisfied to 5: very satisfied.

Statistics

A total of 40 patients were evaluated, 20 in each group. No sample calculation was performed as it was a pilot study. Quantitative variables were expressed as numbers, means, and percentages. The t-Student test was used for independent samples.

Results

Forty Spanish patients between 23 and 45 years (mean: 33.6 years) were evaluated. 93% were Caucasian and 80% had a higher degree. There were no differences between groups in the baseline demographic data.

The number and characteristics of episiotomies and tears in each of the groups are shown in table 1.

Variables	Group A	Group B
Episiotomy n, (%)	10 (50%)	9 (40%)
No Episiotomy n, (%)	10 (50%)	11 (55%)
Mediolateral n, (%)	10 (50%)	8 (40%)
Media n, (%)	0 (0%)	1 (5%)
With muscle strains n, (%)	7 (35%)	5 (25%)
Without muscle strains n, (%)	13 (65%)	15 (75%)
Grade I n, (%)	6 (30%)	4 (20%)
Grade II n, (%)	7 (35%)	10 (50%)
Grade III n, (%)	0 (0%)	1 (5%)

Table 1: Number and characteristics of episiotomies and tear grades.

There were no significant differences between groups in the number and location of episiotomies. In the intervention group (A) there will be a slight tendency to present less tears and less gradation compared to the control group (35% vs. 25%).

There were statistically significant differences between groups ($p < 0.02$) in terms of the volume of bleeding specifically caused by the episiotomy and/or the tear. 65% of the patients in the massage group had no bleeding or this was minimal vs. 40% of the patients not undergoing perineal massage. Two patients in this group (without perineal massage) had severe bleeding (Figure 1). Fetal expulsion time was slightly faster in the massage group, without reaching significance: the expulsion time was fast (< 30 minutes), moderate (30 - 60 minutes) and slow (> 60 minutes) in 35%, 50% and 15% of patients in group A compared to 25%, 55% and 20% in group B respectively.

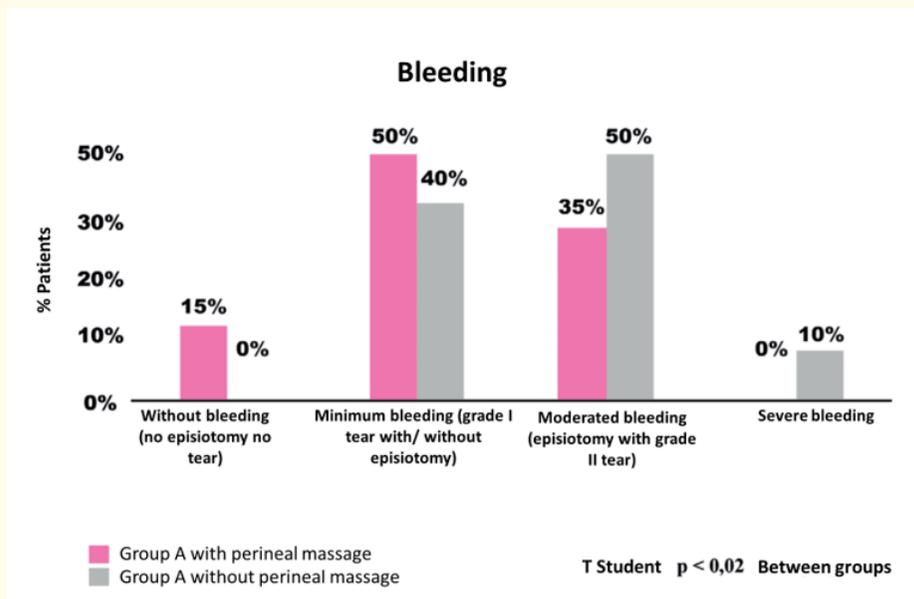


Figure 1: Volume of bleeding caused by the episiotomy and/or the tear.

At the 10 - 15 days postpartum visit, the appearance and healing of the episiotomy were rated excellent in 85% of the patients who received perineal massage and in 35% of those who did not receive it. In this second group, slight inflammation and slight pain to the touch were detected in 60% of the patients compared to 15% of them in the intervention group. The difference between groups was statistically significant ($p < 0.0005$) (Figure 2).

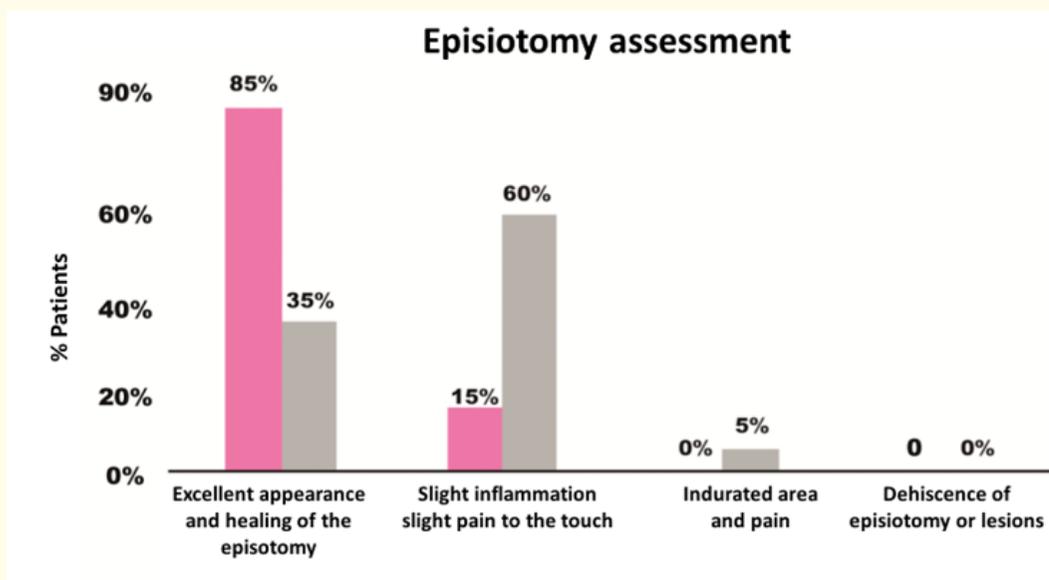


Figure 2: Episiotomy assessment.

The mean pain in patients with perineal massage was 12.4 mm and the mean of the control group was 34.3 mm, on a pain scale of 0 to 100 mm. The pain difference was statistically significant between both groups ($p < 0.0001$). 25% of patients in group A had no pain while all patients in group B had some level of pain. 50% of patients who received massage reported mild pain (1 - 2) compared to 25% of those who did not receive it. Finally, the pain was moderate (3 - 7) in 25% of patients in group A compared to 75% in group B (Figure 3).

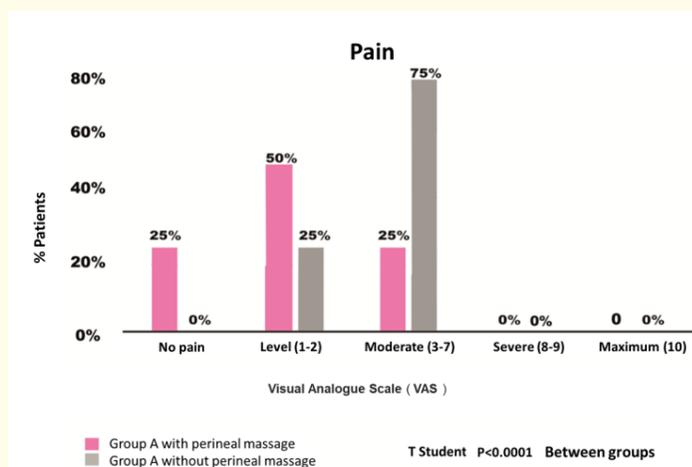


Figure 3: Pain assessment.

Regarding the degree of patient's satisfaction about the appearance and evolution of the vulvo-perineal wound since delivery, in group A, 19 patients (95%) and in group B, 7 patients (35%) were very satisfied or satisfied. In addition, only 4 patients (20%) in group B and none of the patients in group A had a dissatisfaction assessment. The difference between both groups was statistically significant ($p < 0.0001$) (Figure 4).

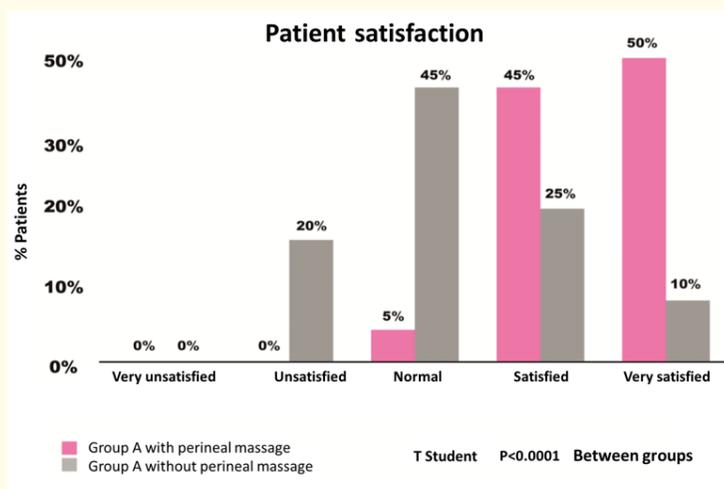


Figure 4: Patient's satisfaction about the evolution of the vulvo-perineal wound since delivery.

Discussion

The results of this pilot study show a beneficial effect of the application of a perineal massage with Palomacare® vulvar gel on primiparous pregnant women. These results show a significant reduction of the bleeding volume during delivery and an improvement in healing of lesions, in the appearance of episiotomy, and its pain at 10 - 15 days postpartum. In addition, there was an excellent degree of patient's satisfaction of the evolution of postpartum vulvo-perineal wound. On the other hand, there is a slight tendency to have less tears and a lower degree, as well as a faster second stage, in patients who received perineal massage.

The results of this pilot study are in line with those of other authors in which the beneficial effect of perineal massage on the number and severity of lacerations was shown [7]. A meta-analysis of 22 trials concluded that perineal massage, during the final stages of pregnancy, is associated with a significant risk of severe perineal trauma (third and fourth degree lacerations) and a high incidence of an intact perineum [11].

In previous studies, the massage was performed with moisturizing or lubricating products. In this study Palomacare® Vulvar Gel was chosen because it has a more complete formula with ingredients with not only moisturizing, but also reparative and healing action [15-19].

Limitations of the Study

The limitations of this study are those of a pilot study with few patients and with a non-randomized and open design, in which bias may be important. Therefore, these findings should be corroborated in a larger study with a randomized design. On the other hand, as far as our knowledge is concerned, it is the first study that evaluates the potential benefits of combined pre and intrapartum perineal massage compared to a control group, in primiparous women.

Conclusion

In conclusion, we believe that primiparous women should be taught the technique of perineal massage by the gynecologist/midwife during the final stages of pregnancy with a product specifically designed for vulvar application and with a complete moisturizing and

restorative action, since it is easy to learn technique that does not carry any risk and has significant effects on the quality of life and the reduction of bleeding during childbirth. In addition, a perineal massage should be applied during labor as it contributes to the reduction and lower severity of lacerations.

Funding Sources

None to report.

Conflict of Interest Statement

Nothing declared.

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