

The Impact of Aloe vera and Calendula on Perineal Healing after Episiotomy in Primiparous Women: A Randomized Clinical Trial

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ARTICLE INFO	ABSTRACT
<p>Article Type: Original Article</p> <hr/> <p>Article History: Received: 25 Jul. 2012 Accepted: 3 Apr. 2013 ePublished: 30 Nov. 2013</p> <hr/> <p>Keywords: Aloe vera Calendula officinalis Ointment Episiotomy Primiparity</p>	<p>Introduction: Episiotomy is used for enlarging the perineum. Aloe vera and Calendula have been used for treating different diseases from ancient times, limited researches have been done regarding the healing of these plants. Since the effect of their ointment on episiotomy healing has not been studied, this study is being done for determining the impact of Aloe vera and Calendula on episiotomy healing in primiparous women.</p> <p>Methods: This clinical trial involves 111 qualified primiparous women admitted in Lolagar hospital. They were randomly categorized into three groups of control (n=1) and experimental (n=2) groups. The women in experimental group used Aloe vera and Calendula Ointment every 8 hours and the control group used hospital routine on episiotomy for 5 days. The data were collected by demographic questionnaire and redness, edema, ecchymosis, discharge and approximation scale (REEDA) which investigated the episiotomy healing before and five days after intervention in two groups. ANOVA, Tukey test, Kruskal-wallis, Chi-square were used for data analysis.</p> <p>Results: The three groups do not have statistically significant different regarding demographic and other intervening variables. Comparing the mean of REEDA in five days after delivery showed statistically significant difference between control and experimental groups.</p> <p>Conclusion: According to the results, using Aloe vera and Calendula ointment considerably increases the speed of episiotomy wound healing so it can be used for quickening the episiotomy healing.</p>

Introduction

Episiotomy means cutting the perineal muscles during the second stage of labor for enlarging the perineum and prevention from delay in removing the fetus head which is used as an auxiliary method for facilitating the vaginal delivery by Ould in 1743.^{1,2} Routine use of episiotomy was decreased in advanced countries; the women in Asian countries use this method due to having short perineal and stiff tissue prone to wide

laceration.³ Its prevalence in Netherland is 8%, in England is 20%, Argentina is 28%, Australia is 40.6%, USA is 50% and Northern America is 54%. The frequency of using this method in Iran was reported as 97.3% in primiparous women.¹ The smallness of episiotomy cut brings us assume that this operation will not cause problem to the mothers, though this area participates in more ordinary activities such as sitting, walking, standing, squatting and urinating due to the availability of many muscles in the pelvic floor and causes discomfort for

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This research is registered in the Iranian Registry of Clinical Trials with the IRCT38805102248N2 code and derived from MSc thesis in Tehran University of Medical Sciences (No: 438).

postpartum women.⁴ According to results of studies, perineal injury not only causes physical damage but it also causes emotional and psychological harms and delay in wound healing leads to bad anatomic results in perineal and delay in linkage of wound edges and increasing the intensity of pain at perineal area.⁵ Perineal healing is one of the issues which shall be taken into account; in this regard Cavanaugh wrote that "it is necessary that perineal shall be healed as soon as possible. This part cannot be directly observable by mother and leads to increasing the maternal complications.⁶ The delay in perineal healing leads to increasing the complications such as bleeding, pain, pain during intercourse, and anxiety.⁷ Although these problems are not acute or life-threatening, their potential impact on daily function of mother is important.⁴ Episiotomy needs care like any other surgery. Many actions have been proposed for quickening the episiotomy wound healing such as using disinfectant techniques during healing, prevention from unnecessary damage in cutting area such as using round-head needle, stitch yarns with high absorbability and less sensitivity, observing perineum health, keeping dry of wound area, using localized methods such as cold or hot water ischiadic bath including salt, cetrimide and betadine, Kegel exercises, using herbal extracts pads such as lavender, chamomile, fecundity and calendula, etc.⁵ At now, the researchers pay attention to using cheap, effective, proper methods which are accessible in health centers apart from hospitals and meanwhile, being acceptable by postpartum women.⁸ In this regard, complementary medicine including traditional and herbal medicine, homeopathy, and Aromatherapy solutions has special place in promoting the care quality after delivery. Nowadays, using non-traditional or comprehensive treatment methods are increasing and according to world health organization, herbal medicine is part of the complementary medicine which is accepted

by many people of the society and 40% of common drugs are derived from plants and natural resources.⁵ Aloe vera (family Liliaceae) is from the group of flowering plants, monocots and native North Africa and is one of the important medicinal species which is being used for treating many diseases from very ancient times. It has healing, anti-inflammation, analgesic, anti-virus, anti-bacteria, antifungal, purgative, anti-itching and moisturizing.⁹ Aloe vera including collagen increases the tissue granules and is effective in wound healing due to its anti-inflammatory properties. Its anti-inflammatory effects are due to the availability of Salicylic acid which inhibits the formation of Bradykinin and Histamine and due to oxidation of arachidonic acid which inhibits Prostaglandin synthesis.¹⁰ Several researches have been done about studying the effect of Aloe vera on wound healing at other parts of the body. The results of study by Avizhgan *et al.*, about studying the healing effect of Aloe vera gel for treating pressure ulcer indicated that the time need for reducing the redness, inflammation, discharge and the time needed for full wound closure were significant while using Aloe vera gel.¹¹ The study by Tafazolie *et al.*, was done for comparing the impact of Aloe vera Gel and Lanolin ointment on treating the nipple fissure, showed that Aloe vera gel is more effective than Lanolin ointment in treating the nipple fissure.¹² Calendula is the other herb which is used for quickening the wound healing which has anti-inflammatory and anti-inflammation properties, anti-virus, anti microbe and antifungal activity, anti-cancer, anti oxidant and healing function.¹³ Flavonoids and saponins in calendula prevents from releasing of harmful and histamine enzymes which cause sensitivity and inflammation and heal the redness and pain and inhibits plasma discretion to the tissues by decreasing the capillary permeability. Meanwhile, it reduces the immigration of white blood cells to inflamed area. Its anti-inflammatory effects are due to

triterpenoids. In a study on animals, calendula stimulates granulation and increases glycoprotein and collagen.¹⁴ No research was done about studying the healing impact of calendula on the wounds at other parts of the body and no research has been done regarding the studying of the impact of Aloe vera and calendula on episiotomy healing but similar researches were done related to the effects of other medicinal herbs. The results of research by Hur et al., at one of the Korean hospitals regarding the effects of lavender extract on perineal wound healing indicated that lavender quickens the healing of episiotomy cutting.^{14,15} The results of study by Golmakanie et al., in Mashhad Omolbanin hospital indicated that turmeric ointment quickens the episiotomy wound healing.¹⁶ The results of study by Khadivzade et al., regarding the effect of lavender cream on episiotomy wound healing showed that the wound healing at the third days does not have statistically significant difference between the experimental and control group.¹⁷ Since a few researches has been done regarding the effect of Aloe vera and Calendula ointment on episiotomy healing, and the findings regarding the effect of herbal medicine on episiotomy wound are controversial, the current study was done in order to determine the effect of Aloe vera and Calendula ointment on episiotomy wound healing compared to routine of hospital (Betadine).

Materials and methods

This is a clinical blind trial which was done in Tehran Lolagar Hospital from 23 Sept. to 21 Dec. 2010. The sample size was determined based on previous studies, 111 primiparous women referring for labor who were undergone episiotomy were selected. All research units were the same regarding type of episiotomy, quantity of anesthetic solution before section and before regeneration, type of consumed thread, type of regeneration,

and delivery factor. The requirements for entering included insensitivity to special drugs in past, absence of drug addiction and psychotropic drugs, lack of previous damage or surgery record and observable lesions in perineal, lack of preterm rupture of membrane for more than 18 hours, lack of quick or prolonged delivery, perineal anesthesia with Lidocaine 1%, episiotomy section as 45 degree by midwife, lack of volvo and vaginal inflammation at the beginning of research, lack of BMI>35. Having obtained written permission from ethical research committee of the university and having obtained necessary permits from university and authorities of hospital and physician, the researcher started her work to collect data. Having considered the entering requirements and selecting the samples, the researcher introduced herself to the mother. Having got the written letter of consent and explaining the confidentiality of research, the samples were allocated randomly in three groups of using Aloe vera ointment group, Calendula ointment group and control group before delivery. Such that, three first qualified persons were allocated in one of three groups randomly and then the other three persons were allocated in groups, this was done until the number of samples was completed. Then the researcher attended on the patient's bed at the time of labor and after removal of fetus and membrane, the perineal statuses were studied to exclude the sample from study in case of laceration. Episiotomy section was regenerated by the midwife and the mothers were monitored for 4 hours postpartum. A questionnaire including demographic particulars, personal specific- ations, at the postpartum section were completed by the research as the tool for gathering data. The necessary information and data were trained to the mother during and after consumption face to face. A primary assessment for determining the healing was done immediately before intervention with REEDA (Redness, Edema, Ecchymosis, Drainage and Approximation) by the researcher. It shall be

noted that REEDA is a global scale and there is no need for measuring the reliability and validity. Four hours after episiotomy, the intervention was done. The subjects were requested to cleanse the episiotomy with water; the researcher rubbed 3 cc of mentioned ointment for the first time on episiotomy area by disposable glove for training and according to given training, the mother continued using ointment every 8 hours. The control group received the hospital routine as episiotomy cleansing with 2 spoons betadine in 4 glasses of water every 4 hours. The researcher became aware of the manner of using ointment by patients by call. In order to blind the study, the second step of assessing the episiotomy healing was done 5 days after intervention by the trained researcher assistant in the hospital clinic and were registered in appraisal form of REEDA. The questions related to postpartum factors were added to the questionnaire by her. All subjects were given a card on which group's code and date of referring for mother's reminding and researcher's Tel was registered, so that the researcher assistant could assess the episiotomy healing without prior awareness and could record it. Although the results of researches have not reported any problem related to consumption of Aloe vera or Calendula, the mother is requested to call the researcher if there would be any problem such as sensitivity, infection or other evidences, so that necessary actions were taken. It shall be noted that the primary intervention was done by researcher and further interventions by trained mother. Meanwhile, the mother was trained about observing personal health and manner of filling the form at home. The excluding criteria were non accurate use of Aloe vera and Calendula ointment, sensitivity to desired ointment, non-willingness to continuing the participation in the study, having sexual intercourse in first 5 days after delivery and not referring to the clinic of which 11 were excluded due to inaccurate use of ointment and 9 due to not referring to

clinic and the qualified samples which were considered on statistical analysis were replaced. SPSS ver. 13 was used for analyzing the data by independent Anova, t-test, Chi-square and Kruskal-Wallis. It shall be noted that the ethical considerations in this study includes the following: the permission for giving up the research subjects at any phase of research, being confident of the confidentiality of all the data of research units, informing the subjects to disrupt using the drug in case of any sensitivity or inflammation at perineal area and to inform the researcher to refer to the specialized physician. Full observing the ethics and trusteeship from other researches and resources by the researcher, observing the contents related to Helsinki convention in the research, publishing detailed and real results even reaching to the results which indicated the ineffectiveness of probable complications of ointments and announcing the research results to the authorities of Lolagar Hospital.

Results

The three groups did not significant different in terms of personal information such as age, education, economical status, job experience, episiotomy length, duration of first, second and third stages of labor, number of surface stitches, head circumference of child, postpartum factors such as mother's position during lactation, time of starting daily activities after delivery and BMI of mothers (Table 1)

Comparing the sum of grades resulted from 5 variables of REEDA scale showed that the mean of REEDA scale grade 5 days after intervention which indicated statistically significant difference among three groups ($P < 0.001$). (Table 2)

Tukey test showed that the mean of REEDA grade 5 days after episiotomy has statically significant different between Aloe vera ointment group and control ($P < 0.001$) and between Calendula and control group ($P < 0.001$) but there was not significant

different between Aloe vera and Calendula ointment groups ($P=0.98$).

Studying episiotomy regarding redness 5 days after intervention showed statistically significant difference among three groups ($P=0.002$). Tukey test showed that the mean grade of redness 5 days after episiotomy had statistically significant difference between Aloe vera ointment and control group ($P=0.006$) and between Calendula ointment and control group ($P=0.016$). There was no significant difference between Aloe vera and Calendula ointment groups ($P=0.94$). Studying edema of episiotomy area 5 days after intervention showed that edema grade in experimental group was lower than control group and the three groups has statistically significant difference ($P=0.003$). Tukey test showed that the mean of edema grade 5 days after episiotomy had statistically significant difference between Aloe vera and control group ($P=0.004$), between Calendula and control group ($P=0.001$). There was not statistically significant difference between Aloe vera and Calendula groups ($P=0.88$). Tukey test showed that the mean of Ecchymosis grade 5 days after episiotomy

had statistically significant difference between Aloe vera and control group ($P=0.009$), between Calendula and control group ($P=0.009$). There was not statistically significant difference between Aloe vera and Calendula groups ($P=0.94$). Studying ecchymosis of wound 5 days after intervention showed that the three groups had statistically significant difference ($P=0.005$). Studying discharge of wound 5 days after intervention showed that the three groups did not have different and did not have statistically significant difference among three groups and also between two experimental groups ($P=0.13$). Studying the approximation showed statistically significant difference among three groups ($P=0.005$). Tukey test showed that the mean of approximation grade 5 days after episiotomy had statistically significant difference between Aloe vera and control group ($P=0.007$), between Calendula and control group ($P=0.04$). There was not statistically significant difference between Aloe Vera and Calendula groups ($P=0.69$) (Table 3).

Table 1: demographic, maternal and neonatal characteristics in 3 groups

Groups variables	Aloe vera (n=37)	Calendula (n=37)	Control group (n=37)	P
age	26.57(5.60)	25.59(4.20)	26.05(5.14)	0.70 ^a
education (diploma)	15(16.3)	20(54.1)	14(37.8)	0.42 ^b
occupation (homemaker)	36(97.3)	35(94.6)	36(97.3)	0.78 ^b
Economical situation (earn equal to spend)	27(73)	27(73)	27(73)	0.98 ^b
BMI	24.39(1.65)	25.56(2.47)	24.92(2.42)	0.13 ^a
Duration of first phase of labor (min)	403.78(85.61)	403.78(85.61)	391.08(90.79)	0.45 ^a
Duration of second phase of labor (min)	61.89(34.98)	52.29(29.52)	58.51(21.66)	0.39 ^a
Duration of third phase of labor (min)	6.57(4.60)	4.08(2.11)	5.44(3.30)	0.16 ^a
Episiotomy length	3.78(0.71)	3.78(0.58)	3.56(0.95)	0.72 ^a
Number of sutures	4.29(0.87)	4.10(0.69)	4.37(0.89)	0.35 ^a
neonatal Head circumference	35.29(0.90)	35.32(0.87)	35.81(0.91)	0.99 ^a
The onset of daily activity after delivery	7.81(3.16)	8.04(3.04)	8.21(2.98)	0.84 ^a
Breastfeeding in sitting position	26(70.3)	28(75.7)	25(67.6)	0.62 ^a

Mean (Standard deviation) for quantitative variables and number (percent) for Qualitative variables. A is sings of use of ANOVA and b is signs of use of Chi-square test

Table2: Mean and Standard deviation REEDA in episiotomy healing before intervention and 5 days after intervention among 3 groups

Time/Group	Aloe vera Mean (SD)	Calendula Mean (SD)	Control Mean (SD)	P
Before intervention	4.32(1.20)	4.40(1.48)	4.32(1.38)	0.939
5 days after intervention	1.62(0.92)	1.67(1.10)	3.48(1.77)	< 0.001

Table3: Mean and Standard deviation Redness, Edema, Ecchymosis, Discharge and Approximation of episiotomy base on REEDA 5 days after intervention in 3 groups

Groups variable	Aloe vera Mean (SD)	Calendula Mean (SD)	Control Mean (SD)	P
Redness	0.59(0.59)	0.64(0.75)	1.10(0.73)	<0.001 ^a
Edema	0.27(0.45)	0.21(0.41)	0.64(0.58)	<0.001 ^b
Ecchymosis	0.18(0.51)	0.18(0.39)	0.59(0.76)	<0.001 ^b
Discharge	-	-	-	0.10 ^c
Approximation	0.45(0.50)	0.56(0.50)	0.86(0.67)	<0.001 ^a

A is signs of use of ANOVA , b is signs of use of Kruskal-Wallis and c is signs of use of Fisher test

Discussion

According to the results of current study, using Aloe vera and Calendula ointment considerable quickens the episiotomy healing 5 days postpartum compared to Betadine. No study has been done regarding the effect of Aloe vera and calendula ointment on episiotomy wound healing but difference studies have been done regarding the effect of herbal plants on episiotomy wound healing. In this regard, Sheykhan *et al.*, conducted a research to study the effect of lavender extract on episiotomy healing and the results indicated that the mean grade of wound healing of samples who used levender extract 5 days after episiotomy were lower than control group ($P < 0.001$) Meanwhile, the study by Malek Pour *et al.*, regarding the effect of Turmeric on episiotomy wound healing is consistent with current study.⁵ The current results are consistent with the results of study by Tork Zahrani aimed at comparing the betadine and water in the process of episiotomy healing. It shall be noted that the control group in the current study used the hospital routine that is betadine. The redness between two groups of using betadine and water was not statistically significant difference. The redness below 3 mm was reported on 46% of betadine group and 60%

of water group. Meanwhile, 5 days postpartum, the edema less than 1 cm was observed in 60% of samples using betadine and 62% of samples using water.¹⁸ Meanwhile, the current study is partially consistent with the study by Golmakanie *et al.*, aimed at studying the effect of turmeric ointment on episiotomy healing. In Golmakanie's study, the mean of redness grade in experimental groups was 1.06 (0.80) and in control group, it was 1.52 (0.76) which showed statistically significant difference. But the mean of edema grade in experimental groups was 0.84 (0.72) and in control group, it was 1.16 (0.73) which did not show statistically significant difference. So this part is not consistence with current study. Meanwhile, none of the samples at the experimental group has ecchymosis at 7 days postpartum. The mean of ecchymosis grade in experimental groups was 0.31 (0.64) and in control group, it was 0.65 (0.79) which showed statistically significant difference. The mean of approximation grade in experimental groups was 0.72 (0.63) and in control group, it was 1.03(0.65) which showed statistically significant difference, so this is consistent with current study.¹⁶ In a study by Vakilian *et al.*, entitled as studying the effect of lavender and betadine on

episiotomy healing, the mean and standard deviation of healing in experimental group was 1.88 (2.66) and in control group it was 3.01 (3.12) which did not show statistically significant difference. The edema grade was reported lower in lavender extract consuming group, the ecchymosis, discharge and approximation grades did not have statistically significant difference between two groups.¹⁹ The reasons for inconsistency of Vakilian et al., research with the current research can be related to the different manner of using Aloe vera ointment, Lavender extract, type of used treatment, difference mechanism of these three herbal plants on wound healing, dosage and time of using medicinal plant, laceration and difference of laceration degree or the availability of infection. The healing is difference in different people and this can be resulted from personal differences, physical status and economical status which can increase or decrease the speed of healing which are considered as the limitation of the research.

Conclusion

Regarding limited studies about the effect of Aloe vera and Calendula ointment on episiotomy healing and controversial results

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from available researches, the researchers propose to do more studies regarding the verification of using these ointment on episiotomy wound healing and regarding the effect of these ointment on quickening the episiotomy healing, and also regarding that none of the mothers has reported auxiliary complication from using the ointments, these ointments are used as promoter of episiotomy healing in primiparous women.

Acknowledgement

All the related expenses were paid by University of Tehran and hereby, the researchers appreciate the research vice-chancellor of the Faculty of Nursing and Midwifery, Barij Essence Pharmacy Company, the professors and reviewers with their great accuracy, the participated mothers and all who assisted us in doing this research.

Ethical issues

None to be declared.

Conflict of interest

The authors declare no conflict of interest in this study.

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