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The Impact of Aloe Vera on Episiotomy Pain and Wound Healing in Primiparous Women

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ABSTRACT

Background: This clinical trial involves 74 qualified primiparous women admitted for labor in Lolagar hospital of Tehran, Iran. They were randomly categorized into two groups: case (Aloe vera ointment) and control groups (usual hospital protocol). **Objective:** Participant's pain recorded using a Visual Analog Scale (VAS) and Redness, Edema, Ecchymosis, Discharge and Approximation Scale (REEDA). **Results:** Pain was evaluated at 4h, 8h, 12h and 5 days following episiotomy and wound healing was evaluated 4h and 5 days after episiotomy. Collected data was analyzed in SPSS 16 using an independent t-test and chi-square. **Conclusion:** There were not statistical differences in pain intensity scores in two groups before intervention ($p \leq 0.58$) and 8 hours ($p \leq 0.69$) after episiotomy. But there were statistical differences in pain intensity score 12 hours and 5 days after episiotomy ($p \leq 0.05$).

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INTRODUCTION

Episiotomy is the most common obstetric operative procedure performing during the second stage of labor for enlarging the vagina to assist childbirth. The first performance was done in 1741 [5, 21]. Considerable variation is found in episiotomy rates, in spite of the fact that its routine use is becoming an increasingly controversial issue; the World Health Organization recommends its limited use in about 10% of normal deliveries. In Brazil, in the last decade, episiotomy was performed in 70% of normal deliveries. In Netherlands, the total intervention rate was 8%, against 14% in England, 50% in the United States of America and 99% in Eastern Europe (Almeida and Riesco 2008). A recent study revealed that episiotomies were performed in 97.3% of 510 primiparous women undergoing vaginal deliveries in Tehran [21]. Rate of episiotomy in the Asian women is more than other ethnicities and that is because of the difference in the anatomy and elasticity of muscles of the pelvic floor [13]. High episiotomy frequencies are often justified as a way to prevent severe perineal lacerations. Certain conditions are mentioned in literature as risk factors for several spontaneous perineal lacerations, such as instrumental delivery (forceps application or vacuum extraction), primiparity, lithotomy position, perineal tissue stiffness, bad adaptation of fetal presentation in the symphysis pubis, anomalous fetal position, fetal macrosomia and rapid fetal delivery [8]. Among the morbidities that are due to episiotomy, some can occur in short term, such as: vaginal bleeding, infection, suture dehiscence and hematoma, and there is a risk of improper wound healing and increasing pain during early puerperium. This can interfere in the breastfeeding process and enhance painful experiences. In long term, dyspareunia, urinary and fecal incontinence and pelvic floor problems can occur [1]. All of these factors have impact on the early maternal-newborn attachment. Perineal pain results from overstretching, edema, and muscle spasm [4]. have been reported as one of the most common causes of maternal morbidities in the puerperal period. The presence of pain entails difficulties to practice motherhood and perform daily activities such as self-care, breastfeeding and newborn care. It also interferes with women's sleep, rest, movements, urination, evacuation and appetite. These difficulties can cause important physical, psychological and emotional problems that cooperate with negative

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delivery experiences [1]. In breastfeeding, pain inhibits the release of oxytocin, the hormone responsible for the ejection reflex (let-down reflex) and production of breast milk. Even when there is a normal production of maternal milk; pain, fatigue and anxiety may impede the delivery of milk to the newborn, increasing maternal anxiety even more and blocking the release of oxytocin [4]. Povidon-iodine is an antiseptic that is widely used in Iran for disinfecting surgical and skin wounds [27], all midwives and obstetricians apply Betadine for postpartum care. To date, no study about Betadine and its side effects has been performed in Iran. In a comparative study of the Betadine and water's effectiveness, no significant difference was found between the two groups in wound healing [29]. Various studies have evidenced that Povidon-iodine does not promote wound healing, and it even impairs wound healing, reduces wound strength or causes skin reactions. Cooper et al. showed that Povidon-iodine with a manner dependent dose can suppress function of fibroblasts and lymphocytes [7]. "The importance of this little operation is out of all proportions for its simplicity" Donald [19]. In patients with episiotomy, it is essential to utilize an appropriate method for management of the perineal suture to reduce the perineal discomfort, promote wound healing and also to protect the stitches against infection and hematoma (Begum 2006). It is a priority for health professionals who attend women in the puerperal period, to identify and value the morbidities deriving from normal delivery, particularly ones relating the presence of pain. Identifying the spontaneous perineal pain and its relieving methods are accomplished to minimize this pain, offering women to experience motherhood in a positive and pleasant way [2]. Various interventions are found to aid pain relief and promote healing process, which include cleanliness, applying ice pack, topical application of dry heat (infrared therapy), sitz bath, performing Kegels' exercise and perineal care with medical plants [18]. Medicinal plants play an important role in pre and postnatal care in many areas of the world [28]. Aloe vera (family: Liliaceae) which has been used in traditional medicine for a long time, is today been using as a medical plant in alternative and complementary medicine. It is one of the most recognizable herbs in the world and the medicinal part of this plant is its succulent leaves. Gel, which is obtained from breaking or slicing its leaf, is the principle part of this plant using in herbal medicine [11]. The gel contains many important nutrients for the body such as amino acids, B vitamins, emollient polysaccharides, glucomannan, Acemannan and etc. The major carbohydrate fraction in the gel is a water-soluble long chain mannose polymer which accelerates wound healing, modulates immune function (particularly macrophage activation and production of cytokines) and demonstrates antineoplastic and antiviral effects. The gel also contains bradykininase, an anti-inflammatory, magnesium lactate which helps prevent itching, salicylic acid and other antiprostaglandin compounds which relieve inflammation and pain [17]. Aloe gel appears to increase blood flow to injured cells and enhances collagen deposition and cross-linking in granulation tissue in rat wounds [6]. It significantly increases wound strength and has antioxidant, antibacterial and antifungal activities [23]. Recently, a study demonstrated that aloe vera cream treatment could reduce healing time in patients with burn injury compared to silver cream (Khorasani et al. 2009) and in another study it has been demonstrated that this cream facilitates wound healing in posthemorrhoidectomy patients [15,10]. In experimentally-induced deep burns in guinea pigs and mice, aloe vera killed bacteria and promoted epithelialization significantly better than placebo, and in some cases as well as silver sulfadiazine ointment. In a study of 27 adults with partial thickness burns, those treated with aloe healed an average of six days faster than those treated with Vaseline gauze [12,14]. Only one study has had an opposite effect; that is, aloe-treated surgical wounds healing by secondary intention took longer to heal than comparison wounds. (Schmidt and Greenspoon 1991) In light of the potential uses for *aloe vera* in wound healing, the present clinical study was aimed to examine the effects of Aloe vera ointment versus Betadine on pain relief and wound healing of episiotomy in primiparous women[24].

METHOD AND MATERIALS

This clinical trial was conducted to evaluate the effect of using Aloe vera ointment to relieve episiotomy and perineal discomfort in Iranian primiparous mothers.

Aloe vera 20% ointment was produced by Barij Essence, Phytopharmaceutical Company in Iran

This clinical trial was registered by Iranian Registry of Clinical Trials as code IRCT38805102248N2. Permission to perform the study was granted from the Ethical Committee at Tehran University of Medical Sciences. This clinical trial was carried out in Lolagar Hospital, Tehran, Iran. During a period of three months between August and April 2010, a convenience sample was identified comprising 74 primiparous women included in the study. The eligible samples to be recruited in this study were Primiparous women with singleton pregnancy, who had a gestational age of over 37 weeks with spontaneous vaginal delivery normal labor, underwent the mediolateral episiotomy and had the anesthetic drug of 10 millimeters of 1 % lidocaine and without tearing. Those without any acute and chronic disease or allergy, without history of psychological problems, contextual disease, eclampsia or preeclampsia during pregnancy, premature rupture of membranes for more than 24 h, problems with physical complications that have impact on the recovery of perineum such as malnutrition, anemia and diabetes mellitus. The exclusion was applied with those who had such complications during ante partum, intra partum and post partum or had a vaginal infection before delivery or those who had a

serious trauma at the perineum as judged by an obstetrician. The cases with following criteria were also excluded and they were those with vulvo vaginitis or hematoma in the perineum occurring up to 12 h after delivery, those who needed obstetrics tool assistance, those who had prolonged 1st, 2nd and 3rd stage of labor, and those with obstetric complications such as postpartum hemorrhage and manual removal of placenta. Written informed consent was signed by all the individuals.

By using a table of random numbers, all 74 subjects were randomly allocated to one of two treatment groups. Subjects in control group were asked to follow a usual hospital routine program of taking 30 min warm sitz baths (+10 ml betadine 10% per 4 L of water) twice a day for 5 days. The case group received Aloe vera ointment (3ml= 60ml/gr) three times a day for 5 days. Episiotomy pain and discomfort were respectively assessed by Visual Analogue Scale (VAS) and REEDA (Redness, Edema, Ecchymosis, Discharge and Approximation) Scales. Pain intensity and discomfort assessment were completed before intervention and in the first 4 hours following to provide a base line assessment of pain and subsequent pain relief. Ratings were repeated at 8 h, 12 h and 5 days post- episiotomy. Wound healing was also recorded using the REEDA scale 5 days after episiotomy. All analgesics used by subjects were recorded. Participants in both groups were routinely allowed to take Mefnamic acid capsules three times during the first 12 h following episiotomy and also were allowed to take analgesic consumption appeared elevated. Two groups were asked to refer to Lolagar hospital for evaluating pain and healing episiotomy line on the 5th day postpartum. Each woman recruited was given a green card labeled "A" or "B", indicates control and case group. Blind examination was performed by a midwife taught how to evaluate episiotomy healing and pain in 5th day postpartum. Subjects were excluded from the study. Individuals who failed to attend for examination or presented with any signs of infection or allergic reaction were similarly excluded from the study. Data analysis was done by SPSS software version 16.00 for Windows, The pain scores and REEDA score in each trial arm were compared using the unpaired T- test and χ^2 95 percent confidence intervals. The use of analgesics by women was compared by using the Chi-square test and 95 percent confidence intervals. The significance level was set at 0.05 (α 0.05).

Results:

The results indicated that there was no significant difference between both groups in terms of demographic information such as age, education, economical status, job experience. There were also no significant differences between obstetric and neonatal factors including: length of episiotomy wound, duration of each labor stage (first to third), numbers of superficial stitches, mothers body mass index 5days post episiotomy, neonatal head circumference or commencement of breast feeding or re-commencing daily activities after delivery ($p > 0.005$) (Table 1).

Table 1: Demographic information, Obstetrical and post partum factors

Variables(Mean±SD)	Aloe vera group (n=37)	Betadine group (n=37)	P-Value
Age	26.57±5.60	26.05±5.14	0.68
Duration of first labor stage	403.78±85.61	391.08±90.79	0.52
Duration of second labor stage	61.89±34.98	58.51±21.66	0.64
Duration of third labor stage	5.70±5.53	5.44±3.30	0.8
Length of episiotomy	3.78±0.71	3.56±0.95	0.27
Number of superficial stitches	4.29±0.87	4.37±0.89	0.69
Neonatal head circumference	35.29±0.90	35.81±0.91	0.01
Body mass index	24.39±1.65	24.92±2.42	0.28
Not start commencing daily activities 5 days after delivery	7.81±3.16	8.21±2.98	0.57
Variables, Number (%)			
Education(diploma)	15(16.3)	14(37.8)	0.46
Economy status (moderate)	27(73)	27(73)	0.98
Job experience (householder)	36(97.3)	36(97.3)	0.77
Sitting status for brest feeding	26(70.3)	25(67.6)	0.74

No similarities in pain intensity were noted. The mean level for the intensity of the pain was 6.24±1.57 in the Aloe Vera group and 6.02±1.77 in control group. There was no significant difference between two groups ($p=0.58$) at this point.

After intervention the mean for pain intensity at 4 h post-op in the experimental group was 5.27±1.67 and 5.43±1.18 for control group. There was no significant difference between two groups ($p=0.69$) at this point.

Mean levels of pain intensity were 4.13±1.68 in the experimental group and 5.43±1.18 for control group 12 h following episiotomy. This indicated a significant difference between groups ($p=0.04$). Mean levels of pain intensity for the experimental group was 1.86±1.45 versus 3.97±2.19 in the control group 5 days following episiotomy ($p=0.000$).

Table 2: Pain score analysis

	AloeVera group	Betadine group	P-Value
before intervention	6.24±1.57	6.02±1.77	0.58
8 h following episiotomy	5.27±1.67	5.43±1.18	0.69
12 h following episiotomy	4.13±1.68	5.02±2.02	0.04
5 days following episiotomy	1.86±1.45	3.97±2.19	0.000

Moreover, 70.95% of subjects in experimental group had not taken analgesia in contrast to 45.55% of participants in the control group who had not consumed analgesics during four days following episiotomy. This differential use of analgesics between the two groups was significant ($p < 0.05$).

There was significant differences between the mean levels of analgesics in 4 and 5 days after delivery ($p = 0.001$).

There were no statistically significant difference detected in Redness, Edema, Ecchymosis, Discharge and Approximation (REEDA) before intervention (Table3).

Table 3: Comparison of REEDA (Redness, Edema, Ecchmosis, Discharge and Approximation) Scales between control and experimental group pre intervention.

Variables(Mean±SD)	Aloe vera group	Betadine group	P-Value
Redness	1.40±0.76	1.37±0.86	0.91
Edema	1.24±0.59	1.35±0.58	0.75
Ecchmosis	0.40±0.49	0.56±0.89	0.81
Discharge	0.10±0.31	0.13±0.34	0.72
Approximation	1.16±0.37	1.02±0.16	0.15
REEDA score	4.32±1.20	4.32±1.38	0.93

The use of Aloe Vera ointment resulted in statistically significant differences detected by the REEDA scores 5 days after episiotomy, compared with Betadine used by control group. There was no difference detected in discharges between the two groups. However the REEDA (Redness, Edema, Ecchymosis, Discharge and Approximation) scale was significantly lower in the experimental group 5 days after episiotomy ($p = 0.000$) (Table4).

Table 4: Comparison of REEDA (Redness, Edema, Ecchmosis, Discharge and Approximation) Scales between experimental and control group post intervention.

Variables(Mean±SD)	Aloe vera group	Betadine group	P-Value
Redness	0.59±0.59	1.10±0.73	0.002
Edema	0.27±0.45	0.64±0.58	0.003
Ecchmosis	0.18±0.51	0.59±0.76	0.009
Discharge	0.10±0.31	0.27±0.50	0.104
Approximation	0.45±0.50	0.86±0.67	0.005
REEDA score	1.62±0.92	3.48±1.77	0.000

Discussion:

To our best knowledge, this is the first study conducted to determine the efficacy of Aloe vera in pain intensity and wound healing of episiotomy. Existing evidence demonstrates that Aloe vera used in a variety of dosage forms tends to increase the rate of success in healing and the rate of epithelialization. In this study, the use of Aloe vera ointment applied to the episiotomy in first till fifth postpartum days was associated with improved pain relief and wound healing. All three outcome measures (pain score, REEDA score and total number of pain medications) showed significant differences between the experimental and control groups. This study revealed that topical application of Aloe vera ointment is an effective way for pain relieving. Since inflammation is one of the main causes of pain in patients in the early post surgery time [22], the anti-inflammatory effects of Aloe contribute to relieving post operative pain. Aloe has an antimicrobial effect; this effect is related to its constituents including anthraquinones and aloe-emodin [12]. This antimicrobial effect could be contributing to the reduction of pain and promotion of wound healing by Aloe vera [17,20]. In this study the REEDA scores before and after compression found statistical significant differences ($p = 0.000$). These effects might be due to several mechanisms including an Aloe vera contains mannose. Mannose containing products increase macrophage activity and promote wound healing. Stimulation of macrophages will increase cell and tissue growth, fibroblast activity and fibroblast proliferation. Acemannan (mannose-6-phosphate) fits the growth factor receptors on the surface of the fibroblasts, enhancing their activity, stimulating fibroblast-cells which produce collagen fibers to strengthen the new tissue formation that heal wounds. Aloe vera contains Gibberellins (a plant growth hormone) promotes wound healing by increasing protein synthesis by binding to a section of DNA and consequently affecting the copying of DNA so as to make protein [9]. In a study in 2009 topical cream containing Aloe vera decreased postoperative pain and pain on defecation and also enhanced wound healing after hemorrhoidectomy when compared with a placebo cream. The use of postoperative analgesic agents was significantly decreased in the aloe group. There were no side-effects observed related to

aloe cream [10]. A recent review of clinical trials 2007 investigating the effect of Aloe vera on burn wounds found that Aloe vera significantly shortened the wound healing time compared to control, they reported that the mean difference in healing time of the Aloe vera group was 8.79 days shorter than those in the control group [17]. Postpartum patients typically complain of pain unrelated to the episiotomy, such as uterine cramping and back pain. Harrison and Brennan have shown that patients who breast-feed their newborn babies respond less to analgesia than those who do not breast-feed. Although patients may have required additional pain medications for pain unrelated to their episiotomy or laceration, the adequate randomization in our study would have controlled this confounder. Our goal was to study if Aloe vera ointment could be an easy, effective, and self-administered analgesia for the patients in the immediate postpartum period. Based on our findings, Aloe vera ointment is more effective than betadine in relieving episiotomy pain.

Conclusion:

Relieving the perineum with Aloe vera ointment after episiotomy for preventing pain and swelling as well as to ease the discomfort at the perineum is a proper method for practical use. Midwives can help the women in relieving the pains and to speed up the healing after episiotomy. Therefore, use of Aloe vera ointment should be further promoted and implemented as routine use in all women following episiotomy. Future randomized clinical trials with large sample size and careful follow-up with close observation is suggested for more confirmation of our results.

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