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The effect of Achillea millefolium and Hypericum perforatum ointments on episiotomy wound
healing in primiparous women

Running Title: Achillea millefolium and Hypericum perforatum on episiotomy healing.

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Abstract

Background: The purpose of this study was assessed the efficacy of *Achillea millefolium* and *Hypericum perforatum* ointments on episiotomy wound healing in primiparous women.

Materials and Methods: This is double blind clinical trial study that was performed on 140 primiparous women. They were randomly divided into four groups each one containing 35 women: 2 control groups including non-intervention and placebo ointment; and 2 case groups including *Hypericum perforatum* ointment, and *Achillea millefolium* ointment. Healing process was assessed by 5 specifications: redness, ecchymosis, edema, discharge and wound dehiscence at 7th, 10th, and 14th days after delivery, pain level was assessed by means of visual analogue scale.

Results: There was significant difference between groups in perineal pain level at 7th & 10th & 14th, redness and edema at 7th & 10th and ecchymosis at 7th days postpartum, as pain level, redness, edema and ecchymosis in groups who consume *Hypericum perforatum* and *Achillea millefolium* ointments were less than control groups ($P < 0.05$). But discharge and dehiscence incidence showed no significant difference between groups ($P > 0.05$).

Conclusion: *Achillea millefolium* and *Hypericum perforatum* ointments reduce perineal pain level, redness, edema and ecchymosis of episiotomy wound so, it seems that consuming them is useful for episiotomy treatment.

Keywords: *Achillea millefolium*, *Hypericum perforatum*, Episiotomy, primiparous.

Introduction

Episiotomy was performed during vaginal deliveries on 1742 for the first time (1). Although vaginal deliveries accompanied by episiotomy declined between 1992 and 2003, it's still performed during almost 33% of vaginal deliveries. By late 1970s, episiotomy incision commonly was performed for almost all women having they first delivery (2). There are no precise statistics for rate of episiotomy in Iran but, considering high rate of births, it might have high frequency in Iran.

According to the documents available in Mashhad's Ommolbanin Women Hospital, the episiotomy rate in nulliparous women has been 88.32 percent in 2005 (3). In a study conducted by Khajavi-e-Shojaei (2008) on 510 nulliparous women referred to the teaching hospitals in

Tehran, the incidence of episiotomy was estimated 97.3 percent that 32.3 percent was median and 67.7 percent was mediolateral (4). Based on a report by Rasouli , the overall rate of episiotomy in 978 cases of vaginal childbirth in Shahroud /Iran was 41.5%, which is much higher than the standards set by the World Health Organization (WHO). Further research is required to provide appropriate solutions to reduce episiotomy (5).

Wound dehiscence is a serious complication in episiotomy. It has been reported to occur in 0.1 to 2 percent of episiotomies depending on the degree of initial laceration; however, data on the prevalence of third degree rupture are much less than the fourth degree (6). Although after delivery it takes three months or more for this wound to heal, faster wound healing (within two weeks after delivery) has become prevalent and seems to be successful (7). Although episiotomy infection and dehiscence is rare, it is a postpartum important complication. The symptoms of episiotomy wound infection include fever, pain, and purulent discharge that usually occur within 6 to 8 days after delivery (8).

Many measures have been proposed to reduce perineal pain and accelerate wound healing that include: perineal hygiene and washing it regularly, keeping the wound dry, using salt and savlone in washing water, using dry heat by irradiation of infrared light, hot and cold shower, kegel exercises, using pads of plant extracts such as lavender, chamomile, Hypericum perforatum, marigold and so forth (9-16). Hypericum perforatum accelerates wound healing that is probably due to the accelerated proliferative phase of wound healing, migration of fibroblasts and stimulation of collagen synthesis (17).

In general, the diet for 30 days after surgery is different for every individual. Some bodies suggest a high-fiber diet and others believe that osmotic laxatives such as milk of magnesia or lactulose have to be used for 10 days after delivery (18, 19). Using NSAID is recommended to relieve pain. Topical lidocaine ointment after episiotomy is not used routinely, since several studies have shown that using topical analgesics is less effective than placebo (20, 21). The routine use of antibiotic prophylaxis is not recommended after primary repair of the lacerations including 3rd and 4th degree lacerations or episiotomy (8).

In Iranian traditional medicine, hypericum perforatum has been used as anti-depressant, analgesic and diuretic, as well as anti-septic and wound healing (21). From other uses of this plant, treatment of wounds, burns and insect bites can be listed (22). The antibacterial and wound healing effects of hypericum perforatum extract have been shown in many studies. For example, in vitro and in vivo studies showed that hypericum perforatum extract has had more positive effects than sulfonylureas amide against Staphylococcus aureus infection (23). A study in Germany found out that the ointment containing hypericum perforatum extract not only has antiseptic effects, but also can treat burns in a short time (24). Moreover, it has been reported that hypericum perforatum contains hyperforin that has antibacterial effects on Staphylococcus aureus (25).

Achillea millefolium, owing to its diuretic properties, is effective in increasing the volume of urine and kidney stone treatment. This plant has anti-fever properties and its extract or brewed in water or alcohol can heal the wounds and injuries of women's breast skin. Achillea millefolium essence is effective in neuralgia and rheumatic (26). Anti-inflammatory effects of flavonoids in Achillea millefolium is because of its effects on the metabolism of arachidonic acid (27). In a study, it was shown that turmeric cream accelerates episiotomy wound healing, that is, it

accelerates or reduces the improvement of episiotomy incision from 14 days to four days; however, in terms of pain, it does not significantly reduce pain severity (28). In another study, lavender oil significantly decreased the redness and inflammation of wound but, in terms of pain severity, infection level, wound dehiscence and the number of unabsorbed sutures no significant difference was observed between the two groups of this study (29).

In other studies, it was shown that pain severity did not decrease in the first 24 hours of postpartum; however, on the 3rd, 5th and 10th days after surgery, pain severity decreased in the case group and, in terms of wound healing, a significant difference was observed in days 5 and 10 after the delivery (10). In Kafali et al. study, it was found that putting a sponge soaked with bupivacaine in episiotomy wound bed reduces both postpartum pain level and need for analgesic (30). In Abedian et al. study, the results revealed that the use of cooling gel pad can significantly improve wound healing, pain reduction and satisfaction with the treatment (3). Seckin et al., in their study showed that hypericum perforatum ointment, probably by reducing the amount of scar, can decrease the pain of cesarean in the 40th day after the surgery without any major side effect; however, it has had no effect on reducing the pain severity 10 days after the cesarean section (31). As the episiotomy has physiologic, psychologic and social – economic consequences so, not only the decision to do it but also the manner of performance and the quality of future cares, are important. The purpose of this study was assessed the efficacy of *Achillea millefolium* and *Hypericum perforatum* ointments on episiotomy wound healing in primiparous women.

Materials and Methods: This is a double-blind clinical trial study that was performed on 140 primiparous women, neither the subjects nor the researchers know which kind of drugs administered.

Hypericum perforatum and Achillea millefolium plants purchased from medical plants sellers and after proving the identity by medical plants research Center of Shahrekord University of Medical Sciences, each plants made broken separately, then extracted by using Ethanol %90 solution. the acquired hydroalcoholic extracts condensed until became dry and these condensed extracts packed with sterile vaseline as base (%5 weight ratio) in 30gr tubes.

placebo was same vaseline tubes without extract. then, unbeknown to researcher, the same drugs and placebo tubes were coded by chemist advisor master. After obtaining study reference from university vice chancellor for research women qualified for research classified at random in one of the four groups below after they completed letter of satisfaction consciously.

: IRCT:2016072629084

The sample of the study consisted of 140 nulliparous women with the gestational age of 37-42 weeks who have referred to Share-kord Health Center both before and after delivery. They were randomly divided into four groups each one containing 35 women: two control groups including non-intervention group(group D) and placebo ointment group(group C) ; and two case groups including the group of hypericum perforatum ointment(group A) , and the group of Achillea millefolium ointment(group B) . The total number of 140 women enrolled that based on the exclusion criteria 134 subjects remained of whom, 35 subjects were included in the non-intervention group, 34 in the placebo ointment group, 32 in the Achillea millefolium ointment group, and 33 in the hypericum perforatum ointment group.

Inclusion criteria: being nulliparous, gestational age of 37-42 weeks; having a single fetus; no use of particular medications (such as glucocorticoids, anticoagulants, chemotherapy, immunosuppressant, and radiotherapy); no history of the diseases that disrupt wound healing process such as chronic systemic diseases, heart, kidney and lung diseases, coagulation disorder, immune deficiency, connective tissue disorders and diabetes; not having anemia, mental illnesses, persistent constipation and hemorrhoids, hemophilia and malnutrition; no history of allergy to herbal medicines; body mass index of 19.8-26; having no active skin diseases such as allergic disorders, having no wound, skin allergy and symptomatic vaginitis; no use of antibiotics after episiotomy; no history of perineum reconstructive surgery; no history of genital warts.

Exclusion criteria: mismatch between the fetus head and the mother's pelvis in pelvic examination; disorder in the labor progress; manual placenta removal; third and fourth degree perineal rupture; prolonged rupture of membranes (more than 18 hours); abnormal postpartum hemorrhage or hematoma; irregular use of the cream as instructed (less than 7 days or 14 times); and the incidence of itching or skin irritation as the side effects of the ointments.

The procedure was as follows: the patients should first wash and dry perineal area; then, at second day after delivery the patients were asked to rub 1cm of the ointment on the area of episiotomy (the sutures), so that ointment cover all surface of the episiotomy, then a sanitary napkin was used; this was continued twice a day for 10 days. The patient's demographic form was completed at this stage.

All patients were given mediolateral episiotomy and had second degree rupture. In 2 days after delivery, pain level of patients was pursued by phone and characteristics of delivery were registered according to documents existing in the hospital and patients information. In case of any complications, for example allergy to the ointment, after the use, intervention were stopped.

Six criteria were assessed in the subjects: pain severity, redness, edema, ecchymosis, wound dehiscence and wound secretion. To assess pain severity VAS tool was used, hereby, the patients were asked to express the level of episiotomy pain on days 2, 7, 10 and 14 after the labor by a number between 0 and 10. Number zero represented no pain, numbers 1-3 represented mild pain, 4-7 indicated moderate pain, and sever pain was indicated by numbers 8-10. Episiotomy wound healing was evaluated by 5 criteria of redness, edema, ecchymosis, wound dehiscence and wound secretion on day 7, 10 and 14 after the labor, that the levels of redness, edema, and ecchymosis were measured by the researcher in terms of millimeters and were recorded in the control form of perineal repair. The collected data were entered into the SPSS software and were analyzed using descriptive statistics and ANOVA, Kruskal-Wallis test and Fisher exact test. Following Kruskal-Wallis test, DUNN test was used to compare the groups in pairs.

Results:

This study showed no significant difference between the groups in terms of such variables as cases' age, gestational age, pre-pregnancy BMI, birth weight, and the length of the first and second stages of labor (Table1) .

Moreover, in terms of education, 11.2 percent of the subjects had secondary education, 27.6 percent high school education, 41 percent had diploma, and 20.1 percent of the subjects were university educated, that there was no significant difference between the groups in terms of education ($P = 0.98$) (Table 1).

In the event of significant Kruskal-Wallis test, Dunn test is used to check two pairs of groups (Table2) .

In terms of pain severity, there has been no significant difference between two groups 2 days after the labor ($P=0.226$). However, on days 7, 10 and 14 after delivery, a significant difference was observed between the groups ($P<0.05$), so that at the day 7, group A was significantly different from groups C and D ($P<0.001$), and group B from group D ($P<0.05$); at day 10, group A was significantly different from groups B, C and D, and group B was different from group C and D (respectively $P<0.05$ and $P<0.01$); and finally, at the day 14, groups A and B were significantly different from groups C and D. At the mentioned day, A and B groups were not significantly different from each other. ($P>0.05$) (result not shown in tables).

In terms of redness at days 7, 10 and 14, and in terms of ecchymosis at days 7 and 10 after the labor, a significant difference was observed between the groups ($P<0.05$), so that the level of redness at days 7 and 10 was significantly different between groups A and B with groups C and D; at day 14, this difference was significant between groups A and B with group D. Moreover, the level of ecchymosis at day 7 was significantly different between group A with groups C and D, and also between groups B and D. Other pair groups were not significantly different. In spite of significant difference between the groups in terms of ecchymosis at day 10, paired comparison of the groups did not show a significant difference between A and B, and C and D pair groups. In addition, at day 14, ecchymosis was not reported in any groups of the study. Totally In terms of redness at days 7, 10 and 14, and in terms of ecchymosis at days 7 and 10 after the labor, a significant difference was not observed between the groups A and B ($P>0.05$). (result not shown in tables).

In terms of edema at days 7 and 10 after the labor, significant difference between groups was as follows; in both days, group A was significantly different from groups C and D, and group B from group D ($P<0.05$). Other pair groups were not significantly different from each other. At

day 14, the level of edema was not significantly different between the groups. These show that Achillea millefolium and Hypericum perforatum ointments are not more effective in reducing the risk of wound dehiscence. This also shows that Achillea millefolium and Hypericum perforatum ointments cannot effectively decrease the risk of wound secretion. Wound dehiscence and wound secretion were not reported at day 14 in any group of the study. (Table2).

Totally the wound dehiscence percent at 7th day postpartum was 16 () that were reported in the groups (A,B,C,D) respectively 31.3 ,18.8 ,18.8 and 31.3 %.

The wound dehiscence percent at 7th day postpartum was 31.3% in A and D groups and 18.8 % in B and C groups. also at 10th day postpartum, 50% in A and D groups and 0% in B and C groups was reported that shows Hypericum perforatum and Achillea millefolium ointments aren't more efficient at reducing probability of episiotomy wound dehiscence.

the wound discharge at 7th and 10th days postpartum, was reported 14.3 and 20 % in A group, 23.8 and 0% in B group, 28.6 and 40% in C group, 33.3 and 40% in D group, respectively, that shows Hypericum perforatum and Achillea millefolium ointments aren't more efficient also in reducing probability of episiotomy wound discharge. The difference between the groups were not significant by Kruskal-Wallis test. wound dehiscence and discharge at 14th day postpartum wasn't reported in any groups.(Table 3)

Discussion and Conclusion:

Evaluating episiotomy pain was done based on the VAS scale and it was revealed that in terms of pain severity at day 2 after the labor there was no significant difference between the groups. However, at days 7, 10 and 14, a significant difference was observed between the groups ($P < 0.05$), so that the ointments of Achillea millefolium and Hypericum perforatum were more

effective than placebo ointment and non-intervention groups in reducing pain severity, that the findings were in line with the following studies:

In a study, the effects of *Hypericum perforatum* ointment have been evaluated on the pain severity of cesarean wound. In this study, 125 women, who had cesarean section, were divided into three groups of non-intervention, placebo ointment and *Hypericum perforatum* ointment (for 16 days). Pain severity was examined by VAS scale at days 10 and 40 after the cesarean section, and it was revealed that *Hypericum perforatum* ointment can reduce the pain severity of cesarean wound at day 40 (32).

The results of a study, indicated that oral *Hypericum perforatum* extract in mice has an anti-inflammatory effect similar to Indomethacin, and a central and peripheral analgesic effect similar to Pentazocine, which was significantly more than placebo (33).

In the current study, evaluating the indicators of episiotomy improvement including redness, edema, and ecchymosis show that in terms of redness and edema level at days 7 and 10 after the labor and ecchymosis at day 7, all groups are significantly different ($P < 0.05$), so that the levels of redness, edema, and ecchymosis in the case groups have been less than the control group. These findings are consistent with the following studies on the effects of *Hypericum perforatum* and *Achillea millefolium* on wound healing:

A study conducted in Germany found out that the ointment containing *Hypericum perforatum* extract, in addition to antiseptic effects, can treat burns in a short time. According to this report, using this ointment can treat first-degree burns in 48 hours, and second and third degree burns three times faster than the conventional methods (24).

According to a study conducted by Benedek et al. the aerial parts of *Achillea millefolium* plant are rich in flavonoids that have anti-inflammatory properties. Anti-inflammatory effect of this plant's flavonoids is due to its effect on the protease (27).

Evaluating the wounds in terms of dehiscence and secretion showed that no significant difference was between the groups ($P>0.05$), and *Achillea millefolium* and *Hypericum perforatum* ointments have not been more effective than the control groups in reducing the likelihood of wound dehiscence and secretion. Phenolic acids such as caffeic acid and salicylic acid in *Achillea millefolium* also have anti-inflammatory and antimicrobial properties (34, 35).

According to the study of Tajik et al. aqueous and alcoholic extracts of *Achillea millefolium* have antimicrobial effects on pathogenic microorganisms such as *Staphylococcus aureus*, *Escherichia coli* and *Pseudomonas aeruginosa*. Among the studied microorganisms, *Staphylococcus aureus* has the greatest sensitivity to *Achillea millefolium* extract (36).

Aljancic et al. have reported that, in the laboratory level, *Achillea millefolium* has a significant inhibitory effect on *Candida albicans* and *Bacillus subtilis*. Moreover, according to these researchers, flavonoids of *Achillea millefolium* extract have an inhibitory effect on *Aspergillus niger* (37).

At the end, it can be said that perhaps one reason for non-effectiveness of *Achillea millefolium* extract on wound dehiscence and secretion has been the way and amount of prescribing this medicine. The antimicrobial effect of *Achillea millefolium* also maybe has been dose-dependent that suggest the need for more research in this area.

Recommendations:

Considering complementary medicine saves time, energy and expenses of patients, extended studies in the future and administration of various types of Hypericum perforatum and Achillea millefolium herbs is recommended so that the possibility of using this drugs as episiotomy wound healing improver in primiparous women to be posed and more desirable services in order to guarantee health and hygiene of women to be presented.

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Table 1: statistic characteristics of underlying variables in patients in subject groups:

	Statistic index	Groups				P value
		HP(A)	AM (B)	Placebo (C)	No intervention (D)	
		Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
Variables	Patient age	25.1 ± 4.3	25 ± 4	25.2 ± 4	24.8 ± 4	0.997
	Gestational age	39.2 ± 1.4	38.8 ± 1.3	38.9 ± 1.2	38.9 ± 1.3	0.651
	BMI	22.2 ± 1.3	22.7 ± 0.9	22.4 ± 1.2	22.6 ± 1	0.22
	Birth weight	3156.1 ± 252.7	3176.6 ± 251.8	3185.3 ± 231.8	3134.3 ± 254	0.833
	First level duration	7.9 ± 1.2	7.9 ± 1.3	7.8 ± 1.2	7.7 ± 1.1	0.883
	Second level duration	43.6 ± 10.7	41.9 ± 10.5	39.6 ± 9.9	42.6 ± 9.3	0.403

Table 2: assessment of subject variables (pain, redness specifications, ecchymosis and wound edema) of patients in subject groups

		Groups																
		HP (A)				AM (B)				Placebo (C)				No in				
Variables	Statistic index	Min	Max	Media	n	IQR	Min	Max	Media	n	IQR	Min	Max	Media	n	IQR	Min	Max
		Pain level	2th Day	3	10	9		2.5	6	10	9		2	3	10	9		2.5
7th Day	0		7	4		2.5	3	8	6		2	1	9	6.5		3	4	9
10th Day	0		5	2		2.5	0	6	4		2	0	8	5.5		1.25	2	8
14th Day	0		3	0		1	0	5	0		2	0	7	3		4.25	0	7
Redness	7th Day	0	8	3		5	0	15	5		6	0	15	7		3.5	5	15
	10th Day	0	5	0		0	0	8	0		2.5	0	12	4		5	0	12
	14th Day	0	0	0		0	0	5	0		0	0	10	0		0.5	0	10
Eccyhmosis	7th Day	0	3	0		0	0	3	0		0	0	6	0		5	0	7
	10th Day	0	0	0		0	0	0	0		0	0	4	0		0	0	4
Edema	7th Day	0	5	0		4.5	0	10	0		5	0	15	5		5.5	0	15
	10th Day	0	0	0		0	0	5	0		0	0	8	0		1	0	10
	14th Day	0	0	0		0	0	0	0		0	0	4	0		0	0	5

Table 3: Frequency of wound dehiscence and wound discharge in patients in subject groups:

statistic index	Groups				P value
	HP(A)	AM (B)	Placebo (C)	No intervention (D)	

		Count	Percentage	Count	Percentage	Count	Percentage	Count	Percentage		
Variables	Dehiscence	7th Day	5	31.3	3	18.8	3	18.8	5	31.3	0.807
		10th Day	2	50	0	0	0	0	2	50	0.306
	Discharge	7th Day	3	14.3	5	23.8	6	28.6	7	33.3	0.655
		10th Day	1	20	0	0	2	40	2	40	0.755

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