ORIGINAL RESEARCH

The Efficacy of Kundur (*Boswellia serrata* Roxb. Ex Colebr.) in Vulvovaginal Candidiasis: A Randomized Control Trial

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ABSTRACT

Context • Kundur, *Boswellia serrata* Roxb. ex Colebr., is prescribed by Unani (Greco-Arab) scholars clinically under conditions similar to vulvovaginal candidiasis (VVC) and has been supported by recent pharmacological studies, but scientific evidence is scarce.

Objectives • The study intended to investigate the drug's scientific parameters and to compare its efficacy and safety to that of Miconazole nitrate (2% w/w) in treatment of VVC.

Design • The research team designed a randomized controlled trial (RCT).

Setting • The RCT was performed in the Department of Ilmul Qabalat wa Amraze Niswan at Luqman Unani Medical College Hospital and Research Center in Vijaypura, India, between November 2018 and March 2020.

Participants • Participants were 40 married women, aged 18 to 45 years, who had been clinically examined and diagnosed with VVC.

Interventions • Participants were randomly allocated to the *Boswellia serrata* (Kundur) group, the intervention group (n = 20), or to the miconazole group, the control group (n = 20). The Kundur group took a one-gram tablet of Kundur as a vaginal insert every day at bedtime for 21 days, while the control group used vaginal suppositories with 100 mg of miconazole (2% w/w) every day at bedtime for seven days.

Outcome Measures • The primary outcome measures were changes: (1) in vulval itching (pruritus), (2) in vaginal discharge, (3) in painful urination (dysuria), (4) in recurrent genital pain (dyspareunia), and (5) in quality of life (QoL). The secondary outcome measures were mycological clearing on a potassium hydroxide (KOH) test and a per-speculum pelvic examination for the presence or absence of curdy discharge, vulval erythema, and vulval swelling.

Results • The response to the intervention was greater than that of the control in reducing pruritus vulvae and vaginal discharge. However, both drugs were equally effective in improving the rest of the parameters, including QoL.

Conclusion • The VVC symptoms were equally and significantly improved in both the intervention and the control groups, and *Boswellia serrata* Roxb. ex Colebr. was shown to be efficacious in the management of VVC. Further studies with a rigorous design and larger sample size are needed to reinforce scientific evidence. (*Altern Ther Health Med.* [E-pub ahead of print.])

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Vulvovaginal candidiasis (VVC), also called vaginal thrush, is a vulvar and/or intravaginal yeast infection,[1] a type of fungus, that is caused by *Candida* and is characterized: (1) by a white, crumbly, and sticky vaginal discharge; (2) by a vaginal burning sensation; (3) by strong pruritus—an intense itching sensation that produces the urge to rub or scratch the skin to obtain relief; (4) by dysuria—painful urination; and (5) by dyspareunia—recurrent genital pain occurring during, before, or after sexual intercourse. It affects three out of four women of childbearing age at least once during their lives.[2–4]

The most common pathogen is *Candida albicans*, which has been isolated in 85% to 90% of all cases.[5] VVC can be precipitated by antibiotic therapy, pregnancy, oral contraceptive pills, or uncontrolled diabetes.[6,7] Luceine et al found that obesity and insulin resistance were predisposing

factors for recurrent VVC.[8] The most common symptoms of VVC are itching and a thick, homogenous vaginal discharge. These symptoms, together with others, can impair a patient's quality of life (QoL) and can lead to sexual problems and depression.[1,9]

VVC is usually diagnosed based on a patient's medical history, a clinical examination, a vaginal pH test, potassium hydroxide (KOH) test, and an assessment of pseudohyphae using wet-mount slides.[10] Although most cases of VVC are mild, untreated infections can increase the risk of HIV/AIDS and other conditions, such as pelvic inflammatory disease, infertility, ectopic pregnancy, pelvic abscesses, menstrual disorders, spontaneous miscarriages, and premature births.[11]

VVC is usually treated with topical and oral antifungal agents, including miconazole, clotrimazole, butoconazole (topical azole), and fluconazole (oral azole), but recent studies have reported failures in VVC treatment due to antifungal-drug resistance.[9,12] Alternatively, complementary therapies, which have fewer side effects, are better tolerated, and are lower in cost, have been shown to result in better patient compliance.[9]

The Unani system of medicine (USM) is a traditional system of medicine that derives directly from ancient Greek (Yunan) medical practices and is based on the four humors, namely blood, phlegm, yellow bile, and black bile. India is the world leader in the use of the Unani system of medicine, owing to the Government of India's support and funding.[13] USM has made significant contributions to date, with a number of traditional medicinal formulations having been scientifically validated.[14–17]

Regarding VVC, the Unani system of medicine has a large group of therapeutics for conditions clinically similar to it. Kundur, *Boswellia serrata* Roxb. Ex Colebr., is a potent phytomedicine and has been mentioned in Unani texts for its beneficial effects in treating the vaginal yellowish-white discharge (*Sayalan al-Rahim*) that can occur due to different diseases.[18] Some pharmacological studies have found the *Boswellia* species to be effective against *Candida albicans*.[19]

Kundur possesses anti-inflammatory (*Muhallil-i Waram*), hemostyptic (*Habis*), astringent (*Qabiz*), detergent (*Jali*), and antiseptic (*Dafi' Ta'ffun*) properties.[20–22] Reductions in pruritus vulvae, dysuria, and dyspareunia may be due to Kundur's anti-inflammatory, detergent, and antiseptic properties.

Pharmacologically, some studies have reported a nti-inflammatory activity for Kundur, inhibiting the pro-inflammatory mediators—interleukin-1 beta (IL-1β), IL-6, tumor necrosis factor alpha (TNF-α), interferon gamma (IFN-γ), and prostaglandin E_2 (PGE_2)—and inducing anti-inflammatory cytokines—IL-4 and IL-10.[11,23]

Menon et al found analgesic and sedative effects for the nonphenolic fraction of Kundur.[24] Employing a mechanical pain model, Prabhavathi et al found increased pain tolerance for healthy individuals using Kundur, as contrasted to the benefits of a placebo.[25]

In treatment of VVC, an improvement in vulval erythema and swelling after treatment with Kundur might be attributable to its anti-inflammatory properties. Pharmacologically, some studies have reported anti-inflammatory effects for methanolic, frankincense, and ethanolic extracts of Kundur, [26–29] and the effects have been attributed to the boswellic acids inherent in it, mainly acetyl-11-keto-β-boswellic acid (AKBA) and 11-keto-β-boswellic acid (KBA). Safayhi et al found that the AKBA can block leukotriene biosynthesis, employing potent anti-inflammatory effects.[26]

A reduction in the curdy white discharge of VVC might be credited to the hemostyptic and astringent properties of Kundur because it helps in the absorption of excessive, abnormal moistness (*Rutubat*) of the vagina according to Unani scholars.[21,22]

The mycological/pseudohyphae clearing by Kundur might be attributed to its anti-inflammatory and detergent properties, which Mohammadi et al's study has supported, indicating an in-vitro antifungal effect for Kundur's essential oil against fluconazole-resistant *Candida albicans*.[12] *Kundur* has been repeatedly prescribed by Unani practitioners to treat abnormal vaginal discharge.[21,22]

Finally, several preclinical and clinical studies have found a significant amelioration in the physical and mental aspects of QoL, which may be due to the analgesic, anesthetic, and anti-inflammatory activities of Kundur.[23,30]

However, scientific evidence is scarce on the benefits of Kundur in treatment of VVC. The current study intended to investigate Kundur's scientific parameters and to compare its efficacy and safety to that of miconazole nitrate (2% w/w) in treatment of VVC.

METHODS

Participants

The randomized controlled trial was performed in the Department of Ilmul Qabalat wa Amraze Niswan at Luqman Unani Medical College Hospital and Research Center in Vijaypura, India, between November 2018 and March 2020. To facilitate participant recruitment, inclusion and exclusion criteria were pasted in all gynecology and obstetrics (Amraz-e-Niswan wa Qabala) outpatient departments (OPDs). If a patient had relevant clinical characteristics for VVC and was willing to participate in the research study, she was referred to the Research OPD, where the principal investigator conducted a thorough examination and eligibility screening.

Potential participants were included in the study if they: (1) were married women, (2) were aged 18 to 45 years, and (3) had been clinically examined and diagnosed with VVC that had been confirmed by the presence of pseudohyphae on a KOH mount. The study included exclusively married women due to the difficulty of delivering medications to unmarried women and to cultural barriers.

Potential participants were excluded in the study if they: (1) were less than 18 years or more than 45 years of age; (2) were pregnant or lactating mothers; (3) were unmarried women; (4) had concurrent vaginal infections; (5) had been on antifungal, antibiotic, or corticosteroid therapies within the two weeks prior to the study's start; (6) had a history of or

currently had diabetes mellitus or a sexually transmitted diseases; (7) were using oral contraceptive pills (OCPs); (8) had anemia; or (9) had hypothyroidism. Participants were withdrawn from the study if they failed to follow the protocol therapy or experienced any adverse drug reaction or adverse event.

The research team evaluated 233 potential participants, and 193 women were excluded from the study: 38 were pregnant; 19 were unmarried; 26 had diabetes mellitus; 20 had anemia; 12 had hypothyroidism; 13 were OCP users; 16 were using antibiotic or antifungal drugs; 37 had a concurrent vaginal infection; and 12 declined to participate.

The study's protocol, including the informed-consent document and case-report form, was analyzed and approved by the institutional ethics committee of LUMC, Vijayapura (Ref. no. BJP/LUMC/PG/IEC/2017-18/03/IQAN/01). Moreover, the trial was prospectively registered with the Clinical Trial Registry – India (Id: CTRI/2019/02/017861). The study was performed according to the updated tenets of the Declaration of Helsinki, as revised in 2013.

Procedures

Kundur. The medication was selected using the classical Unani books *Al-Jami al-Mufradat al-Advia wa Aghzia* and *Khazain al-Advia.*[20,21] The plant material was procured from a registered herbalist in Mumbai, while the plant's origin was in Gujarat, India. The plant material was subjected to taxonomic identification and authentication by Vidyashree Suryavanshi, a botanist, from the Socio Economic Cultural Association Bijapur's (SECAB's) ARS Inamdar Arts, Science, and Commerce College for Women in Bijapur (Vijayapura), Karnataka, India.

The identified plant specimen was also deposited in the museum of the Luqman Unani Medical College Hospital and Research Center in Bijapur, Karnataka, India, in herbarium file no. 01/HERB/LUMC/17, with the voucher specimen numbers indicating "Boswellia serrata Roxb. ex Colebr. (DBARSI-BJP1707)."

As per the standard operating procedure of Unani medicine, the Kundur for the intervention group was finely powdered, sieved through sieve no. 80, and formed into one-gram tablets, using a tablet-making machine. The control group was given 100 mg of miconazole nitrate (2% w/w) as vaginal suppositories.

Randomization. The participants included in the study were assigned to the Kundur group, the intervention group, or the miconazole group, the control group, using a random number table generated on a website.[31]

Intervention. The treatment duration was three weeks, 21 days,[20,21] for the Kundur group and one week, seven days, for the miconazole group.[32]

Outcome measures. The study measured changes in the severity of pruritus vulvae, vaginal discharge, dysuria, and dyspareunia and assessed participants' QoL at baseline and postintervention using the 12-Item Short Form (SF-12) survey, version 1.0.[33] The study also evaluated the mycological clearing, as assessed using the KOH test on a wet-mount preparation of scrapings or smears,[22] and the research team performed a per-speculum pelvic examination for the presence or absence of erythema, swelling, and curdy white discharge.

Follow-up. The patients were instructed to visit the OPD the following week on the same day. On each follow-up, patients were interviewed about any unused tablets or suppositories, any new clinical findings, and any symptomatic changes, and were clinically examined from head to toe, with a focus on pelvic examination. As the miconazole group lasted only 7 days, all outcomes were also measured on the first follow-up, whereas in the *Kundur* group, outcomes were not measured until the third follow-up. All the findings were recorded on a case-report form (CRF) designed by research team and approved by ethics committee. The CRF was intended to contain demographic information, case history, general physical and systemic examinations, and all outcome measures. All forms were custom-designed for each follow-up and group.

Intervention

The participants in the Kundur group received 21 Kundur tablets, and the miconazole group received seven vaginal suppositories. Both drugs were supplied in identical opaque, locking plastic bags labeled with the study's registration number, drug information, and investigator as well as the institution's details and the phrase "For clinical studies only." The intervention group was advised to use one tablet per day of Kundur for 21 days and the control group one miconazole suppository per day for 7 days.

Outcome Measures

Pruritus vulvae, vaginal discharge, dysuria, and dyspareunia. The study measured the changes in these variables using an arbitrary, 10-point linear scale, with 0 = not severe and 10 = extremely severe. The scale was based on the visual analogue scale introduced by Hayes and Patterson (1921) as well as Freyd (1923), and validated by Aitken and Zealley.[34]

SF-12 survey. The SF-12 is a validated, shortened version of the SF-36. It is a self-reported outcome measure that assesses the impact of health on a person's daily life. The SF-12 and SF-36 share the same eight domains: (1) Physical activity restrictions due to health conditions, (2) Limitations in social activities resulting from physical or psychological issues, (3) Limitations in typical role activities due to physical health conditions, (4) Physical discomfort, (5) General mental health, (6) Limitations in typical role activities due to emotional difficulties, (7) Vitality, (8) General perceptions of health. The scores for each health domain contribute to the Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. The SF-12 provides two summary scores: a mental component score (MCS-12) and a physical component score. The average PCS-12 and MCS-12 scores for the United States population are both 50 points. This study utilized version 1.0 of the SF-12 questionnaire.

Figure 1. CONSORT Flow Diagram of the Participants

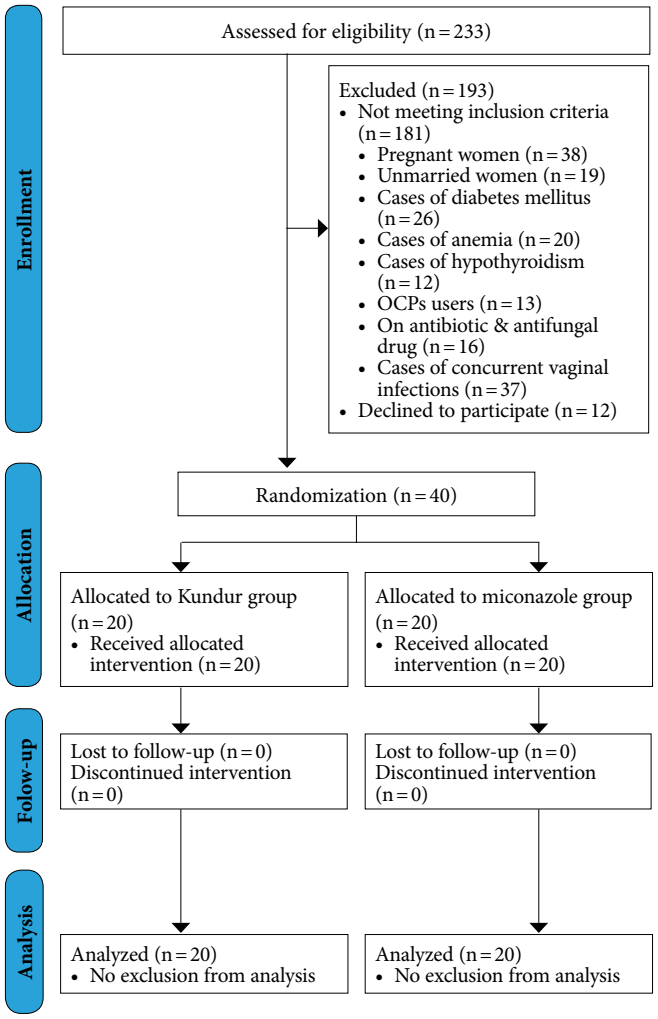

Table 1. Distribution of the Participants' Demographics in the Kundur and Miconazole Groups. The *t* test wasn't significant for age or duration of symptoms ($P > .05$), and the Chi-square text wasn't significant for BMI ($P > .05$).

	Kundur Group n = 20	Miconazole Group n = 20	*P* value
Demographic Profile, mean (SD)			
Age, y	28.60 (6.52)	32.25 (7.77)	.116
BMI, kg/m^2, n (%)			
<18.5	0 (0%)	0 (0%)	0.677
18.5-24.9	6 (30%)	7 (35%)	
25-29.9	14 (70%)	13 (65%)	
>30	0 (0%)	0 (0%)	
Disease Profile, mean (SD)			
Duration of symptoms in days	4.85 (1.53)	4.90 (1.37)	.914

Abbreviations: BMI, body mass index.

The SF-12 has been revised in order to align the scores with more recent U.S. demographics. However, these updates, unlike the original SF-12, are proprietary.[33,35]

KOH test. The KOH test was performed by placing vaginal discharge over the slide with a dropper. Then, 10% KOH was added to the slide, and the cover glass was pressed down to eliminate air bubbles. The slide was then examined under a microscope to determine whether or not pseudohyphae were present. The presence of hyphae was deemed diagnostically significant for VVC.[36]

Pelvic examination. A pelvic examination was performed on each patient. Prior to evaluation, verbal consent was obtained, and the patient was instructed to empty her bladder. The vulva and perineum were examined in the lithotomy position for any discharge, erythema, excoriation, edema, or other abnormalities. Afterwards, Cusco's speculum was softly introduced to notice the cervical texture, external os, hypertrophy, erosion, and any discharge after cleaning the genitalia with 10% savlon. The uterus was examined bimanually to determine its position (AV/RV), movement, size, and texture.

Safety assessment. The safety evaluation was based on clinical-assessment and adverse-event documentation.

Statistical Analysis

The sample size of 40 participants, with 20 in each group, was based on feasibility because no previous data was available on the trial drugs to derive the variables necessary for sample-size calculation. The trial data were entered into Microsoft Excel spreadsheet software and analyzed using IBM SPSS Statistics, v23 (IBM Corp., New York, US). The data were presented in the form of proportions (%) and means and standard deviations (SD). Inferences were made using paired and independent-sample *t* tests; $P < .05$ was considered to be significant. For homogeneity, chi-square and Fisher exact tests were performed.

RESULTS

Participants

Of the 233 potential participants, 40 participants, 20 in each group, were enrolled and completed the required therapy. No participant was omitted from the analysis (Figure 1).

Clinico-demographic Profile

The mean (SD) ages of participants in the Kundur and miconazole groups were 28.60 (6.52) and 32.25 (7.77) years, respectively (Table 1). Most participants' BMIs fell between 25.0 and 29.9, with 14 participants in the Kundur group (70%) and 13 in the miconazole group (65%) having BMIs in that range, followed by participants with BMIs between 18.5 and 24.9, with 6 participants (30%) and 7 participants (35%) in the Kundur and miconazole groups, respectively.

The mean (SD) durations of symptoms from VVC in the Kundur and miconazole groups were 4.85 (1.53) and 4.90 (1.37) days, respectively. In both groups, the distribution of

patients based on their demographic characteristics was normal, and the differences weren't statistically significant at baseline ($P > .05$).

Primary Outcomes

Pruritus vulvae. The mean (SD) values in the Kundur and miconazole groups were 5.40 (2.39) and 5.80 (2.09), respectively, at baseline, and those values had decreased significantly for both groups postintervention to 0.35 (0.49) and 1.15 (0.88), respectively, with $P < .0001$ for the intervention group and $P < .001$ for the control group. The between-group analysis showed that the Kundur group had significantly better results postintervention compared to those of the miconazole group in reducing pruritus vulvae, with $P < .001$.

Dysuria. The mean values in the Kundur and miconazole groups were 3.00 (3.42) and 2.35 (3.00), respectively, at baseline, and those values had decreased significantly for both groups postintervention to 0.30 (0.57) and 0.15 (0.37), respectively, with $P = .001$ and $P = .002$, respectively. The difference between the Kundur and miconazole groups wasn't statistically significant postintervention, with $P = .329$.

Vaginal discharge. The mean (SD) values in the Kundur and miconazole groups were 6.75 (1.94) and 7.40 (0.94), respectively, at baseline, and those values decreased significantly for both groups postintervention to 0.60 (0.68) and 1.30 (0.98), respectively, with $P < .0001$ for the intervention group and $P < .001$ for the control group. The between-group analysis showed that the *Kundur* group had significantly better results postintervention compared to those of the miconazole group in reducing vaginal discharge, with $P = .012$.

Dyspareunia. The mean (SD) values in the Kundur and miconazole groups were 2.60 (3.00) and 1.60 (2.85), respectively, at baseline, and those values had decreased significantly for both groups postintervention to 0.20 (0.52) and 0.25 (0.64), respectively, with $P = .001$ and $P = .023$, respectively. The difference between the Kundur and miconazole groups wasn't statistically significant postintervention ($P = .788$).

QoL. The mean values in the Kundur and miconazole groups for the physical-component summary (PCS) were 32.71 (3.17) and 32.81 (2.95), respectively, at baseline, and those values had increased significantly for both groups postintervention to 50.74 (2.85) and 51.23 (0.37), respectively, revealing a statistically significant change in both groups, with $P = .0001$ for both groups (Table 3). However, the between-group analysis found no significant difference between the groups postintervention, with $P = .46$.

Similarly, the mean values in the Kundur and miconazole groups for the mental- component summary (MCS) were 34.76 (3.45) and 36.03 (3.48), respectively, at baseline, and those values had increased significantly for both groups postintervention to 57.08 (4.61) and 55.62 (2.40), respectively, exhibiting statistically significant changes in both groups, with $P = .0001$ for both groups.

Table 2. Change in Primary Outcome Measures Between Baseline and Postintervention for the Kundur and Miconazole Groups. The research team used a paired samples *t* test for the comparison of changes within groups and an independent samples *t* test for the comparison of changes between groups.

Variables	Comparison of Changes Within Groups	Kundur Group n = 20	Miconazole Group n = 20	Comparison of Changes Between Groups *P* value
Pruritus Vulvae	Baseline	5.40 (2.39)	5.80 (2.09)	.577
	Postintervention	0.35 (0.49)	1.15 (0.88)	.001[a]
	P value	<.0001[b]	<.001[c]	-
Dysuria	Baseline	3.00 (3.42)	2.35 (3.00)	.526
	Postintervention	0.30 (0.57)	0.15 (0.37)	.329
	P value	.001[b]	.002[c]	-
Vaginal Discharge	Baseline	6.75 (1.94)	7.40 (0.94)	.186
	Postintervention	0.60 (0.68)	1.30 (0.98)	.012[a]
	P value	<.0001[b]	<.001[c]	-
Dyspareunia	Baseline	2.60 (3.00)	1.60 (2.85)	.287
	Postintervention	0.20 (0.52)	0.25 (0.64)	.788
	P value	.001[b]	.023[c]	-

[a]$P < .05$, indicating a significant difference in the changes for the variable between the Kundur group and the Miconazole group
[b]$P < .05$, indicating a significant change between baseline and postintervention for the variable for the Kundur group
[c]$P < .05$, indicating a significant change between baseline and postintervention for the variable for the Miconazole group

Table 3. Changes in QoL Variables, Based on the SF-12, Between Baseline and Postintervention for the Kundur and Miconazole Groups. The research team used a paired samples *t* test for the comparison of changes within groups and an independent samples *t* test for the comparison of changes between groups.

Variables	Comparison of Changes Within Groups	Kundur Group n = 20	Miconazole Group n = 20	Comparison of Changes Between Groups *P* value
PCS	Baseline	32.71 (3.17)	32.81 (2.95)	.913
	Postintervention	50.74 (2.85)	51.23 (0.37)	.460
	P Value	.0001[a]	.0001[b]	-
MCS	Baseline	34.76 (3.45)	36.03 (3.48)	.252
	Postintervention	57.08 (4.61)	55.62 (2.40)	.216
	P Value	.0001[a]	.0001[b]	-

[a]$P < .05$, indicating a significant change between baseline and postintervention for the variable for the Kundur group
[b]$P < .05$, indicating a significant change between baseline and postintervention for the variable for the Miconazole group

Abbreviations: QoL, quality of life; SF-12, 12-Item Short Form survey; PCS, physical-component summary; MCS, mental-component summary.

Table 4. Changes in Secondary Outcome Measures Between Baseline and Postintervention for Kundur and Miconazole Groups. The research team used the Wilcoxon Signed Ranks Test for the comparison of changes within groups and the Mann-Whitney U Test for the comparison of changes between groups.

Parameters	Comparison of Changes Within Groups	Kundur Group n = 20		Miconazole Group n = 20		*P* value
		Absent	Present	Absent	Present	
Erythema	Baseline	4 (20%)	16 (80%)	2 (10%)	18 (90%)	0.382
	Postintervention	20 (100%)	0 (0%)	20 (100%)	0 (0%)	1.000
	% change	80%		90%		-
Vulval Swelling	Baseline	9 (45%)	11 (55%)	8 (40%)	12 (60%)	0.752
	Postintervention	20 (100%)	0 (0%)	20 (100%)	0 (0%)	1.000
	% change	55%		60%		-
Curdy Discharge	Baseline	0 (0%)	20 (100%)	2 (10%)	18 (90%)	0.152
	Postintervention	15 (75%)	5 (25%)	17 (85%)	3 (15%)	0.435
	% change	75%		75%		-
Pseudohyphae on KOH Mount	Baseline	0 (0%)	20 (100%)	0 (0%)	20 (100%)	1.000
	Postintervention	18 (90%)	2 (10%)	17 (85%)	3 (15%)	1.000
	% change	90%		85%		-

Abbreviations: KOH, potassium hydroxide.

The between-group analysis found no significant difference between the groups postintervention, with $P = .216$. Moreover, the mean scores for PCS and MCS postintervention were around the mean of 50 for the US population.[35]

Secondary Outcomes

The between-group analysis of erythema, vulval swelling, curdy discharge, and pseudohyphae on the KOH test showed that both groups' interventions equally and significantly improved outcomes, and the differences between groups weren't statistically significant for erythema, with $P = 1.000$; vulval swelling, with $P = 1.000$; curdy discharge, with $P = .435$; or the KOH mount test, with $P = 1.000$ (Table 4).

Erythema. At baseline, 16 participants in the Kundur group (80%) and 18 participants in the miconazole group (90%) had erythema, which had resolved for all participants in both groups postintervention.

Vulval swelling. At baseline, vulval swelling was present in 11 participants in the Kundur group (55%) and in 12 participants in the miconazole group (60%) and had been resolved for all participants in both groups postintervention.

Curdy discharge. At baseline, the curdy discharge was present in 20 participants in the Kundur group (100%) and 18 participants in the miconazole group (90%), and 5 participants in the Kundur group (25%) and 3 participants in the miconazole group (15%) had the discharge postintervention, attaining a 75% change in both groups.

Pseudohyphae. At baseline, pseudohyphae was observed on the KOH mount in all participants in both groups and had been cleared in 18 participants in the Kundur group (90%) and 17 participants in the miconazole group (85%) postintervention.

DISCUSSION

The current study compared the clinical efficacy of a *Kundur* tablet and a miconazole suppository in the treatment of VVC. Likewise, the study intended to compare the therapeutic value of both drugs in improving the QoL of VVC patients. After completion of the protocol therapies, the Kundur and miconazole groups demonstrated significant improvements in primary and secondary outcome measures. The between-group analysis, on the other hand, found that no statistically significant differences existed for most outcomes, except for pruritus vulvae and vaginal discharge, which improved more in the Kundur group.

The mean (SD) age of all 40 participants was 30.43 (7.32) years, similar to Zaki et al's and Ebrahimy et al's findings, in which the mean ages of participants suffering from candidiasis were 31 years and 32 years, respectively.[9,37] The BMI of the participants was between 25.0 and 29.9 in most of the cases, indicating that obesity and insulin resistance could be predisposing factors for the VVC, as Luceine et al had shown.[8]

Kundur's effects in the current study might be credited to the biomedical properties inherent in it, as prior studies have shown.[11,12,21–25,30] These actions could have played an important role in alleviating the severity of pruritus vulvae, dysuria, and dyspareunia in the current study.

The current study's safety assessment was done for both groups, and no subjective or objective adverse effects took place. The limitations of the current study were the small sample size and the differences in the dosage forms of the two drugs. Additionally, the difference in treatment length should be considered when interpreting the study outcomes, because Kundur was administered for 21 days whereas miconazole was administered for just 7 days. Thus, more specific studies with rigorous criteria and standard measurement tools for efficacy and safety parameters should be carried out to reinforce the scientific evidence.

CONCLUSIONS

In the current study, the response to the intervention was greater than that of the control in reducing pruritus vulvae and vaginal discharge. However, dysuria, dyspareunia, vulval erythema, vulval swelling, curdy discharge, and clearing of mycological hyphae as shown on the KOH mount were equally and significantly improved in both the intervention and the control group. The Kundur, *Boswellia serrata* Roxb. Ex Colebr., was well tolerated, and no adverse events were noticed during the trial. The results for Kundur are worth further investigation with rigorously designed multicentric, randomized controlled trials with larger sample sizes to verify the current results.

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