Taylor & Francis
Taylor & Francis Group

The Journal of Maternal-Fetal & Neonatal Medicine

ISSN: 1476-7058 (Print) 1476-4954 (Online) Journal homepage: https://www.tandfonline.com/loi/ijmf20

Use of calendula ointment after episiotomy: a randomized clinical trial

Carlo De Angelis, Arianna Di Stadio, Silvia Vitale, Gabriele Saccone, Maria Chiara De Angelis, Brunella Zizolfi & Attilio Di Spiezio Sardo

To cite this article: Carlo De Angelis, Arianna Di Stadio, Silvia Vitale, Gabriele Saccone, Maria Chiara De Angelis, Brunella Zizolfi & Attilio Di Spiezio Sardo (2020): Use of calendula ointment after episiotomy: a randomized clinical trial, The Journal of Maternal-Fetal & Neonatal Medicine, DOI: 10.1080/14767058.2020.1770219

To link to this article: https://doi.org/10.1080/14767058.2020.1770219


Published online: 27 May 2020.


Submit your article to this journal


Article views: 3


View related articles


View Crossmark data

Full Terms & Conditions of access and use can be found at
https://www.tandfonline.com/action/journalInformation?journalCode=ijmf20

THE JOURNAL OF MATERNAL-FETAL & NEONATAL MEDICINE
https://doi.org/10.1080/14767058.2020.1770219

Taylor & Francis
Taylor & Francis Group

ORIGINAL ARTICLE

Check for updates

Use of calendula ointment after episiotomy: a randomized clinical trial

Carlo De Angelis[a,b], Arianna Di Stadio[a], Silvia Vitale[a], Gabriele Saccone[c], Maria Chiara De Angelis[d], Brunella Zizolfi[d] and Attilio Di Spiezio Sardo[d]

[a]Casa di Cura Accreditata Fabia Mater, Rome, Italy; [b]Department of Obstetrics and Gynecology, Sapienza University of Rome, Roma, Italy; [c]Department of Neuroscience, Reproductive Sciences and Dentistry, School of Medicine, University of Naples Federico II, Naples, Italy; [d]Department of Public Health, University of Naples Federico II, Naples, Italy

ABSTRACT

Objective: Episiotomy is associated with an increased risk of postpartum pain, bleeding, and dyspareunia. The hypothesis of this trial was that in women with singleton pregnancy, and spontaneous labor at term, use of calendula ointment would reduce pain after episiotomy.

Methods: This was a single-center parallel group randomized trial of women with singleton pregnancies and spontaneous labor at term who were randomized to either use of calendula ointment (i.e. intervention group) or standard care (i.e. control group) after episiotomy. Eligible women were those with singleton gestations in spontaneous labor and vertex presentation at term. Women with premature rupture of membranes were excluded from the study. Women in the intervention group were recommended use of calendula ointment 4 h after the episiotomy and then every 8 h for 10 days. The primary outcome was the pain level. Pain level was self-reported and recorded using the verbal rating scale (VRS). The effect of the calendula ointment was quantified as mean difference (MD) with 95% confidence interval (CI).

Results: During the study, 100 women agreed to take part in the study, underwent randomization, and were enrolled in this trial. Of the 100 randomized women, 50 were randomized to the calendula ointment group, and 50 to the control group. No women were excluded after randomization or lost to follow up.Women who received calendula ointment after episiotomy compared to standard care had a significantly lower pain level starting from day two and during all the follow-up. Calendula ointment also improve wound healing in terms of redness and edema.

Conclusions: Use of calendula ointment significantly reduce pain after episiotomy.

ARTICLE HISTORY
Received 25 March 2020
Accepted 13 May 2020

KEYWORDS
Episiotomy; laceration; cesarean delivery; wound healing; pregnancy

Introduction

Perineal trauma is a major complication after delivery [1]. Perineal lacerations are injuries in the genital area can have been associated with short-term (e.g. bleeding) and long-term morbidities (e.g. urinary incontinence) [2]. Different techniques, such as Ritgen's maneuver, or use of warm package, have been studied to prevent perineal trauma [3–6]. Episiotomy, a surgical cut of the vagina and perineum, can be performed during the second stage of labor to either quickly enlarge the opening for the baby to pass through or to prevent severe perineal trauma [7]. A Cochrane review including 12 trials with 6177 women, showed that believing that routine episiotomy reduces perineal trauma was not justified by current evidence [7]. However, some clinical situations, such as an instrumental vaginal delivery or labor dystocia, still need the use of episiotomy [8]. Different studies showed episiotomy is associated with an increased risk of postpartum pain, bleeding, and dyspareunia [9]. Therefore, improving would healing and reducing pain after episiotomy is a major concern for obstetricians.

Objective

The hypothesis of this trial was that in women with singleton pregnancy, and spontaneous labor at term, use of calendula would reduce pain after episiotomy and improve wound healing.

Methods

Study design and participants

This was a single-center parallel group randomized trial of women with singleton pregnancies and spontaneous labor at term who were randomized to either use of calendula (i.e. intervention group) or standard care (i.e. control group) after episiotomy in the second

CONTACT Gabriele Saccone gabriele.saccone.1990@gmail.com Department of Neuroscience, Reproductive Sciences and Dentistry, School of Medicine, University of Naples Federico II, Naples, Italy

© 2020 Informa UK Limited, trading as Taylor & Francis Group

stage of labor at the Casa di Cura Accreditata Fabia Mater (Rome, Italy) from 1 March 2017 to 23 October 2017. The trial was approved by the local ethics committee (Codice) Eligible women were those with singleton gestations in spontaneous labor and vertex presentation at term. Women with premature rupture of membranes were excluded from the study. Obese women, defined as those with body mass index (BMI) >35, and those with an estimated fetal weight >4000 g were also excluded.

Randomization and masking

Eligible participants were randomly allocated in a 1:1 ratio to either use of calendula or no calendula. Women were randomized by a web-based system to the intervention or control group. The recruiters and the trial coordinator did not have access to the randomization sequence. The allocation code was disclosed only after the patient's initials was confirmed.

The trial was open-label, but the data analysts were blinded to allocated treatment group, until the entire analysis was completed.

Intervention and control group

Women in the intervention group were recommended use of calendula ointment 4 h after the episiotomy and then every 8 h for 10 days. Women in the control group received standard care.

Primary endpoint

The primary outcome was the pain level. Pain level was self-reported and recorded using the verbal rating scale (VRS). VRS for pain ranged from 0 (no pain) to 10 (unbearable pain).

Secondary endpoint

The secondary outcome of the trial was the wound healing assessed by the REEDA (Redness, Edema, Ecchymosis, Drainage, and Approximation). For each item, a score ranged from 0 to 3 can be assigned.

Sample size calculation

The sample size calculation was based on detecting an effect that would produce significant reduce in pain level using calendula ointment after episiotomy [10]. Based on prior data [10], we determined that a sample size of 100 (50 per group) patients would provide a power of 80% with a 2-sided type 1 error of 5%.

Statistical analysis

Data are shown as means with standard deviation, or as number (percentage).

Univariate comparisons of dichotomous data were performed with the use of the chi-square test with continuity correction. Comparisons between groups were performed with the use of the *T*-test to test group means by assuming equal within-group variances.

The primary analysis was an intention to treat comparison of the treatment assigned at randomization.

The effect of the calendula ointment on pain level was quantified as mean difference (MD) with 95% confidence interval (CI). A 2-sided p value less than .05 was considered significant. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) v. 19.0 (IBM Inc).

Results

Trial population

During the study, 100 women agreed to take part in the study, underwent randomization, and were enrolled in this trial.

Of the 100 randomized women, 50 were randomized to the calendula ointment group, and 50 to the control group.

No women were excluded after randomization or lost to follow up (Figure 1).

Table 1 shows the baseline demographic and clinical characteristics for each group. Three women (6%) in the calendula group, and three (6%) in the control group delivered with vacuum. No cases of severe perineal lacerations were recorded in either groups.

Primary and secondary outcomes

Table 2 shows primary and secondary endpoints. Women who received calendula ointment after episiotomy compared to standard care had a significantly lower pain level starting from day two and during all the follow-up. Calendula ointment also improve wound healing in terms of redness and edema. Discharge and approximation were scored zero in both groups during all the follow-up.

Adverse events

During follow-up, no serious adverse events were reported.

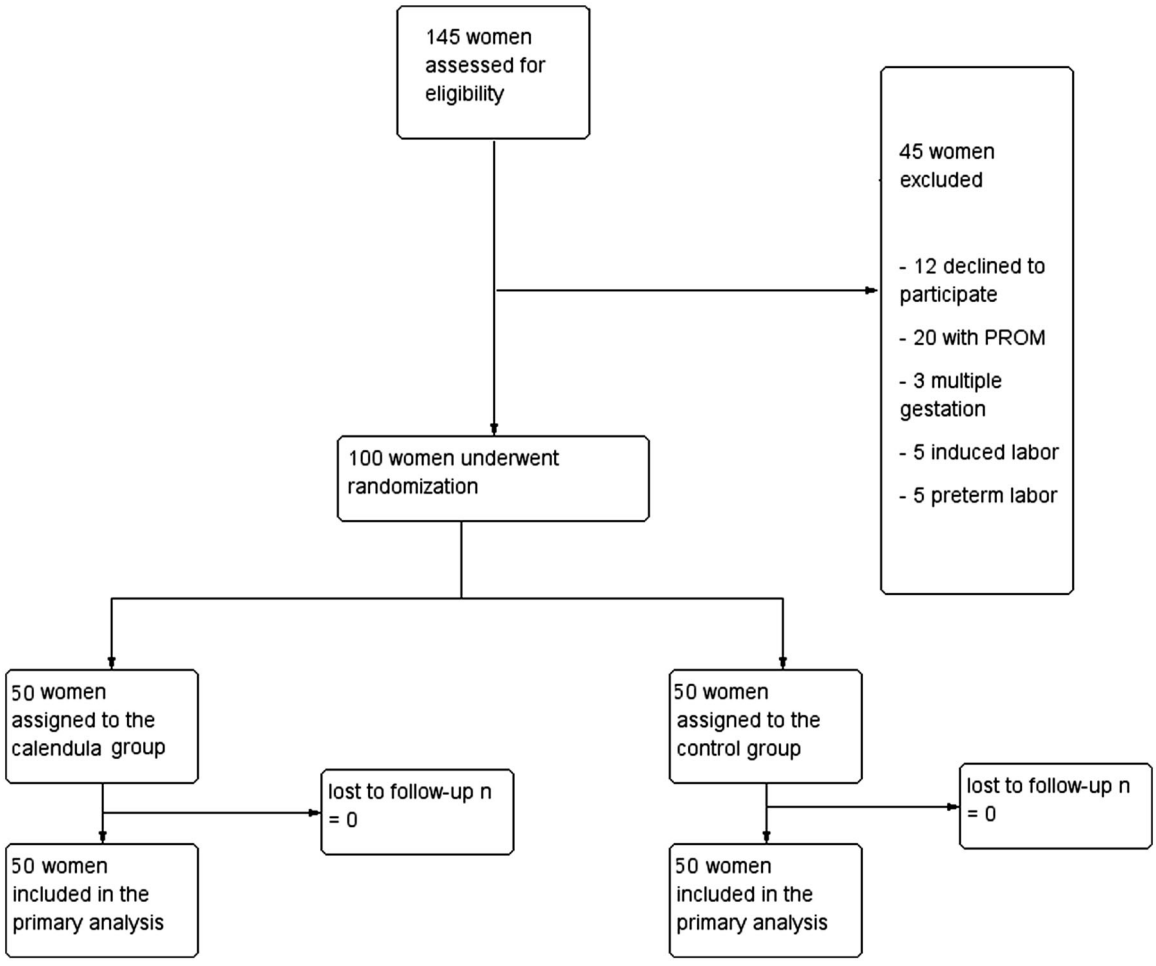

Figure 1. CONSORT Study flow-chart.

Table 1. Characteristics of the included women.

	Calendula group $N = 50$	Control group $N = 50$
Age		
Mean ± SD (years)	33.3 ± 4.6	31.3 ± 4.9
Race		
Caucasian *n* (%)	50 (100%)	50 (100%)
Gestational age at randomization mean ± SD (weeks)	39.7 ± 0.9	39.4 ± 1.2
BMI		
Mean ± SD (Kg/m^2)	24.7 ± 5.2	25.1 ± 6.2
Nulliparous *n* (%)	20 (62.5%)	23 (79.3%)
Operative vaginal delivery *n* (%)	3 (6.0%)	3 (6.0%)
Perineal lacerations 1st or 2nd degreen (%)	11 (22.0%)	17 (34.0%)
Severe perineal lacerations 3th or 4th degree *n* (%)	0	0

Data are presented as number (percentage) or as mean ± standard deviation.
SD: standard deviation; PTB: preterm birth??.

Discussion

Main findings

Episiotomy is associated with an increased risk of postpartum pain, bleeding, and dyspareunia. The hypothesis of this trial was that in women with singleton pregnancy, and spontaneous labor at term, use of calendula ointment would reduce pain after episiotomy. The study, including 100 women, showed that use of calendula was associated with reduced pain after episiotomy. Use of calendula ointment was also associated with improved would healing in terms of redness and edema at day three, four, seven, and nine, and in terms of ecchymosis at day five after episiotomy.

Findings from this trial were limited by the small sample size and by the open label study design and

Table 2. Primary and secondary endpoints during the follow-up.

	Calendula group $N = 50$	Control group $N = 50$	MD (95% CI)
DAY ONE			
Redness	2.20 ± 0.4	2.28 ± 0.7	−0.08 (−0.30 to 0.14)
Edema	2.06 ± 0.7	2.18 ± 0.3	−0.12 (−0.33 to 0.09)
Ecchymosis	1.44 ± 0.9	1.14 ± 0.2	0.30 (0.04 to 0.56)
VRS pain	3.92 ± 1.4	3.88 ± 2.1	0.04 (−0.66 to 0.74)
DAY TWO			
Redness	2.14 ± 0.4	2.26 ± 0.8	−0.12 (−0.37 to 0.13)
Edema	1.88 ± 0.8	2.18 ± 0.4	**−0.30 (−0.55 to −0.05)**
Ecchymosis	1.42 ± 1.1	1.16 ± 0.8	0.26 (−0.12 to 0.64)
VRS pain	3.10 ± 1.3	4.02 ± 1.1	**−0.92 (−1.39 to −0.45)**
DAY THREE			
Redness	1.82 ± 0.5	2.26 ± 1.1	**−0.44 (−0.77 to −0.11)**
Edema	1.48 ± 0.7	2.16 ± 0.8	**−0.68 (−0.97 to −0.39)**
Ecchymosis	1.28 ± 0.4	1.12 ± 1.3	0.16 (−0.22 to 0.54)
VRS pain	2.64 ± 0.6	3.84 ± 0.9	**−1.20 (−1.50 to −0.90)**
DAY FOUR			
Redness	1.52 ± 0.6	2.06 ± 1.3	**−0.54 (−0.95 to −0.14)**
Edema	1.16 ± 0.5	1.72 ± 1.1	**−0.56 (−0.89 to −0.23)**
Ecchymosis	1.06 ± 0.8	1.04 ± 1.1	0.02 (−0.36 to 0.40)
VRS pain	2.06 ± 1.1	3.30 ± 1.4	**−1.24 (−1.73 to −0.75)**
DAY FIVE			
Redness	1.36 ± 0.7	1.86 ± 0.8	**−0.48 (−0.77 to −0.19)**
Edema	0.86 ± 0.9	1.52 ± 2.2	−0.66 (−1.32 to 0.00)
Ecchymosis	0.74 ± 0.7	0.88 ± 0.8	**0.68 (0.39 to 0.97)**
VRS pain	1.62 ± 0.4	2.92 ± 1.3	**−1.30 (−1.68 to −0.92)**
DAY SIX			
Redness	1.10 ± 1.4	1.76 ± 2.0	−0.66 (−1.34 to 0.02)
Edema	0.66 ± 1.1	1.28 ± 0.9	**−0.62 (1.01 − 0.23)**
Ecchymosis	0.48 ± 1.3	0.62 ± 1.7	−0.14 (−0.73 to 0.45)
VRS pain	1.02 ± 0.5	2.52 ± 1.1	**−1.50 (−1.83 to −1.17)**
DAY SEVEN			
Redness	1.00 ± 0.8	1.46 ± 1.1	**−0.46 (−0.84 to −0.08)**
Edema	0.46 ± 1.3	1.16 ± 1.1	**−0.70 (−1.17 to −0.23)**
Ecchymosis	0.30 ± 0.7	0.44 ± 0.8	−0.14 (−0.43 to 0.15)
VRS pain	0.76 ± 0.5	2.10 ± 1.1	**−1.34 (−1.67 to −1.01)**
DAY EIGHT			
Redness	0.62 ± 1.1	1.24 ± 1.6	**−0.62 (−1.16 to −0.08)**
Edema	0.34 ± 0.8	0.98 ± 1.1	**−0.64 (−1.02 to −0.26)**
Ecchymosis	0.16 ± 0.8	0.26 ± 0.1	−0.10 (−0.32 to 0.12)
VRS pain	0.46 ± 1.0	1.58 ± 0.7	**−1.12 (−1.46 to −0.78)**
DAY NINE			
Redness	0.40 ± 0.7	1.04 ± 1.1	**−0.64 (−1.00 to −0.28)**
Edema	0.20 ± 0.3	0.68 ± 0.5	**−0.48 (−0.64 to −0.32)**
Ecchymosis	0.04 ± 1.3	0.14 ± 1.2	−0.10 (−0.59 to 0.39)
VRS pain	0.22±	1.12±	**−0.90 (−1.01 to −0.79)**
DAY TEN			
Redness	0.20 ± 0.4	0.52 ± 0.5	−0.32 (−0.77 to 0.13)
Edema	0.16 ± 0.7	0.52 ± 1.4	−0.36 (−0.79 to 0.07)
Ecchymosis	0.00 ± 0.1	0.06 ± 0.1	−0.06 (−0.15 to 0.03)
VRS pain	0.10 ± 0.4	0.66 ± 0.5	**−0.56 (−1.01 to −0.11)**

Data are presented as mean ± standard deviation. Boldface data, statistically significant.
MD: mean difference; CI: confidence interval.

therefore required confirmation from large placebo-controlled trial. Another major limitation of the study is the single center study design that limited the generalizability of the findings.

Implication

Vaginal delivery may cause tears and lacerations to the perineum. Major lacerations can be severe and extend to the anal sphincter. Women experience pain, bleeding, infection, and dyspareunia after perineal trauma [1,2]. Perineal lacerations are classified as follows: first-degree (involving the fourchette, perineal skin, and vaginal mucous membrane), second-degree (involving the perineal muscles and skin), third-degree (involving the anal sphincter complex), and fourth-degree (extending through the anal sphincter complex to anal epithelium). Episiotomy has been studied to prevent major perineal lacerations and to facilitate the birth of the baby [7–9]. Ideally, an episiotomy would relieve pressure on the perineum resulting in an easily repairable incision when compared to uncontrolled vaginal trauma. The different types of episiotomy incisions include the midline, the modified-median, the mediolateral, J-shaped, lateral, anterior, and radical [11,12]. The two most common techniques are midline (the US and Canada) and mediolateral (Europe). In the United States, episiotomy was once a widely used technique until when the American College of Obstetricians and Gynecologists (ACOG) made a recommendation against its routine use [2,7]. Episiotomy may increase the risk of several complications, including bleeding and infection. Therefore, it is important to improve wound healing after episiotomy and prevent complications. In this randomized trial, use of calendula ointment is associated with reduced pain level as assessed by VRS scale, and improved wound healing in terms of redness and edema of the wound, during ten day follow-up after episiotomy.

Conclusion

In summary, use of calendula ointment significantly reduce pain and improve wound healing after episiotomy.

Disclosure statement

No potential conflict of interest was reported by the author(s).

ORCID

Gabriele Saccone http://orcid.org/0000-0003-0078-2113

References

[1] McCandlish R. Perineal trauma: prevention and treatment. J Midwifery Womens Health. 2001;46(6):396–401.
[2] Practice Bulletin No. 165: prevention and management of obstetric lacerations at vaginal delivery. Obstet Gynecol. 2016;128(1):e1–e15.

[3] Aquino CI, Saccone G, Troisi J, et al. Is Ritgen's maneuver associated with decreased perineal lacerations and pain at delivery? J Matern Fetal Neonatal Med. 2019; 1–8. DOI:10.1080/14767058.2019.1568984. [Online ahead of print].

[4] Aquino CI, Guida M, Saccone G, et al. Perineal massage during labor: a systematic review and meta-analysis of randomized controlled trials. J Matern Fetal Neonatal Med. 2020;33(6):1051–1063.

[5] Magoga G, Saccone G, Al-Kouatly HB, et al. Warm perineal compresses during the second stage of labor for reducing perineal trauma: a meta-analysis. Eur J Obstet Gynecol Reprod Biol. 2019;240:93–98.

[6] Pierce-Williams RAM, Saccone G, Berghella V. Hands-on versus hands-off techniques for the prevention of perineal trauma during vaginal delivery: a systematic review and meta-analysis of randomized controlled trials. J Matern Fetal Neonatal Med. 2019;3:1–9.

[7] Jiang H, Qian X, Carroli G, et al. Selective versus routine use of episiotomy for vaginal birth. Cochrane Database Syst Rev. 2017;2:CD000081.

[8] Tsakiridis I, Giouleka S, Mamopoulos A, et al. Operative vaginal delivery: a review of four national guidelines. J Perinat Med. 2020;48(3):189–198.

[9] Sultan AH, Thakar R, Ismail KM, et al. The role of mediolateral episiotomy during operative vaginal delivery. Eur J Obstet Gynecol Reprod Biol. 2019;240: 192–196.

[10] Eghdampour F, Jahdie F, Kheyrkhah M, et al. The impact of *Aloe vera* and calendula on perineal healing after episiotomy in primiparous women: a randomized clinical trial. J Caring Sci. 2013;2(4):279–286.

[11] Kalis V, Laine K, de Leeuw JW, et al. Classification of episiotomy: towards a standardisation of terminology. BJOG. 2012;119(5):522–526.

[12] Barjon K, Mahdy H. Episiotomy. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020.