

Effect of Vaginal Cream with the Combination of Honey, Olive, and Propolis on the Symptoms of Uterine Cervicitis Symptoms in Women: A Double-Blind Randomized Controlled Clinical Trial Study

Abstract

Background: Uterine cervicitis in women requires careful selection of a suitable and straightforward treatment. This study aimed to examine the effect of Nika vaginal cream on the symptoms of uterine cervicitis in women. **Materials and Methods:** This double-blind, randomized, controlled clinical study was conducted on 66 women who were referred to Hamadan health centers in 2021 (33 people in each group). The participants in the intervention group were instructed to use Nika vaginal cream every night for 14 nights, along with a single dose of one gram of azithromycin, 400 mg of cefixime, and 500 mg of metronidazole twice a day for both the patient and her husband. The control group received a placebo cream and the same drugs as the intervention group. After the 14-day treatment period, clinical signs were assessed through examinations, and participants completed questionnaires again. **Results:** The study found that participants in the Nika user group experienced a 69.70% improvement in symptoms related to uterine cervicitis. This improvement was significantly higher than the control group, which only showed a 45.50% improvement. Although the Risk Ratio (RR) between the two groups was 53% higher in the intervention group, this difference was not statistically significant ($p=0.06$). However, the Risk Difference (RD) of 0.24 between the groups was found to be statistically significant ($p=0.04$). Additionally, participants in the intervention group reported a 76.00% reduction in dyspareunia ($p=0.03$) and an 84.00% reduction in urinary frequency ($p=0.05$). **Conclusions:** According to the result of RD, Nika vaginal cream had a significant effect on the improvement of cervicitis symptoms.

Keywords: Honey, olea, prodromal symptoms, propolis, uterine cervicitis

Introduction

Uterine cervicitis is the inflammation of the cervix, which can be caused by infections or non-infectious factor. Initially, the endocervical glands are affected, but inflammation can also involve the squamous cells of the ectocervix. This condition can present in acute or chronic forms and may lead to pelvic infections or endometritis.^[1,2] Sexually transmitted diseases such as Chlamydia trachomatis, Neisseria gonorrhea, herpes simplex, Trichomonas vaginalis, and Mycoplasma genitalium can lead to uterine cervicitis, which can be passed on to a sexual partner.^[3] Mucopurulent discharge from the vagina, postcoital bleeding, burning and frequent urination, dyspareunia, and irritation of the vulva and vagina are some of the symptoms of uterine cervicitis.^[4] It can impact the fetus, placenta, and amniotic fluid during pregnancy.

Without proper treatment, these issues may result in pelvic infection, infertility, and ectopic pregnancy.^[5] Ceftriaxone, azithromycin, doxycycline, and acyclovir are among the recommended treatments for this disease.^[6] Due to the recurrence of the disease and resistance to medical treatments, the use of herbal medicines is recommended in treating this disease.^[7]

Nika vaginal cream is a combination of honey, propolis, and olive oil, which has strong antimicrobial, anti-inflammatory, antioxidant, immune system activator, and reparative properties.^[8] Honey contains a variety of enzymatic and non-enzymatic antioxidants, including glucose oxidase, catalase, L-ascorbic acid, flavonoids, phenolic acids, carotenoids, organic acids, amino acids, and proteins.^[9] The antioxidants in honey are highly effective in protecting

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against oxidative damage and preventing the development of chronic diseases.^[10] The osmotic property of honey creates a protective layer between the tissues and the bandage, which prevents pain and re-injury of new cells.^[11] This cream contains honey that, upon contact with the body's moisture, releases an enzyme that effectively eliminates bacteria and other infectious agents in wounds without causing tissue damage. Additionally, the honey accelerates the healing process by absorbing fluids and delivering essential nutrients to the damaged cells.^[12] Olive oil is one of the substances that increase the speed of healing and treating wounds in traditional medicine without knowing its mechanism of action.^[13] Compounds like oleuropein exhibit antioxidant, anti-atherosclerotic, and anti-inflammatory properties.^[14]

Additionally, olive oil is abundant in polyphenols, which help repair cells by eliminating free radicals. Olive oil also helps prevent wounds from drying out. When combined with honey, the anti-inflammatory and antioxidant properties of olive oil work together to reduce inflammation and swelling while also neutralizing free radicals.^[15] Propolis is a natural substance produced by bees using resin from poplar and cone-bearing trees. It is known for its beneficial properties, including anti-cancer, antioxidant, anti-inflammatory, and antibiotic effects against a variety of pathogens such as bacteria, viruses, and fungi.^[16] The propolis in the cream has anti-coagulant and anti-tumor activity in addition to its antiseptic properties. The therapeutic properties of this cream have been proven in treating diabetic foot ulcers, burns, and scars.^[17] In Parsapour's study, Nika vaginal cream was effective in the treatment of vaginal candidiasis.^[8] Our study aimed to investigate the effects of Nika vaginal cream, containing a combination of honey, propolis, and olive oil, on the symptoms of uterine cervicitis in women. This research was motivated by the known antimicrobial properties of these ingredients and the lack of existing studies on their specific effects on this condition. The present study was conducted to investigate the effect of Nika vaginal cream in the treatment of uterine cervicitis.

Materials and Methods

The present study was a double-blind, randomized clinical trial with the code: IRCT20120215009014N383 on 66 eligible women aged 18–44 referred to health centers in Hamadan in 2020–2021. The sample size for each group in the study conducted by NabiMeybodi *et al.*^[18] was determined using Stata-13 software and the Sampsi module. In this study, the test reliability, test power, and the amount of sample loss were 95, 90, and 10%, respectively. The minimum required sample size in each group was then determined to be 33 cases (a total of 66 samples for both groups).

The inclusion criteria included willingness to participate in the project, married women of childbearing age (18–44 years), diagnosed with endocervicitis, lack of recent intake of antibiotics, immunosuppressive drugs, and vaginal medications, over the past two weeks, and further criteria continue with that

they took uterine cervicitis over the past four weeks before the study, had no abnormal uterine bleeding, no pregnancy, no breastfeeding, no frequent vaginal douching, no alcohol consumption, and no particular diseases such as liver and kidney disease, history of cervical dysplasia, known immunodeficiency, and sexually transmitted diseases. The exclusion criteria included drug sensitivity, lack of the medicine intake fully and in the determined period, abnormal Pap test over the past 12 months, intake of any medicine that was effective on the medication taken, and intake of any medicine that was effective on the symptoms treatment of uterine cervicitis.

Sampling began after obtaining a license and receiving an ethics code from Hamadan University of Medical Sciences. The implementation protocol of the research project was then explained to each volunteer. After obtaining permission from Hamadan Health Centers and conducting the necessary coordination, Hamadan was geographically divided into three districts. Using the draws, two health centers were randomly selected from each of the north, center, and south districts. Two clinics were selected from each region. A total of six clinics were randomly selected from comprehensive health centers and assigned to intervention ($n = 33$) and control ($n = 33$) groups. Women who met the eligibility criteria signed a consent form to participate in the study. The allocation sequence was determined through blocked randomization in groups of 4, by an individual unaware of the study details. Based on this sequence, participants were given sealed packets containing either the intervention or control group assignments. The drugs were placed in some opaque closed pockets and numbered according to predetermined sequence. The third author registered and allocated participants to groups. The study was conducted using a double-blind design, where both the participants and outcome assessors were unaware of the allocation. Initially, the medications were categorized and subsequently distributed by an individual who was unaware of the specific types of drugs [Figure 1]. The main researcher was not aware of the allocation of people and the type of drugs used in the two groups. The samples were separated into intervention and control groups, each consisting of 33 individuals.

The gynecologist, with ten years of consistent clinical experience, diagnosed uterine cervicitis in participants showing symptoms such as mucopurulent, vaginal discharge, redness and inflammation, lesions on the cervix, discharge from the internal os of the cervix, erosion of the cervix, or contact bleeding, and included them in the study. In the intervention group, people were asked to apply the 60-gram Nika vaginal cream with a full applicator every night for 14 nights, along with one gram of azithromycin (single dose) + 400 mg of cefixime (single dose) + 500 mg of metronidazole twice a day for seven days for herself and her husband. In the control group, placebo vaginal cream was used accompanied by one gram of azithromycin (single dose) + 400 mg of cefixime (single dose) + 500 mg of metronidazole twice a day for seven days for the patient and her husband.

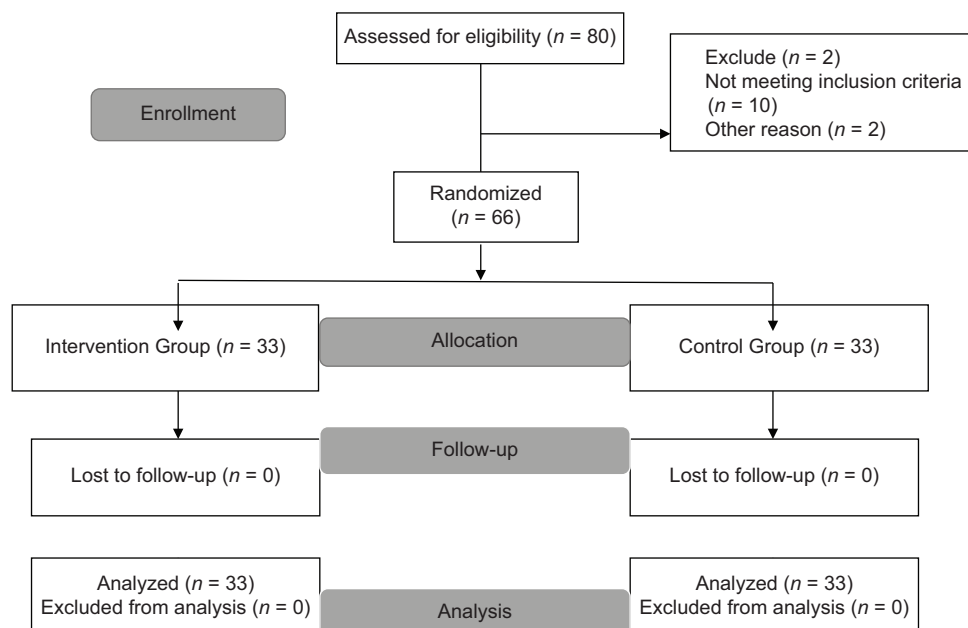


Figure 1: The consort diagram of selecting samples

Nika cream contains olive oil, propolis, and honey and has a license from the Ministry of Health since 2015 with the number: 7177482515095332 and is offered in pharmacies. The cream is made by heating and mixing 100% organic propolis produced by bees with olive oil. The mixture is then cooled and combined with honey and propolis. Olive and Honey Nika cream contains organic ingredients known for their healing properties and is effective in treating various wounds. This product is prepared fresh without the use of solvents. Metals are added within permitted limits, and uric acid is used for standardization.

This study used a placebo to achieve accurate and correct results and create the same conditions for both intervention and control groups. The placebo vaginal cream was made by the Faculty of Pharmacy of Hamadan University of Medical Sciences and is similar to the Nika vaginal cream in terms of color and smell that was given to eligible participants. Both groups of women used vaginal creams for two weeks, applying one applicator every night. The researcher taught the participants how to use the vaginal cream applicator correctly. Correct drug use was monitored weekly by phone. In addition, the researcher's phone number was given to samples to be contacted by the researcher. Individuals in both groups were asked to follow up 14 days after treatment. After 14 days of treatment, a gynecologist assessed clinical signs by examination, and the checklist was completed. The checklist included clinical signs before and after treatment, the type of medication used (yellowish vaginal discharge from the entrance of the cervix, fragile cervix, edematous and inflamed cervix, dyspareunia, etc.). After treatment, both groups showed improvement in uterine cervicitis symptoms such as bleeding after intercourse, spotting during menstrual cycles, green or yellow discharge, dyspareunia, vaginal burning and itching,

frequent urination, and abdominal pain. The reliability of the checklist created by the researchers was assessed by faculty members from the Hamadan School of Nursing and Midwifery. There were no dropouts in either group during the study. The primary focus of the study was the reduction of cervicitis in both groups, with the secondary focus being the decrease in associated symptoms. This study showed all the data as mean and frequency for quantitative and qualitative variables. Initially, the normality of data distribution was evaluated using the Kolmogorov-Smirnov test. Multivariate logistic regression was used to analyze the symptoms of uterine cervicitis with controlling fore before intervention rates. Binomial regression was used to calculate Risk Ratio (RR) and Risk Difference (RD) to evaluate the effect of treatment on uterine cervicitis. A $p \leq 0.05$ was considered statistically significant. Statistical analysis of data was performed using Stata-13.

Ethical considerations

The protocol was approved by the Medical Research Ethics Committee of Hamadan University of Medical Sciences (IR. UMSHA.REC.1399.902). Written informed consent was obtained from all the study participants. The study's objectives and the procedure taken to conduct it were explained to the participants. Moreover, they were reassured about the anonymity and confidentiality of their information and the right to leave the study if they wished so.

Results

A comparison of the two groups in terms of mean age showed that the mean (SD) age of "participants" in the control group was higher than that in the intervention group (35.63(8.23) years and 33.81(10.94) years, respectively). The two groups did not differ significantly in terms of background variables; the results are reported in Table 1.

The binomial regression results showed that the patients with uterine cervicitis had improved after treatment in 69.70% of the intervention group; this was 45.50% in the control group. Therefore, the probability of response to treatment in the group receiving Nika vaginal cream was 53.00% higher than that in the control group, and this difference was not statistically significant ($p = 0.06$). Also, the RD value was equal to 0.24, which was also statistically significant ($p = 0.04$) [Table 2]. The efficacy of Nika vaginal cream was assessed by calculating the Number Needed to Treat (NNT) value, which was determined to be 5. This means that for every five patients with uterine cervicitis treated with Nika vaginal cream, one patient experienced recovery. This highlights the significant impact of the intervention on the recovery of uterine cervicitis.

Multivariate logistic regression was utilized to analyze the symptoms related to uterine cervicitis, including

mucopurulent vaginal discharge, redness and inflammation or lesions on the cervix, discharge from the internal os of the cervix, erosion of the cervix, contact bleeding, and dyspareunia [Table 3]. The effect of these symptoms in the pre-intervention phase was controlled, and the results showed that the chance of emergence of all the mentioned symptoms in the post-intervention phase decreased in the intervention group compared to that in the control group, but this decrease was statistically significant only in the case of dyspareunia and urinary frequency. In the post-intervention phase, the subjects in the intervention group reported 76% less dyspareunia than the control group ($p = 0.03$). This was 84.00% for urinary frequency ($p = 0.05$).

Discussion

The findings of this study showed that treatment with a

Table 1: Comparison of demographic and obstetric information of participants

Variables		Intervention group $n=33$	Control group $n=33$	Statistic	p
Age (year), mean (SD)		33.81 (10.94)	35.63 (8.23)	$t=-0.76$	0.44
BMI, n (%)	≤ 24.99	9 (27.30)	16 (48.50)	$\chi^2=4.99$	0.08
	25–29.99	15 (45.50)	14 (42.40)		
	≤ 30	9 (27.30)	3 (9.10)		
Education, n (%)	Elementary	6 (18.20)	6 (18.20)	–	1.00
	\leq diploma	24 (72.70)	25 (75.80)		
	University	3 (9.10)	2 (6.10)		
Job	Employed	1 (3.00)	3 (9.10)	–	0.61
	Housewife	32 (97.00)	30 (90.90)		
Number of marriages, n (%)	Once	30 (90.90)	32 (97.00)	–	0.61
	Twice	3 (9.10)	1 (3.00)		
Gravida, n (%)	0	4 (12.10)	4 (12.10)	–	1.00
	1	9 (27.30)	8 (24.20)		
	≤ 2	20 (60.60)	21 (63.60)		
PID history, n (%)	Yes	2 (6.10)	0	–	0.49
	No	31 (93.90)	33 (100.00)		
Cervicitis history, n (%)	Yes	7 (21.20)	10 (30.30)	$\chi^2=0.71$	0.39
	No	26 (78.80)	23 (69.70)		
Vaginitis history, n (%)	Yes	31 (93.90)	28 (84.80)	–	0.42
	No	2 (6.10)	5 (15.20)		
Contraceptive methods types, n (%)	Hormonal	1 (3.00)	3 (9.10)	–	0.40
	IUD	7 (21.20)	3 (9.10)		
	Sterilization	4 (12.10)	1 (3.00)		
	Condom	4 (12.10)	7 (21.20)		
	Withdrawal	10 (30.30)	12 (36.40)		
	No method	7 (21.20)	7 (21.20)		
Number of sex during a month, n (%)	No sex	6 (18.20)	5 (15.20)	$\chi^2=0.59$	0.74
	≤ 10	19 (57.60)	22 (66.70)		
	< 10	8 (24.20)	6 (18.20)		

Table 2: Comparison of Uterine cervicitis treatment rates in two groups

Variables		Intervention group $n=33$ n (%)	Control group $n=33$ n (%)	Risk ratio* (95% CI)	Risk difference* (95% CI)
Improvement of uterine cervicitis	Yes	23 (69.70)	15 (45.50)	1.53 (0.99, 2.37)	0.24 (0.01, 0.47)
	No	10 (30.30)	18 (54.50)		

*Binomial regression

combined vaginal cream of honey, olive, propolis (Nika) along with routine treatment, in comparison with placebo cream with routine treatment, was effective in remission and improvement of the uterine cervicitis symptoms such as mucopurulent, vaginal discharge, redness and inflammation or lesion of the cervix and discharge from the internal os of the cervix and erosion of the cervix, and contact bleeding, especially dyspareunia and urinary frequency. Honey, propolis, and olive oil are used in Nika combined cream. Honey probably plays a role in treating inflamed tissues with antibiotic-resistant bacteria.^[19] NabiMeybodi *et al.*^[18] conducted a study using only honey, which was similar to our own study. They concluded that a vaginal product containing flaxseed honey could effectively treat clinical symptoms of uterine cervicitis, regardless of the underlying cause, without causing any severe side effects. The study by Johnston *et al.* showed that honey has antibacterial properties due to its unique compounds and is effective on a wide range of diseases.^[20] The effect of honey on wound healing may be due to the stimulation of inflammatory cytokines that play an essential role in wound healing and tissue repair, as well as reducing the synthesis of E2, F2 α prostaglandins^[21] Taghavian *et al.*^[22] conducted a study similar to ours in terms of methodology and outcomes, revealing that a vaginal gel with propolis extract effectively treats dyspareunia caused by trichinellosis. The study also found no significant gastrointestinal or neurological complications associated with the treatment. Niraldo Paulino, in line with our study, concluded that propolis was effective in treating uterine cervicitis. The anti-inflammatory effect of propolis may be due to inhibiting inducible nitric oxide synthase (iNOS)

gene expression through interference in NF- κ B sites in the iNOS promoter associated with decreased prostaglandin E2 production. These results suggest propolis may be an important new bioproduct during chronic uterine cervicitis.^[23] Propolis also increases the synthesis of type 1 and 3 collagens in damaged tissues.^[24] In the study by Mahishale *et al.*,^[25] which is consistent with our study, olive oil was effective in wound healing. Behmanesh *et al.*^[26] found that incorporating olive oil into postpartum sitz baths can effectively reduce perineal pain and damage following childbirth. Olive oil contains omega 3, 6, and 9 fatty acids, known for their antioxidant, anti-cancer, and restorative properties. These fatty acids are crucial in reducing inflammation and promoting wound healing.^[27] Research suggests that olive oil and its compounds have anti-inflammatory mechanisms that can accelerate the healing process of wounds.^[26]

According to Parsapour *et al.*'s^[8] study, both Nika vaginal cream (containing olive oil, honey, and propolis) and clotrimazole were found to be equally effective in treating candida vaginitis. The study recommended the use of Nika vaginal cream for this condition. According to the results of our study, honey has wound-healing properties, and its simultaneous use with olive oil and propolis has synergistic effects and accelerates wound healing. In the current study, the group that received standard treatment with vaginal cream containing honey, olive oil, and propolis did not experience any significant side effects. This lack of adverse side effects may indicate the cream's high effectiveness. The use of Nika vaginal cream containing the combination of honey, propolis, and olive oil for the treatment of uterine cervicitis is another strength of this study, while other studies have examined each of these compounds alone, and the use of Nika combination cream in the treatment of uterine cervicitis is an innovation. One limitation of the current study was the small sample size, which resulted from challenges in tracking individuals and the project's time constraints. This restricts the ability to generalize the findings to all women. Additionally, despite providing thorough explanations to women on medication administration during patient examinations and follow-ups, there may have been instances of carelessness in following these instructions. Although the study's results demonstrated a significant impact of the intervention, the RR did not reach statistical significance. Therefore, this study is suggested to be repeated with a larger sample size. However, the limitation of our study was the small sample size due to the time limit in sampling, and follow-up of women with VVC was performed for a short time. Accordingly, there is a need for further studies in this field to obtain definitive results regarding the effect of Nika in the treatment of uterine cervicitis.

Conclusion

According to the recovery of uterine cervicitis in one-fifth of women with symptoms, it can be concluded that treatment with Nika vaginal cream containing honey, olives, and

Table 3: Multivariable analyzes of symptoms (mucopurulent vaginal discharge, redness, and inflammation or lesion of the cervix and discharge from the internal os of the cervix and erosion of the cervix, contact bleeding, and dyspareunia) with uterine cervicitis in two groups

Post-intervention stage	Groups	*Odds ratio (95% CI)	Z	p
Spotting	Control	Reference group	-1.04	0.29
	Intervention	0.32 (0.03, 2.74)		
Smelly discharge	Control	ref.	-1.11	0.26
	Intervention	0.51 (0.15, 1.67)		
Dyspareunia	Control	ref.	-2.15	0.03
	Intervention	0.24 (0.06, 0.88)		
Itching	Control	ref.	-0.74	0.46
	Intervention	0.64 (0.19, 2.08)		
Dysuria	Control	ref.	-1.11	0.26
	Intervention	0.33 (0.04, 2.30)		
Urinary frequency	Control	ref.	-1.92	0.05
	Intervention	0.16 (0.02, 1.03)		
Pelvic pain	Control	ref.	-1.53	0.12
	Intervention	0.43 (0.14, 1.26)		

*Adjusted for pre-intervention assessments of the same symptom

propolis, along with routine treatment, was more effective in improving patients with uterine cervicitis and the associated symptoms, especially dyspareunia and urinary frequency, compared to placebo cream accompanied by routine treatment.

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Conflicts of interest

Nothing to declare.

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