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Effect of Cleocin Cream mixture on episiotomy Wound Healing

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Abstract

The wound healing process is a complex process that involves the replacement of injured tissue with new tissue, which involves coagulation, inflammation, tissue reorganization and proliferation. Aim To study the effect of Cléocin Cream on episiotomy wounds healing. This case control study was conducted on 150 primiparous females admitted in the Al Zahraa University Hospitals for normal vaginal delivery and follow up for one month. Patients assigned into to 2 groups: examine group (*number* = hundred) and control group (*number* = fifty). The study group used Cléocin ointment every 3 ,4 times after suturing the episiotomy wound. This study was conducted at Obstetrics & Gynecology Department, Faculty of Medicine, Al-Azhar University. Statistically insignificant variance was observed among the examined group according to kind of episiotomy wound, presence of infections (P value >0.05), using additional medications, complications of episiotomy healing and additional surgical interference (P value >0.05), while statistically significance variance was observed among the examined group according to associated tears (P-value less than 0.05). Highly statistically significant reduction was observed in REEDA index (Redness Edema Echymosis Discharge Approximation of edges) in the study group than control group according to hyperemia, edema, ecchymosis, discharge, coaptation and total score (p value <0.001). In which REEDA index decreases within examine group compared to control group. Cleocin cream mixture may be safe and effective management for healing of wounds following episiotomy as it was discovered which the utilize of cleocin cream mixture elevated episiotomy wound healing.

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Keywords: Cléocin Cream, episiotomy, wound healing, primiparous females.

1. Introduction

Episiotomy is a natural vaginal delivery intervention that involves a direct incision into the perineal body or posterior vaginal wall to facilitate the 2nd stage of labor in approximately fifteen to ninety-five percent of deliveries [2]. One of the most frequently performed surgical maneuver in the field of obstetrics is episiotomy, which involves the surgical enlargement of the vaginal opening through an incision of the perineum through the last part of the 2nd stage of labor [3]. Episiotomy reduces the

risk of perineal laceration; however, it induces numerous negative impacts, including pain. Pain associated with episiotomy is most severe on the 1st day and can be sufficiently severe to cause disruption the puerperium**.[4]**

The wound healing process is a complicated procedure that involves the replacement of injured tissue with new tissue, which involves tissue reorganization, proliferation, coagulation and inflammation. The wound is cleaned by macrophages phagocytizing infectious debris, which necessitates inflammation. Their absence leads to a delay in the repair of wounds**.[5]**

The process of wound healing following skin injury is complex, requiring numerous overlapping pathways such as tissue remodeling, proliferation, and inflammation [6]. In the first 48 hours after injury, the inflammation phase activates a signaling cascade, resulting in the accumulation of macrophages and neutrophils at the site of wound to stop infection**.[7]**

Antibiotics taken orally are frequently advised for episiotomy wound healing, as topical therapies aren't frequently utilized **.[8]**

Presently, the investigators are focused on the utilization of cost-effective, appropriate, and efficient techniques that are available in health centers, in addition to hospitals, and that are also satisfactory to postpartum women **.[9]**

Cléocin Cream is a formulation which combines twelve naturally driven active ingredients with particle size alteration technology. These ingredients include Dexapanthenol, Shikonin, Niacinamide Horsetail extract, Centella Asiatica, Tea Tree Oil, Horse Chestnut, Calendula, Propolis, Aloe Vera, Licorice, and Chlorhexidine**.[10]**

The objective of this investigation was to study the influence of Cléocin Cream on the recovery of episiotomy wounds**.**

2. Patients and Methods

This case control study has been conducted on 150 primiparous females admitted in the Al Zahraa University Hospitals for normal vaginal delivery and follow up for one month. Patients assigned into two groups: examine group (number = 100) and control group (number 50). The study group used Cléocin ointment every 3 ,4 times for one month after suturing the episiotomy wound. This study was conducted at Obstetrics & Gynecology Department, Faculty of Medicine, Al-Azhar University. (from June 2023to June 2024).

2.1 Inclusion criteria

Approximately twenty to forty years of age, term pregnancy (thirty-seven to forty-two weeks), body mass index (BMI) less than 35, primigravida, no indication for cesarean section, willing to participate in the study and not allergic for Cléocin drugs**.**

2.2 Exclusion criteria

Multiparity, having the history of allergic for Cléocin drugs and indication for cesarean section.

2.3 Latency period

Time from admission till delivery.

2.4 Ethical consideration

An informed consent has been collected from all subjects prior to enrollment in the research. This research has been accepted by the Institutional Review Board (IRB). All procedures were explained for each patient. No conflict of interest. Full case history, general investigation, abdominal examination and local pelvic examination

2.5 Methods:

2.5.1 All patients have been exposed to Full case history, general investigation, abdominal examination and local pelvic examination**.**

2.5.2 Intervention

Patients of both groups were planned for vaginal delivery with episiotomy.

2.5.3 Management of the 2nd stage of labor

When the cervix had completely dilated and the head was at station "0" (the least part of the occiput is at the level of the maternal ischial spines), the case was transferred to the delivery room. They have been positioned to maintain a lithotomy position during uterine contractions and rest among them. The head is delivered slowly and controlled, while the head is maintained in flexion utilizing a modified Ritgen's manoeuvre. The shoulders are delivered one at a time, the anterior first, and the posterior second, by lateral flexion of the body.

2.5.4 Episiotomy

All episiotomies have been carried out as mediolateral procedures at the top of contraction. The muscular layer of the perineum and vaginal mucosa have been closed with a non-locking, loose suture, and the skin has been closed with the same suture (vicryl 0) to approximate the subcutaneous tissue. For the purpose of repair, females have been positioned in the lithotomy position for repair. The same resident obstetricians conducted all of the techniques.

2.5.5 Follow up and assessment of the patients

2.5.6 Reeda Score

It acts as an international index for the assessment of episiotomy wound repair. It is the abbreviation of five criteria (Redness_Edema_Echymosis_discharge__ Approximation of edges) The sum of these is zero to fifteen, with each item containing zero to three points. A wound repair that is more successful is indicated by a lesser index. A greater index is indicative of inadequate wound healing. Each area is given a minimum score of 0 and maximum score of 3

The total score is 15, it is scored as

- No infection means healed wound (0) score.
- mild infection (1_5) score
- moderate infection (6_10) score
- severe infection not healed (11_15) score

REEDA SCALE

Points	Redness	Oedema	Ecchymosis	Discharge	Approximation
0	None	None	None	None	Close
1	Within 0.25 cm of the incision bilaterally	Perineal, less than 1 cm from incision	Within 0.25 cm bilaterally or 0.5 cm unilaterally	Serum	Skin separation 3 mm or less
2	Within 0.5 cm of the incision bilaterally	Perineal and/or between 1 to 2 cm from the incision	Between 0.25 cm to 1 cm bilaterally or between 0.5 to 2 cm unilaterally	Serosan-guinous	Skin and subcutaneous fat separation
3	Beyond 0.5 cm of the incision bilaterally	Perineal and/or vulvar, greater than 2 cm from incision	Greater than 1 cm bilaterally or 2 cm unilaterally	Bloody, purulent	Skin, subcutaneous fat and fascial layer separation
Score					
				Total	

Reeda Scale (Alvarenga et al., 2015) (22).

3. Results

As shown in Table .1 statistically insignificant variance was observed among the examined groups according to gestational age, parity and onset of Labor (P-value higher than 0.05), While statistically significant variance was observed among the examined group according to BMI and age (P-value less than 0.05). As shown in Table .2 statistically insignificant variance was observed among the examined groups according to onset of Labor, cervical dilatation at entrance in the hospital, effacement, station, membrane, position, latency period, type of delivery and baby condition (P value >0.05). As shown in Table .3, there was no statistically significant difference between the studied group according to type of episiotomy wound and presence of infections (P value >0.05), while there was statistically significance difference between the studied group according to associated tears (P value <0.05). As shown in Table .4, statistically insignificant variance was observed among the examined groups according to using additional medications, complications of episiotomy healing and additional surgical interference (P value >0.05), while highly statistically significance difference was observed among the examined group according to application of Cleocin per day (p value <0.001). As shown in Table .5 demonstrates which, highly statistically significant reduction was observed in REEDA index in the examine group compared to control group according to hyperemia, edema, ecchymosis, discharge, coaptation and total score (p value <0.001). In which REEDA index decrease in study group than control group.

Table (1): Correlation between the two standard groups according to demographic data and patient history.

	Examine group (Number= hundred)	**Control group (number = fifty)**	**P value**
Age (year)			
Mean ± SD	21.45±2.38	20.56±2.18	0.028
BMI (Kg/m^2)			
Mean ± SD	24.73±2.94	27.26±2.30	<0.001
Gestational Age (weeks)			
Mean ± SD	38.61±0.68	38.52±0.90	0.495
Parity			
Primigravida	100(100%)	50 (100%)	0.478

P value <0.05 is statistically significant, P value >0.05: Not significant, SD: standard deviation, p<0.001 is highly significant.

Table (2): Correlation among both standard groups according to maternal and neonatal characteristics.

	Examine group (Number= hundred)	**Control group (number = fifty)**	**P value**
cervical dilatation at entrance in the hospital (cm)			
Mean ± SD	7.56±1.50	7.34±1.27	0.375
Effacement (%)			
Mean ± SD	72.6±9.05	70.6±7.93	0.186
station			
-1	12(12%)	3(6%)	0.502
zero	69(69%)	36(72)	
+1	18(18%)	11(22%)	
+2	1(1%)	0(0%)	
Membrane			
intact	70 (70%)	39 (78%)	0.30
ruptured	30 (30%)	11 (22%)	
Position			
OA	80 (80%)	42 (84%)	0.553
OP	20 (20%)	8 (16%)	
latency period (min)			
Mean± SD	144.3±90.34	166.8±57.2	0.110
Baby condition			
living	100 (100%)	50 (50%)	1

OA: occiput anterior, OP: occiput posterior

Table (3): Correlation among both standard groups according to tears, infection and episiotomy wound

	Examine group (Number= hundred)	**Control group (number = fifty)**	**P value**
Type of episiotomy wound			
Routine episiotomy does not tear	100 (100%)	50 (50%)	1
Associated tears			
vaginal tear	8 (8%)	0 (0%)	0.02
cervical tears	5 (5%)	0 (0%)	
No tear	87 (87%)	50 (100%)	
presence of infections			
Vaginal infection	23 (23%)	10 (20%)	0.675
No infection	77 (77%)	40 (80%)	

Table (4): Correlation between the two standard groups according to the Application of Cleocin, additional medications, Complications and surgical interference.

	Examine group (Number= hundred)	**Control group (number = fifty)**	**P value**
Application of Cleocin per day			
3 per day	100 (100%)	0 (0%)	<0.001
Using additional medications			
oral antibiotics	100 (100%)	50 (50%)	1
Complications of episiotomy healing			
No	100 (100%)	50 (50%)	1

P value >0.05: Not significant, P value <0.05 is statistically significant, p<0.001 is highly significant., SD: standard deviation.

Table (5): Correlation among both standard groups according to REEDA index.

	Examine group (Number= hundred)	Control group (number = fifty)	P value
REEDA index			
Redness in cm			
Mean± SD	0.27± 0.44	1.3± 1.05	<0.001
Edema in cm			
Mean± SD	0.08± 0.27	1.14± 1.06	<0.001
Ecchymosis in cm			
Mean± SD	0	0.62± 0.77	<0.001
Discharge			
Mean± SD	0.06± 0.27	0.94± 1.09	<0.001
Approximation of edges in mm			
Mean± SD	0.13± 0.41	1±1.16	<0.001
Score			
Mean± SD	0.42±0.63	5.06±4.56	<0.001

4. Discussion

Episiotomy is a surgery conducted to enlarge the vaginal orifice by making an incision in the perineum during the late second stage of labor to facilitate the expulsion of the fetus and reduce grades 3 and 4 perineal tears occurring during the second stage of labor.

The current research revealed that according to general characteristics in the examined groups, statistically insignificant variance was observed among the examined groups according to parity and age of gestation (P value >0.05), While statistically significant variance was observed among the examined group according to BMI (body mass index) and age (P-value less than 0.05).

Our outcomes in accordance with Maternity et al., [11] that aimed to evaluate the efficacy of aloe Vera to be a wound medication on the perineum of postpartum females. There are twenty-five participants (respondents) represent the experimental group. They reported which statistically significant variance was observed among the examined group according to BMI (P-value=0.017) and age (P-value =0.003).

Regarding maternal and neonatal characteristics among the examined groups, we revealed that statistically insignificant variance was observed among the examined group according onset of labor, cervical dilatation at entrance in the hospital, effacement, station, membrane, position, latency period, type of delivery and baby condition (P value >0.05).

Our outcomes agreement with Hadizadeh-Talasaz et al., [12] who discovered which statistically insignificant variance among the examined group according to baby condition (P value >0.05).

Regarding distribution of episiotomy wound, tears and infection between the examined groups, we discovered that statistically insignificant variance was observed among the examined group according to type of episiotomy wound and presence of infections (P value >0.05), while statistically significance variance was observed among the examined group according to associated tears (vaginal tear, cervical tears) (P value <0.05).

In the same line, Shahrahmani et al., [13] who aimed to detect the impact of green tea ointment on wound-healing and episiotomy pain. They reported which statistically insignificant variance was observed among the examined group according to Length of episiotomy repair (min) and episiotomy length.

The current research demonstrated that statistically insignificant variance was observed among the examined group according to using additional medications, complications of episiotomy healing and additional surgical interference (P value >0.05), while highly statistically significance variance among the examined group according to application of Cleocin per day (p value <0.001).

Similarly, the present research in agreement with Asgharikhatooni et al., [14] that aimed to studied the efficiency of topical application of Equisetum arvense (Horse Tail) ointment in pain relief after episiotomy, reduction of inflammation and wound healing. They revealed which statistically insignificant variance was observed among the examined group according to adverse events during ten Day.

Moreover, Aradmehr et al., [15] who revealed which statistically insignificant variance was observed among the examined group according to lidocaine dose used (ml)

According to follow up and assessment of the patients between the studied groups, our outcomes reported which highly statistically significant decrease was observed in REEDA index in study group compared to control group according to hyperemia, edema, ecchymosis, discharge, coaptation and total score (p value <0.001). In which REEDA index decrease in study group than control group.

Our results in concordance with Eghdampour et al., [16] who found that the mean of REEDA grade five days following

episiotomy was statistically significantly variant among the Aloe vera ointment group and the control group (P-value less than 0.001) among the Calendula and control groups (P-value less than 0.001). The mean of edema grade five days following episiotomy showed a statistically significant variance among the Aloe vera and control groups (P-value =0.004) and the Calendula and control groups (P-value=0.001). There was a statistically significant variance in the mean of Ecchymosis grade among the Aloe vera and control groups five days following episiotomy (P-value =0.009) and among the Calendula and control groups (P-value =0.009).

In dissimilarity with the present investigation, Kazemi et al., [17] that objected to identify the impact of green tea ointment on healing of wound and pain following episiotomy. They stated which the mean episiotomy wound repair scores in the green tea group have been lesser than those in the placebo group 10 days following the intervention (0.22 versus 0.15); nevertheless, statistically insignificant variances were observed. Statistically insignificant variance was observed among both groups in the pre-intervention phase (p = 0.92). Furthermore, comparing with the scores on day five revealed a 0.1 variance among both groups, which statistically insignificant.

The present study demonstrated that REEDA index showed significant positive correlation with presence of infections, while showed no correlation with latency period.

Our outcomes are in accordance with, Mohaghegh et al., [18] who revealed which the mean REEDA score demonstrated a significant and declining pattern over an extended period, suggesting that the wound healing over period.

As well, our outcomes are consistent with Nouh Ibrahim El Galada et al., (2024) (19) who aimed to determine the impact of lavender oil droplets on the intensity of perineal pain and episiotomy wounds healing in primiparous females. They found that regarding the total score of episiotomies healing process, using REEDA, a highly statistically significant variance was observed among both groups according to perineal healing scores (p =0.000) during the 5th postnatal days and after 10th postnatal days (p < 0.0001) which indicate improvement of healing of episiotomy wound

In our study REEDA index showed significant positive correlation with presence of infections, while showed no correlation with latency period as in our study and controlle groups delivered in optimum time.

In disagreement with Yan, Chunmei, Xiaohui et.al (20) who claimed that meta-analysis of 23 randomized controlled trials (8,615 women) showed that shorter latency period was beneficial to both the mother and newborn. However, short latency period in patients with Preterm premature rupture pf membranes between 28 and 34 weeks carries some maternal and neonatal risks with no additional benefits

Also, in disagreement with MEMON, MUHAMMAD HANIF, et al. (21) who claimed that it was noted that prolonged latency duration of >24 hours after Preterm premature rupture of membranes is associated with a considerable increase in adverse neonatal and maternal outcome.

5. Conclusion

Utilization of cleocin cream mixture has been demonstrated to be effective and safe therapy for episiotomy wound healing, as it has been observed to enhance healing of episiotomy wound. Finally, it is necessary to perform additional supplementary investigations with a similar methodology and larger sample size to verify the results of this research.

References

1. International Zeng T, Yuan M, Wu M, Chen Y, Zhang K. Why do pregnant women with fear of birth prefer vaginal birth? A qualitative study in China. *Front Psychol*. 2023; 14:1110116. Published 2023 Feb 23. doi:10.3389/fpsyg.2023.1110116

2. Falagario M, Greco F, De Padova M, Morena MG, Palieri T, D'Antonio F, et al. The Role of Episiotomy in Emergency Delivery. InPractical Guide to Simulation in Delivery Room Emergencies 2023 Jun 14 (pp. 893-914). Cham: Springer International Publishing. DOI: https://doi.org/10.1007/978-3-031-10067-3_59

3. Bohren MA, Tunçalp Ö, Miller S. Transforming intrapartum care: Respectful maternity care. *Best Pract Res Clin Obstet Gynaecol*. 2020; 67:113-126. doi: 10.1016/j.bpobgyn.2020.02.005

4. Fang X, Huan Y, Tao Y, Song Y, Du W, Liu Z et al. Incidence, severity, and determinants of uterine contraction pain after vaginal delivery: a prospective observational study. *Int J Obstet Anesth*. 2021; 46:102961. doi:10.1016/j.ijoa.2021.102961

5. Wilkinson HN, Hardman MJ. Wound healing: cellular mechanisms and pathological outcomes. *Open Biol*. 2020;10(9):200223. doi:10.1098/rsob.200223

6. Čoma M, Fröhlichová L, Urban L, Zajíček R, Urban T, Szabo P. et al. Molecular Changes Underlying Hypertrophic Scarring Following Burns Involve Specific Deregulations at All Wound Healing Stages (Inflammation, Proliferation and Maturation). *Int J Mol Sci*. 2021;22(2):897. Published 2021 Jan 18. doi:10.3390/ijms22020897

7. Komi DEA, Khomtchouk K, Santa Maria PL. A Review of the Contribution of Mast Cells in Wound Healing: Involved Molecular and Cellular Mechanisms. *Clin Rev Allergy Immunol*. 2020;58(3):298-312. doi:10.1007/s12016-019-08729-w

8. Alamri OS. *Incidence of Surgical Site Infections Following Caesarean Section and The Associated Risk Factors at King Abdulaziz University Hospital* (Doctoral dissertation, King Abdulaziz University Jeddah-Saudi Arabia).

9. East CE, Dorward ED, Whale RE, Liu J. Local cooling for relieving pain from perineal trauma sustained during childbirth. *Cochrane Database Syst Rev*. 2020;10(10):CD006304. Published 2020 Oct 9. doi: 10.1002/14651858.CD006304.pub4

10. Leyden JJ, Gans EH. Evaluation of the antimicrobial effects in vivo of Triaz® Gel (benzoyl peroxide special gel), Cleocin-T® Lotion (clindamycin phosphate lotion), and Azelex® Cream (azelaic acid cream) in humans. Journal of dermatological treatment. 1997 Jan 1;8(sup2):S7-10. https://doi.org/10.3109/09546639709160296

11. Maternity D, Dwijayanti R, Susilawati S. Aloe Vera effectiveness for Perineal Wound Healing for Post Partum Mothers. Women, Midwives and Midwifery. 2022 Jun 28;2(2):15-24.

12. Hadizadeh-Talasaz F, Mardani F, Bahri N, Rakhshandeh H, Khajavian N, Taghieh M. Effect of Rosemary Cream on Episiotomy Wound Healing in Primiparous Women: A Randomized Clinical Trial. *BMC Complement Med Ther*. 2022;22(1):226. Published 2022

Aug 26. doi:10.1186/s12906-022-03675-1

13. Shahrahmani H, Kariman N, Jannesari S, Rafieian-Kopaei M, Mirzaei M, Ghalandari S. et al. The effect of green tea ointment on episiotomy pain and wound healing in primiparous women: A randomized, double-blind, placebo-controlled clinical trial. *Phytother Res*. 2018;32(3):522-530. doi:10.1002/ptr.5999

14. Asgharikhatooni A, Bani S, Hasanpoor S, Mohammad Alizade S, Javadzadeh Y. The effect of equisetum arvense (horse tail) ointment on wound healing and pain intensity after episiotomy: a randomized placebo-controlled trial. *Iran Red Crescent Med J*. 2015;17(3):e25637. Published 2015 Mar 31. doi:10.5812/ircmj.25637

15. Aradmehr M, Azhari S, Ahmadi S, Azmoude E. The Effect of Chamomile Cream on Episiotomy Pain in Primiparous Women: A Randomized Clinical Trial. *J Caring Sci*. 2017;6(1):19-28. Published 2017 Mar 1. doi:10.15171/jcs.2017.003

16. Eghdampour F, Jahdie F, Kheyrkhah M, Taghizadeh M, Naghizadeh S, Hagani H. 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. Published 2013 Nov 30. doi:10.5681/jcs.2013.033

17. Kazemi F, Masoumi SZ, Shayan A, Refaei M, Moradkhani S, Firozian F. Effect of green tea ointment on perineal pain and wound healing after episiotomy: A randomized double-blind clinical trial. European Journal of Integrative Medicine. 2021 Jan 1;41:101258. https://doi.org/10.1016/j.eujim.2020.101258

18. Mohaghegh Z, Golfakhrabadi F, Faal Siahkal S, Dastoorpoor M, Abdevand ZZ, Montazeri S et al. The Effect of Malva Sylvestris Cream on Episiotomy Pain and Healing: A Randomized Controlled Clinical Trial. *Int J Community Based Nurs Midwifery*. 2022;10(4):248-258. doi:10.30476/IJCBNM.2022.95772.2082

19. Nouh Ibrahim El Galada H, Aly Mohamed Abd-Elrahman D, Mansour Lamadah S. Effect of Lavender Oil Drops Application on Perineal Pain Intensity and Episiotomy Wound Healing Among Primiparous Women. Alexandria Scientific Nursing Journal. 2024 Mar 1;26(1):75-86. DOI: 10.21608/asalexu.2024.354343

20. Yan, Chunmei, Xiaohui Deng, and Fanzhen Hong. "Analysis of maternal and neonatal outcome of patients with preterm prelabor rupture of membranes." *Journal of Healthcare Engineering* 2022.1 (2022): 8705005.

21. MEMON, MUHAMMAD HANIF, et al. "Adverse Neonatal Outcomes of Prolonged Latency after Premature Rupture of Membranes (PROM)." *Pak Pediatr J* 46.1 (2022): 9-14

22. Polyphenols, flavonoids, and saponins in binahong leaf can accelerate epithelialization of wounds. The first degree of perineal wound in postpartum mothers treated by using binahong leaf extract is recovered for 6 days (Aditia et al., 2017). ...