

The Effect of *Camellia Sinensis* Ointment on Perineal Wound Healing in Primiparous Women

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ABSTRACT

BACKGROUND AND OBJECTIVE: Delay in recovery of episiotomy can lead to infection and persistence of perineal pain. Perineal pain is a stressful problem for primiparous women and has a negative effect on their function. The present study was conducted to determine the effect of Green tea ointment on the healing process of episiotomy.

METHODS: This three-blind clinical trial was conducted on 60 primiparous participated in this research, were divided in two groups: Green tea ointment and placebo ointment. According to the routine of the hospital, 500 mg capsule cephalexin was given to all mothers every six hours for seven days. Mothers used an ointments every 12 hours for a period of ten days in the area of sutures. Wound healing was measured on the fifth and tenth day after delivery using REEDA scale.

FINDINGS: There was no significant difference in demographic features and obstetric variables (for example age and weight newborn). Before the intervention, two groups did not have a significant difference in score of the perineal evaluation scale ($p=0.475$). The average of this scale on the fifth day in the green tea group was (1.83 ± 1.147) and in placebo group it was (3.33 ± 1.155) on the 10th day, the average of the perineal evaluation scale was (1.2 ± 0.805) for the green tea group and (2.63 ± 1.066) for the placebo group. The average of REEDA scores on the 5th and 10th day after delivery was significantly different between the two groups ($p<0.00001$)

CONCLUSION: Green tea can improve episiotomy wound healing, due to its healing properties.

KEY WORDS: Episiotomy, Perineum, Wound Healing, *Camellia Sinensis*

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Introduction

Episiotomy means cutting the perineal muscles is the most common surgical intervention at the end of the second stage of labor (1). It was first used in 1742 by Ould to facilitate the process of delivery (2). The episiotomy rate is 62.5% in the United States, 30% in Europe and higher in Latin America (3). In Iran, there is no accurate statistics on the prevalence of episiotomy, but it is common practice in hospitals in Iran (4). In the study of Khajavi Shojae et al., the prevalence was 97.3% in Tehran (5), and 88.7% were reported in Sari (6). One study found that 41% of the cases of episiotomy wounds did not fully recover within three weeks of delivery (7).

Delay in the process of episiotomy wound healing can lead to infection (8). Septic shock with a mortality of 10 to 15 percent and necrotizing fasciitis occur due to infection of episiotomy site despite its rarity [9]. In addition, delay in repairing the perineal ulcer can increase the severity of perineal pain (7). Perineal pain has always been a stressful problem for mothers (10). Initial management of an acute injury can effectively reduce the duration of repair and reconstruction (11). Non-drug therapies, herbal remedies and chemical drugs can be used to improve episiotomy wounds (12). Medicinal plants include lavender (13), olive (14), arabia (15), cinnamon (16) and chamomile (17), chemical drugs including phenytoin (18) normal saline and povidone-iodine could be considered (19). In a review study, a variety of therapeutic and non-therapeutic treatments for the treatment of episiotomy wounds were investigated.

The results of this study showed that although the therapeutic methods have been effective, it is recommended to do further research in order to obtain the appropriate drug with less side effects (12). Today Povidone-iodine is used as an antiseptic for disinfection and wound healing, while according to the investigations it does not have any effect on wound healing, but even results in delay in the inflammatory phase (21, 20). On the other hand, the presence of complications and the high cost of chemical treatments has led to an increase in tendency towards traditional wound healing (22). Today, medicinal plants are better accepted by the public due to their higher immunity and fewer complications (23). Green tea with scientific name of *Camelliasinensis* belongs to the family of *Tiaceae*, which is used as an herb in many Asian countries such as India, China and Thailand (25,24). Green tea contains polyphenols such as flavonol,

flavonoids and phenolic acids. The main ingredient in green tea is Epigallocatechin gallate (26). The results of a study by Yaghmayei et al., that used green tea extract to repair surgical wounds in rats, showed that green tea can accelerate the healing process by reducing the duration of inflammation, improving the reproduction stage and early onset of collagen renewal (27). The results of the study by Asadi et al. indicated that the green tea improves the wound by re-forming the epithelial and its antioxidant activity (28). In a study by Kim et al., the collagen sponge impregnated with epigallocatechin gallate was used for wound healing. The results of this study showed that this compound can improve wound by increasing epithelialization and angiogenesis (29).

A review of previous studies showed that so far no research has been done on the effect of green tea on the improvement of perineal ulcer. Therefore, given the known anti-inflammatory and anti-ulcer effects of green tea, the acceptability of using this plant in the community, its cost and availability, the aim of this study was to determine the effect of green tea ointment on the improvement of perineal ulcer in primiparous women.

Methods

This three-blind clinical trial study with Clinical Trials Control Numbers: IRCT2016011225983N confirmed by the ethics committee of Shahid Beheshti University of Medical Sciences with registration code SBMU2.REC.1394.9 was performed on 60 primiparous women referred to Afzalipour Hospital in Kerman. The sample size was determined 27 individuals in each group using data from a related study (30) with a test power of 90%, type I error of 0.05 and a confidence interval of 0.64 that thirty people were estimated in each group, including 10% sample loss. Data were collected using demographic information form, obstetric specifications, used antibiotic registration form, drug side effects, and health status assessment. To validate these forms, the content validity method was used.

Health assessment form consists of 8 questions in the field of health issues, which was previously used in two studies (31, 14). In this study, the reliability of health status form was confirmed by correlation coefficient of 0.85. Primiparous women aged 18-35 years old, resident of Kerman province, in the case of literacy, gestational age of 42-38 weeks, body mass

index ranging from 19.8 to 30.8, live embryos with cephalic presentation, vaginal delivery with mediolateral episiotomy, newborn weight between 2500-4000 gr, Lack of manual removal of placenta, No water bag rupture for more than 24 hours, without underlying disease, eclampsia, preeclampsia in pregnancy, no interference in progression of labor, no rupture and no auxiliary equipment, no admission of infant or neonatal anomalies, no drug addiction and no psychotropic drugs, no previous history of injury or previous surgery or lesions in the perineum, no hematoma in the episiotomy site, allergic history to topical drugs, constant constipation (according to the patient statement) and absence of chronic diseases were included. Exclusion criteria include reoperation of the perineum after episiotomy repair, no referral to the hospital's clinic on the fifth and tenth day after delivery, having sex during the first ten days after delivery, being allergic to green tea ointment, not using the ointment regularly and according to the order (less than once a day), reluctance to continue to participate in the study, the use of effective drugs for wound healing during the study, severe bleeding during the first 24 hours of labor and episiotomy wound infection. In order to prepare green tea ointment, first hydroalcoholic extract with 70% alcohol was prepared using the massage method (soaking) in the medicinal herbs research center of Shahrekord University of Medical Sciences. For this purpose, 1000 gr green tea were transferred to an Erlenmeyer, and then 2 liters of 70% ethanol was added and was kept in the laboratory temperature.

After 48 hours, the extract was squeezed by filtration to be smooth and compacted until it was completely discharged. These steps were repeated again by adding ethanol to the pulp; then, using a vacuum evaporation unit, the extract was concentrated and volume were supplied to 20 ml. Condensed extract was completely dried at a temperature of 50 ° C, then washed with a spatula and washed in the mortar. At the end, the extract was dissolved in a little distilled water and 1% green tea was prepared with Vaseline and ocersin as the base. Ointments were prepared in 30 g tubes. Ointments are sterilized at the center of atomic energy using gamma rays. The placebo was also made from the same green ointment. The study was performed in the maternity ward of hospital after obtain the necessary permissions. The research goals were submitted to eligible mothers and then the written consent was obtained. Samples were divided into two

groups of green tea ointment and placebo on the basis of Excel software and randomly. The research units were similar in terms of interventional factors such as episiotomy (mediolateral), repair method, type of used thread, amount of anesthetic substance before and after cutting, delivery factor and restorer. After delivery, training was provided to mothers. After two hours of delivery, a baseline assessment of episiotomy wounds was first performed and then the first intervention was done by the mother with the guidance of the researcher. After washing the hands and washing and drying the perineal area, the mothers placed the ointment in a uniform position, about 2 cm on the sutured area, and after 1-2 minutes they used a clean sanitary napkin. This work was continued twice a day, up to ten days after childbirth.

According to the routine of the hospital, 500 mg capsule cephalixin was given to all mothers every six hours for seven days. On the fifth and tenth day after delivery, the mothers referred to the same clinic. The single-use paper ruler was used for evaluating the perineal improvement, and the reliability of the ruler was measured with a non-resistive meter of Italian-made Leica type with a precision of 1 mm. Evaluation of the rate of healing of the perineal wound in the lithotomy position and using the test light was done by the REEDA scale. Perineal improvement control scale (REEDA scale) includes five variables: redness, edema, bruising, wound secretion, and opening of the sides of the wound, which has been used in several studies to investigate the improvement of perineal wound healing (32,33). In this scale each variable has score 0-3. The score for each variable is computed separately. The scores are between 0-15 and the closer score to 15 indicates more traumatic (34). The validity and reliability of this scale have been documented in several studies (14,31).

In the present study, the reliability of the research tool was confirmed by an inter-rater consistency test. For this purpose, at the same time, the form of control of perineal improvement in 10 samples was completed on the fifth day after the birth by a researcher and one colleague who was scientifically aligned with the researcher. The results were compared with Spearman test and correlation coefficient was 0.8. In this study, the drug and placebo study was blinded by the pharmacist; therefore, the researcher and the samples did not know the contents of the pack, and all the evaluations were done by an individual who did not know the type of treatment received by the mothers.

Follow-up dates for the side effects of the drug (sensitivity, infection, severe pain, itching, burn, dryness in the wound area and fever and chills) were completed for the mother. The mother was also asked to contact the researcher if she had any complications. SPSS software version 22 was used to analyze the data. Also, for independent quantitative variables, independent t-test for non-normal quantitative variables, the Mann-Whitney test, for qualitative variables, Chi-square test and Fisher's exact test, and Friedman test was used for the comparison of the intra-group of non-formal quantitative variables. $P < 0.05$ was considered significant.

Results

During the study, 6 persons were excluded. The mean of REEDA scale on the fifth day in the green tea group was (1.1 ± 83.147) and placebo group was (3.1 ± 33.155), which was statistically different between the two groups ($p < 0.0001$). On the 10th day, the average of the perineal evaluation scale in the green tea group was (1.0 ± 20.805) and the placebo group was (2.1 ± 63.066), and there was a significant difference between the two groups in terms of the mean score of REEDA ($p < 0.0001$) (Table 1). On the fifth day, one person in the green tea group was excluded due to non-referral and one person in the placebo group was excluded from the study due to the admission of the newborn. On the fifth and tenth day, two participants were excluded in the group of green tea ointment and

two participants in the placebo group due to lack of regular use of ointments. These individuals were randomly replaced with qualified samples during the sampling process (Fig 1).

Table 1. Comparison of episiotomy wound healing score before intervention, fifth and tenth day after childbirth, in two groups of green tea and placebo in primiparous women

Group Time	Green tea ointment Mean $\pm$ SD	Placebo ointment Mean $\pm$ SD	P-value**
Before intervention	0.53 $\pm$ 0.629	0.4 $\pm$ 0.498	0.475
Fifth day after delivery	1.83 $\pm$ 1.147	3.33 $\pm$ 1.155	<0.0001
Tenth day after delivery	1.2 $\pm$ 0.8	2.63 $\pm$ 1.066	<0.0001
Level of significance*	<0.0001	<0.0001	

* Friedman test, Mann-Whitney test **

The results of this study showed that there was no significant difference between the two groups in terms of demographic characteristics and midwifery characteristics (Table 2 and 3). On the fifth day after delivery, there was no significant difference between the two groups in terms of REEDA variables. On the tenth day after delivery, there was a significant difference between the two groups in terms of inflation ($p < 0.037$) (Table 4).

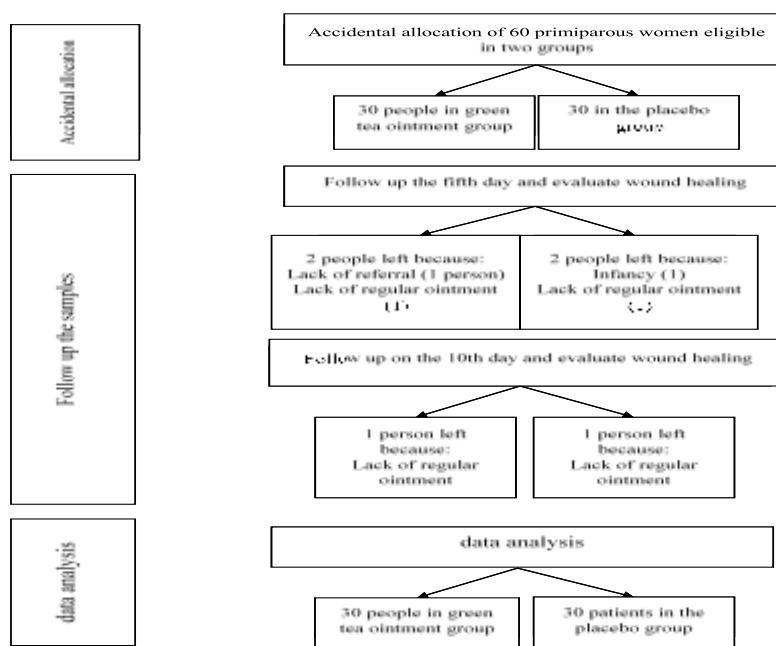


Figure 1. Flowchart of the study process

Table 2. Frequency distribution of personal and midwifery information in primiparous women divided into two groups of green tea and placebo in primiparous women.

Variable	Groups	Green tea ointment	Placebo ointment	P-value
		N(%)	N(%)	
Number of sutures on the skin *	5	17(56.7)	15(50)	*0.605
	6	13(43.3)	15(50)	
Mother education **	Non-academic	26(86.7)	24(80)	*0.641
	Academic	4(13.3)	6(20)	
Mother's job **	Employee	3(10)	4(13.3)	**0.339
	Free	6(20)	2(6.7)	
	housewife	21(70)	24(80)	
Health condition **	Good	7(23.3)	10(33.3)	
	medium	23(76.7)	20(66.7)	

* Chi-square, Fisher's exact **

Table 3. Comparison of individual and midwifery information in nulliparous women divided into two groups of green tea and placebo in primiparous women

Demographic and midwifery characteristics	Green tea ointment				Placebo ointment				P-value
	Mean±SD	Lowest data	Most data	Median	Mean±SD	Lowest data	Most data	Median	
Age*(years)	23.2±3.68	-	-	-	24.27±3.423	-	-	-	*0.25
BMI* (m2kg)	24.999±1.872	-	-	-	24.728±3.423	-	-	-	*0.552
Gestational age* (week)	38.53±1.358	37	41	38	38.37±1.033	37	40	38.5	**1
Birth weight* (gr)	3121.67±307.852	2600	3600	3050	3244.67±300.858	2670	3700	3300	**0.126
Baby head circumference*(cm)	33.8±0.961	31	35	34	34.23±0.858	33	36	34	**0.101
Episiotomy cut length (cm)	3.2833±0.30747	3	4	3.25	3.2833±0.25608	3	3.7	3.45	**0.872
Duration of hospitalization (hours)	12.33±3.863	7	20	11.5	14.17±4.202	7	24	15	**0.07

* Independent T test, ** Man Whitney

Table 4. Comparison and distribution of the variables of the REEDA scale (redness, edema, secretion, bruising and interval of two-edges of the wound) before the intervention, on the fifth and tenth day after delivery, divided into two groups of green tea and placebo in primiparous women

Variable	Group	Green tea	Placebo	P-value*
		N(%)	N(%)	
Redness	Before intervention	2(6.7)	5(16.7)	0.424**
	Fifth day	26(86.7)	27(90)	1**
	Tenth day	28(93.3)	26(86.7)	0.671**
Edema	Before intervention	15(50)	17(56.7)	0.42*
	Fifth day	17(56.7)	21(70)	0.248*
	Tenth day	9(30)	17(56.7)	0.037*
Bruising	Before intervention	0	0	-
	Fifth day	2(6.7)	3(10)	1**
	Tenth day	0	1(3.3)	1**
Secretion	Before intervention	0	0	-
	Fifth day	7(23.3)	3(10)	0.166*
	Tenth day	2(6.7)	6(20)	0.254**
Interval of two-edges of the wound	Before intervention	0	0	-
	Fifth day	8(26.7)	11(36.7)	0.405*
	Tenth day	2(6.7)	6(20)	0.254**

* Chi-square test, ** Fischer's exact test

Discussion

The results of this study showed that green tea ointment is effective in better repair of episiotomy ulcer. A review of the literature found that studies on the effect of green tea on wound healing in human specimens were very limited; therefore, the results of this study were further examined by studies conducted in the laboratory environment. Fuji et al. used green tea and normal saline for one month to treat bed sores and their obtained results showed a significant difference between the two groups in terms of mean scores for the bed sores. Also, the amount of wound infections in the group treated with green tea was lower (35).

The wound infection and the presence of microorganisms at its surface prolong the stage of inflammation and delay the healing process of the wound (36); the results of study of Ashrafpour et al. showed that the leaf extract of green and black tea had antifungal activity, and this effect is dose and time - dependent (37). Therefore, given the known antibacterial and anti-fungal properties of green tea (37, 24), it is possible that green tea can accelerate the wound healing by reducing the amount of wound infection and keeping the wound surface sterilized. The results of the study by Asadi et al., which investigated the effect of green tea extract on the healing process of surgical and burn wounds in rats, showed that green tea ointment accelerated the healing process of the wound (28). The results of this study are in line with the results of this study.

De Almeida Neves et al. in a study entitled "Green tea effects on wound healing" used green tea extract to treat surgical wound, and then examined the rate of edema and tissue formation. The results of this study showed that green tea resulted in wound healing by expediting the formation of epithelium. This study confirms the findings of this study (38). Hajiaghaalipour et al., in a study aimed investigating the effect of green tea extract on surgical wound healing, showed that in the group treated with green tea there is a higher blood vessel formation, more collagen and less inflammation; therefore, green tea is probably effective in wound healing by influencing different phases of the wound healing process, such as inflammatory stage, angiogenesis and proliferation. The results of this study are consistent with the findings of this study (39).

Yaghmayei et al., investigated the effect of hydroalcoholic and aqueous extract of green tea on

surgical wound healing and compared the effect of different doses of these two extracts on surgical wounds in rats. Results showed no significant difference between the two groups in terms of wound healing, but at higher doses restorative effect of green tea is better. The findings of this research confirm the findings of this study (40).

Epigallocatechin gallate is probably the main constituent of green tea. It is effective in increasing angiogenesis. Since wound healing is an angiogenesis-dependent process, it is likely that this mechanism is one of the mechanisms of green tea in the process of wound healing (42,41).

On the other hand, epigallocatechin gallate affects the role of beta-transferin growth factor in fibroblast and the production of collagen gel. This factor is known as an important factor in stimulating fibroblast proliferation, production of collagen, fibroblast differentiation into myofibroblasts and wound contraction (43). Research has shown that green tea polyphenols have antifungal, anti-inflammatory and healing effects (44), and also inhibit collagenase activity against collagen and contribute to collagen stabilization (45), in addition, green tea polyphenols can lead to differentiation and proliferation of epidermal keratinocytes (46). Another prominent mechanism for green tea rejuvenation is the proven anti-inflammatory properties of this plant. Studies have shown that excessive anti-inflammatory response results in tissue damage and poor wound healing, and in fact, better wound repair occurs when there is a balance between inflammatory and anti-inflammatory factors (47).

The other mechanism of green tea in wound healing is probably due to the antioxidant properties of the flavonoid compounds of green tea (48). Free oxygen radicals play important role in wound healing at different stages of wound healing, but high levels of free oxygen radicals result in oxidative stress, cell death, and delayed wound healing (49). In these conditions, antioxidants act to minimize damage (50). Therefore, the role of antioxidants in wound healing is important (51).

Since green tea has anti-oxidant properties, this mechanism is likely to be effective in wound healing. There was no side effect from the use of green tea ointment. The limitation of the present study was the inability to control factors such as nutritional status and physical activity in each person, and tried to control the same education and random selection of

individuals. One of the strengths of the study is to control the intervening factors, follow up by the phone and examine the healing of the wound by one person. The results of this study showed that green tea has been effective in the faster and better improvement of perineal ulcer without causing any side effects. Today, the use of medicinal herbs is cheap and with fewer side effects and more acceptance. In this regard, the results of this study showed that green tea can be effective in repairing episiotomy ulcer; therefore, it can be considered as a wound healing agent. Further studies

are recommended to assess the effects of different doses and possible side effects.

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