Original Article

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Comparison of Vaginal Cream of Coconut Oil and Clotrimazole on Candidal Infection of Vagina

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ABSTRACT

BACKGROUND AND OBJECTIVE: Candidiasis is the second common vaginal infection, and commonly used drugs are azoles. Over-consumption of Azol is associated with resistance to drug and treatment failure. Studies conducted in vitro confirm the antifungal effects of coconut oil. The aim of this study was to compare the effect of vaginal cream of coconut oil and clotrimazole on vaginal candidiasis infection.

METHODS: This clinical trial study was performed on 71 women with Candida infection in two groups receiving vaginal cream of coconut oil: 35(78%) and clotrimazole (36%) (1%) who were treated for 7 nights (one applicator per night). One week after the completion of the treatment, patients were re-examined. Itching, burning, pain and secretion were compared in two groups.

FINDINGS: After the mean intervention (itching in the coconut group was 0±0 and in the clotrimazole group was 19±0.46 (p=0.017), (burning in the coconut group was 0.08±0.20 and in the clotrimazole group was 57% (p=0.046), (secretion in the coconut group was 0.05±0.23 and in the clotrimazole group was 66.6±0.98 (p=0.001) (pain during sex in the coconut group 23 0.05 and 0.30±0.62 in the clotrimazole group (p=0.031). However, the success of the treatment (negative culture) was not significant between the two groups (p<0.05).

CONCLUSION: The present study showed that vaginal cream of coconut oil and clotriamzole both improve vaginal candidiasis infection. Therefore, vaginal cream of coconut oil can be used as an alternative treatment for vaginal candidiasis.

KEY WORDS: *Vaginal Candidiasis, Coconut Oil, Clotrimazole*.

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Introduction

Candida vagina infection is the second most common cause of vaginal infections in women and is diagnosed in more than 40% of women (1). Candida vagina infection is the first cause of vaginal infections in Europe and its second cause in the United States. In the whole world, women of all ages and at any age are infected with candida vagina, and the disease is one of the most important and most recurrent diseases (2). The cost of treatment in the United States is estimated 1 billion dollars a year (3). The prevalence of Candida infection in Iran has been reported between 25% and 45% (4). Although Candida vagina infection does not endanger life, the person suffers from a number of complications (5).

These complications include physical problems, effects on sexual activity and psychological problems, which are a waste of time and cost for treatment and stress in patients (6). Candida albicans are responsible for creating 85-90% of Candida vagina infection. Other Candida species, such as Candida tropicalis and Candida glabrata, which develop symptoms of Candida infection, are usually resistant to treatment (7). Pregnancy, antibiotics, corticosteroids, immunosuppressive diseases and frequent vaginal showers are risk factors for vaginal candidiasis (8). The main symptom of the candidiasis is itching, irritation, or both. Itching may be quite intense in the vulva or vagina, and irritation may be accompanied by burning up and pain during the sex. Vaginal secretion is as crusty cheese or dense and white and abundant and sometimes watery (9).

For the treatment of vaginal candidiasis, the combination of topical azole group, including clotrimazole, is the first line of treatment (10). Painful urination, depression due to systemic absorption, itching, dermatitis, burning and itching in the partner's penis and blood secretion are also side effects of local antifungal drugs (11).

Medicare, consumer and healthcare systems bear cost and their side effects are not low (12). One of the important branches of herbal medicine is the use of medicinal herbs in the treatment of diseases from ancient times, and humans have experienced the beneficial effects of herbs. Also, due to less complications and more adaptation of patients with these drugs, herbal medicine has been considered in recent decades (13). The Cocosnucifera of the palm family, commonly known as coconut, is an important fruit product in tropical countries (14).

Coconut oil compounds include lauric acid, myristic acid and caproic acid, and the antifungal effect of coconut oil is also due to these compounds (15). The laboratory study of Ogbolu et al. and Kannan et al showed the antifungal efficacy of coconut oil. This lab study also showed that coconut oil is cost effective and has no complications (16,17). The Purwanto and colleagues' clinical study that examined the effect of antifungal coconut oil orally on the treatment of vaginal candidiasis was not able to prove the efficacy of this plant (15).

Due to the controversy in the results of laboratory and clinical studies and the emphasis on further studies in this field and the lack of clinical studies on the comparison of the effect of vaginal cream of coconut oil with vaginal cream of the Clotrimazole in the treatment of women with candidiasis of the vagina, given that the coconut The herb has no complications. Also, considering that coconut is planted in southern Iran, the present study was designed to compare vaginal cream of coconut oil with clotriamzole vaginal cream in treatment of women with Candida vagina infection. To this end, a step has been taken to reduce the use of drug therapy for Candida vagina infection, and this will prioritize the use of non-pharmacological methods for the treatment of Candida vagina infection.

Methods

This randomized, controlled clinical trial was approved at the Ethics Committee of Mashhad University of Medical Sciences with the code, IR.MUMS.REC.1395.157, and registered on a clinical trial basis with the code 1N201542521934IRCT. This project was done on 71 subjects (35 women in the vaginal cream of coconut oil group and 36 women in the clotrimazole group) have entry criteria including ages 15 to 45 years, signs and symptoms of Candida vagina infection and positive culture, no antibiotic and antifungal treatment from 14 days before the study, no vaginal drug use for 48 hours before the start of the study, no vaginal shower use or have no sex 24 hours before the study either not taking immunosuppressive drugs, no pregnancy or lactation, no history of repeated candidiasis in the past year, no bleeding of menstruation or abnormal bleeding, no known medical condition, such as diabetes, thyroid problems, anemia and immune system diseases, no use of IUD, as well as the absence of pelvic inflammatory disease, cervicitis, vaginal infection except candida was performed on the examination. The sample size, considering the success variable in the treatment as the main variable, using the formula for comparing two ratios (18) and the rate of

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the first error is 0.05 and the probability of testing is 95% of 32, with a probability drop of sample 20%, 38 women in each group was determined. To calculate p1=0.30 and p2=71/0, a 10-member sample was used as a pilot sample. Patients with informed consent were selected by Convenience Sampling method from gynecologic clinics of Qa'im Hospital and Imam Reza (AS) and Amolbanin (Mashhad) in 1395. Convenience sampling was done and then the research units were randomly assigned to two groups of intervention and control. In order to blindness (patient, researcher (midwife) and statistician) and coding, vaginal cream of coconut oil 78% after the construction in Mashhad Pharmaceutical Faculty evacuate in a similar tube of Clotrimazole1% and separately the code of each drug was determined by the pharmacist.

Demographic and observational data logging was used to collect data. The validity was determined by content validity and reliability with a correlation coefficient r = 0.94. Based on the clinical diagnosis of vaginal candidiasis, which includes vaginal irritation, itching, burning, secretion, and pain during the sex (one to three points in each case), A patient that achieves a minimum score of three is considered clinically infected (19). After selecting the sample and obtaining the informed consent and introducing the researcher and expressing the research goals, the study unit was placed in a lithotomy condition and the wet speculum with normal saline was placed in the vagina without lubricant. Initially, the vagina and cervix were observed in terms of symptoms such as ulcers, redness and secretions were evaluated and according to the examination and clinical signs of other vaginitis and cervicitis was rejected.

Three sterile cotton swabs were sampled from the lateral walls and posterior foreskin vaginal discharge, one of swabs was pulled on a lamella sample and examined for the whiff test. In the laboratory, in the presence of myciliume, and Hypha and Blastospore under the microscope by magnification of 40 was considered to be positive. The second and third swabs were placed in normal saline containers for transfer to culture media. Sample specimens were transferred to the Sabrouraud dextrose agar medium for 48 h at incubator at 37 °C.

After confirming the diagnosis, the patients were asked to take the drug for seven nights each night using an applicator (5 g) in the vagina every night and after finishing the treatment they were asked to refer for examination and re-treatment. Negative culture treatment was considered as success. Statistical analysis was performed using SPSS software version 19 and paired t-test, t-test, Chi-square and Fisher's exact test were done. P<0.05 was considered significant.

Results

Two groups of coconut oil and clotrimazole were homogeneous in terms of age, occupation, education, main complaint, vaginal irritation, itching, burning, secretion and pain during sex at the beginning of the study (Table 1).

Table1. Comparison of demographic characteristics and the main complaint of the disease in two groups of vaginal cream of coconut oil and vaginal cream of clotrimazole

Variable	Group	Coconut oil (n=35) Mean±SD	Clotrimazole (n=36) Mean±SD
Age (Year)		31.48±6.97	32.22±6.84
		N (%)	**N (%)**
Occupation	House keeper	33(94.3)	29(80.6)
	Employed	2(5.7)	7(19.4)
Education	Primary	9(25.7)	6(16.7)
	Elementary	9(25.7)	5(13.9)
	High school	9(25.7)	15(41.7)
	Post graduate	8(22.9)	10(27.8)
Main complaint	Itching	15(42.9)	16(44.4)
	Burning	5(14.3)	8(22.2)
	Vaginal secretion	13(37.1)	11(30.6)
	Others	2(5.7)	1(2.8)

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The mean of itching in the coconut oil group was 1.48±0.98 at the beginning of the study. After intervention, all the units in this group improved in terms of this sign (p<0.001). In the clotrimazole group, the itching decreased from 1.20±0.81 at the beginning of the study to19.0±0.46 at the end of the study (p<0.001). After the intervention, improvement of itching the difference between the two groups of coconut oil and clotrimazole was statistically significant (p=0.017). The mean burning rate in the coconut oil group decreased from 1.82±1.04 at the beginning of the study to 0.08±0.20 at the end of the study (p<0.001) and in the clotrimazole group was 1.50±1.13 at the beginning of the study and 30.0±57.0 at the end of the study (p<0.001). There was a significant difference between the two groups in terms of burning healing (p=0.046). The average secretion level in the coconut oil group, decreased from 2.54±0.61at the beginning of the study to 0.05±0.23 at the end of the study (p<0.001) and in the clotrimazole group was 2.38±0.87 at the beginning of the study and at the end of the study, it was 66.0±0.98 (p<0.001), there was a significant difference between the two groups after the intervention (p=0.001). The mean pain during the sex in the coconut oil group at the beginning of the study was 1.37±1.00 reduced to 0.05±0.23 at the end of the study (p<0.001). In the clotrimazole group, the mean of pain during the sex was 0.88±1.14 at the beginning of the study to 0.39±0.62 at the end of the study (p<0.001), which had a significant difference in pain relief between the two groups after the intervention (p=0.031) (Table 2). However, there was no statistically significant difference between the two groups of coconut oil and clotriamzole in the two signs of vaginal and vulva irritation after intervention.

After treatment, in the coconut oil group, 77.1% and 69.4% of the colostomyosol negative culture for candida showed in vaginal secretions and the difference between the two groups in terms of success therapy (negative result) had no significant (Table 3). Three people in the coconut oil group and two in the clotrimazole group were excluded due to the loss of entry conditions. Also, none of the research units reported a drug side effect.

Table2. Comparison of Candida infection symptoms in two groups of vaginal cream of coconut oil and vaginal cream of clotrimazole

Variable	Group	Coconut oil(n=35) Mean±SD	Clotrimazole (n=36) Mean±SD	T-Test
Vagina irritation	Before treatment	1.11±1.05	0.69±0.95	0.082
	After treatment	0.02±0.16	0.13±0.35	0.096
	Paired t=Test	P<0.001	P<0.001	
Vulva irritation	Before treatment	0.6±0.88	0.47±0.84	0.535
	After treatment	0±0	0.05±0.23	0.160
	Paired t=Test	P<0.001	P=0.004	
Itching	Before treatment	1.48±0.98	1.5±1.08	0.954
	After treatment	0±0	0.19±0.46	0.017
	Paired t=Test	P<0.001	P<0.001	
Burning	Before treatment	1.82±1.04	1.5±1.13	0.208
	After treatment	0.08±0.24	0.3±0.57	0.046
	Paired t=Test	P<0.001	P<0.001	
secretion	Before treatment	2.54±0.61	2.38±0.87	0.391
	After treatment	0.05±0.23	0.66±0.98	0.001
	Paired t=Test	P<0.001	p<0.001	
Pain during the sex	Before treatment	0.37±1	0.88±1.14	0.063
	After treatment	0.05±0.23	0.30±0.62	0.031
	Paired t=Test	P<0.001	P<0.001	

Table3. Distribution frequency of treatment success in two groups of coconut oil and of clotrimazole

Variable	Group	Coconut oil N(%)	Clotrimazole N(%)
The result of the cultures after treatment	Positive	8(22.9)	11(30.6)
	Negative	27(77.1)	25(69.4)
Test	Chi-square		p= 0.65

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Discussion

In this study, the percentage of treatment success (negative result of culturing) in the week after treatment was higher in the coconut oil group than the clotrimazole group, but the therapeutic success between coconut oil group and clotrimazole group was not significant. In a study by Ogbolu, an antifungal effect of coconut oil compared to fluconazole. Antifungal effects of coconut oil have been proven (16).

A laboratory study of Kannan et al., and Mohammed et al., which investigated the effect of coconut oil inhibition on Candida, showed that inhibitory activity was closely related (17). In other laboratory studies, the antifungal effect of coconut has also been proven (15, 20 and 21). In a laboratory study by Singla et al., coconut has been described as an anti-tumor, anti-parasite, antidote, anti-inflammatory, anti-constipation, sexual enhancement, antimicrobial, anti-fever, appetizer and anti-worm (14).

The only clinical trial that was not consistent with our study was Purwanto et al., in which patients with candida infection of the vagina consumed one spoon of coconut oil orally and the control group was without any treatment (20). The reason for the inconsistency of our study with Purwanto et al. is to improve the vaginal candidiasis in oral coconut oil consumption. Also, the number of samples in this research was very low and 10 people. itching, the most common symptom, was not significant in patients with vaginal candidiasis infection between the two treatment groups and the control before treatment, and the two groups were similar in this regard. In the re-evaluation after completing the course of treatment, none of the research units in the intervention group reported itching. However, this symptom after treatment in the clotrimazole group was still present in a number of research units and there was a significant difference in the presence of this sign after completing the course of treatment between the two treatment groups. In the study of Farshbaf et al. and the study of Buitrón et al., the most common symptom was itching (21), which agrees with the findings of this study. In the Adiban Fard et al. study, the most commonly sign was discharge (22) that is not consistent with the present study. In the present study, none of the patients reported a drug complication that is consistent with the study by Adiban Fard et al. (22) and is not consistent with Bahadoran et al. (11).

The limitations of this study are the differences in the immune and physiological system of the studied units. Also, loss of samples and lack of referrals to some of the research units for post-treatment culture was another limitation of our study. Considering that the present study has not been done so far, it is recommended to do similar studies with more samples. According to the results of this study, after treatment, the success of treatment of coconut oil was not only similar to clotrimazole, but also was more effective in many of the symptoms of the disease, and the antifungal properties of coconut oil were proven to be used as an alternative treatment for clotrimazole.

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References

1.Vicariotto F, Del Piano M, Mogna L, Mogna G. Effectiveness of the association of 2 probiotic strains formulated in a slow release vaginal product, in women affected by vulvovaginal candidiasis: a pilot study. J Clin Gastroenterol. 2012;46 Suppl:S73-80.

2.Babic M, Hukic M. Candida albicans and non-albicans species as etiological agent of vaginitis in pregnant and non-pregnant women. Bosn J Basic Med Sci. 2010;10(1):89-97.

3.Foxman B, Muraglia R, Dietz JP, Sobel JD, Wagner J. Prevalence of recurrent vulvovaginal candidiasis in 5 European countries and the United States: results from an internet panel survey. J Low Genit Tract Dis. 2013;17(3):340-5.

4.Akbarzadeh M, Bonyadpoure B, Pacshir K, Mohagheghzadeh A. Causes and clinical symptoms of vaginal candidiasis in patients referring to selective clinics of Shiraz University of Medical Sciences (2009). Arak Med Univ J. 2010;13(3):12-20.

5.Meyer H, Goettlicher S, Mendling W. Stress as a cause of chronic recurrent vulvovaginal candidosis and the effectiveness of the conventional antimycotic therapy. Mycoses. 2006;49(3):202-9.

6.Donders G, Bellen G, Byttebier G, Verguts L, Hinoul P, Walckiers R, et al. Individualized decreasing-dose maintenance fluconazole regimen for recurrent vulvovaginal candidiasis (ReCiDiF trial). Am J Obstet Gynecol. 2008;199(6):613. e1-9.

7.Weissenbacher T, Witkin S, Ledger W, Tolbert V, Gingelmaier A, Scholz C, et al. Relationship between clinical diagnosis of recurrent vulvovaginal candidiasis and detection of Candida species by culture and polymerase chain reaction. Arch Gynecol Obstet. 2009;279(2):125-9.

8.De Seta F, Parazzini F, De Leo R, Banco R, Maso GP, De Santo D, et al. Lactobacillus plantarum P17630 for preventing Candida vaginitis recurrence: a retrospective comparative study. Eur J Obstet, Gynecol Reprod Biol. 2014;182:136-9.

9.Bornstein J, Zarfati D. A universal combination treatment for vaginitis. Gynecol Obstet Invest. 2008;65(3):195-200.

10.Vacheva-Dobrevski R, Kovachev S, Nacheva A, Stoev S, Vasilev N. [Comparative study of itraconazole and fluconazole therapy in vaginal candidosis]. Akush Ginekol (Sofiia). 2004;43(1):20-3.

11.Bahadoran P, Rokni FK, Fahami F. Investigating the therapeutic effect of vaginal cream containing garlic and thyme compared to clotrimazole cream for the treatment of mycotic vaginitis. Iran J Nurs Midwifery Res. 2010;15(Suppl 1):343-9.

12.East CE, Begg L, Henshall NE, Marchant PR, Wallace K. Local cooling for relieving pain from perineal trauma sustained during childbirth. Cochrane Data Syst Rev. 2012;5:Cd006304.

13.Naeini A, Khosravi A, Chitsaz M, Shokri H, Kamlnejad M. Anti-Candida albicans activity of some Iranian plants used in traditional medicine. J Mycol Médicale. 2009;19(3):168-72.

14.Singla RK, Jaiswal N, Bhat V, Jagani H. Antioxidant and antimicrobial activities of Cocos nucifera Linn.(Arecaceae) endocarp extracts. Indo Global J Pharm Sci. 2011;1(4):354-61.

15.Winarsi H, Purwanto A. Virgin Coconut Oil (VCO) Enriched with Zn as Immunostimulator for Vaginal Candidiasis Patient. HAYATI J Biosci. 2008;15(4):135-9.

16.Ogbolu D, Oni A, Daini O, Oloko A. In vitro antimicrobial properties of coconut oil on Candida species in Ibadan, Nigeria. J Med Food. 2007;10(2):384-7.

17.Kannan N, Mohammed A. Comparative evaluation of antifungal activity of cocos nucifera oil against candida albicans. Int J Phytother Res. 2014; 4(2): 23-7.

18.Lachin JM. Introduction to sample size determination and power analysis for clinical trials. Control Clin Trials. 1981;2(2):93-113.

19.Kordi M, Jahangiri N, Rakhshandeh H, Gholami H. Comparison of the effect of Garlic extract vaginal douche and clotrimazol vaginal cream in the treatment of women with vaginal candidiasis. Iran J Obstet Gynecol Infertil. 2005;8(2):33-40.[In Persian]

20.Winarsi H, Hernayanti H, Purwanto A. A Supplement Based on Zn-Enriched Virgin Coconut Oil as an Antifungal agent for Vaginal Candidiasis Patients. Microbiol Indones. 2008; 2(2):69-72.

21.Buitrón García-Figueroa R, Araiza-Santibáñez J, Basurto-Kuba E, Bonifaz-Trujillo A. Candida glabrata: an emergent opportunist in vulvovaginitis. Cir Cir. 2009;77(6):423-7. [Article in English, Spanish]

22.Adiban Fard F, Tork Zahrani S, Akbarzadeh Bagheban A, Mojab F. Therapeutic Effects of Nigella Sativa Linn (Black Cumin) on Candida albicans Vaginitis. Arch Clin Infect Dis. 2015;10(1): e22991.

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