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Research Article

Therapeutic Effect of a Polyherbal Unani Formulation in Sayalan Al-Rahim (Abnormal Vaginal Discharge) - A Clinical Study

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ABSTRACT

Sayalan al-Rahim (abnormal vaginal discharge) is one of the very common female complaints encountered in daily practice. It is an important public health problem in India and can occur mostly due to sexually and non-sexually transmitted infections. A clinical trial was conducted in the Department of Ilmul Qabalat wa Amraze Niswan, NIUM, Bengaluru. 30 patients of Sayalan al-Rahim were included in the study after obtaining their informed consents. All the patients were clinically assessed and diagnosed on the basis of thorough history, presence of abnormal vaginal discharge and other associated symptoms. Then, polyherbal Unani formulation was administered orally 5 gm twice daily with water from 5th day of menses for 21 days. The severity of disease and efficacy of treatment was assessed on the basis of subjective and objective parameters. Clinical improvement of 70% in *Sayalan al-Rahim* was observed. Mean ± SD of vaginal discharge before and after treatment was 2.87 ± 0.35 and 0.37 ± 0.61, VSS scale before and after treatment was 23.53 ± 3.49 and 10.33 ± 4.05 and VAS scale for LBA and LAP before and after treatment were 6.37 ± 2.36 to 2.37 ± 1.87 and 2.43 ± 1.96 to 0.03 ± 0.18, respectively with p=< 0.001** considered strongly significant. Polyherbal unani formulation was found safe and effective in improving the sign and symptoms of *Sayalan al-Rahim*. It was concluded that polyherbal Unani formulation can be used safely and effectively for the treatment of *Sayalan al-Rahim.*

Introduction

In classical Unani texts, *Sayalan al-Rahim* includes any discharge other than blood coming out from the uterus; therefore, it covers almost all types of discharge caused by any infection in the female genital tract.[1,2] Unani scholars describes that, the causative factors of *Sayalan al-Rahim* are weakness of *quwwat jadhiba rahim* (which causes excessive body waste and dominance of *akhlat e-arba]*[3] and *kasrat-i-warm al-rahim* (uterine inflammation) and presence of morbid material within the uterine vessels. He also mentions that *sayalān al-mani* is the physiological excessive vaginal discharge and *Sayalan al-Rahim* is the abnormal vaginal discharge (AVD).[4]

An estimated 357 million new cases of curable reproductive tract infections (RTIs) or sexually transmitted infections (STIs) occur annually in adults.[5] Women suffering from RTI/STI syndrome suffer from pain, discomfort, anxiety, PID, pelvic abscess, menstrual disorders, infertility and ectopic pregnancy. Studies have reported abnormal vaginal discharge as the most common complaint of women suffering from RTI/STI syndrome.[1,6] Approximately 75% of women experience leucorrhoea in their lives and 45% experience recurring conditions.[7]

Unani physicians enlist various etiological factors of *Sayalan al-Rahim* such as *suzak*, *ātshak*, *waram al-rahim* (metritis/RTIs*), waram al-mahbil* (vaginitis*), su'al-qinya* (anemia) and general weakness.[8,9] As per the conventional system of medicine, any combination of physiological and pathological factors causes it.[7] Physiological discharge is thick and sticky for most of the menstrual cycle but

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becomes clearer, wetter, and stretchy for a short period.[10] Pathological vaginal discharge may be of vaginal or cervical origin. Discharge of vaginal origin may be associated with bacterial vaginosis (BV) and infection with *Candida spp.* and *Trichomonas vaginalis* (TV). Cervical origin may be infection with *Neisseria gonorrhea*, *Chlamydia trachomatis*, and *Mycoplasma genitalium*.[11] Abnormal vaginal discharge is characterized by change in color, volume and odor and may be associated with itching, soreness, dysuria, pelvic pain, intermenstrual or postcoital bleeding.[8-10,12]

History and clinical examination of the patient should be carried out before deciding whether investigations and treatment is required.[12] Bacterial vaginosis is diagnosed with Amsel's criteria, although Nugent's scoring system is the diagnostic standard.[13] Vulvovaginal candidiasis (VVC) is diagnosed with a combination of associated clinical signs and symptoms with potassium hydroxide microscopy and culture and trichomoniasis with NAAT. CDC's recommended metronidazole 500 mg orally twice daily for 7 days[14-16] or 2 gm metronidazole single oral dose[15] but adverse effects like nausea, vomiting and may induce bacterial resistance with repeated use and relapse rates are high after completion of treatment.[1]

Hence, there is a need for an alternate therapy that should be safe, effective and easily available with less adverse effects. Several *mufarad* (single) and *murakkab* (compound) drugs are available for treating *Sayalan al-Rahim* and various other gynecological diseases and are used orally as well as locally.[12]

In classical literature, it has been mentioned that the Unani formulation consisting *taj* (*Cinnamomum cassia* Presl.), *majeeth* (*Rubia cordifolia* Linn.), *gul-i-pista* (*Pistacia vera* Linn.), *gokharū* (*Tribulus terrestris* Linn.) and *gond-i-dhāk* (*Butia monosperma* (Lam.) Taub.[12] were selected as a test drug as they possess the properties of *qābiḍ* (Astringent), *tanqiya* of fāsid and mutaffun rutūbat of rahim,[17] muḥallil al-waram (anti-inflammatory),[17,18] *musaffi-i-khun wa balgham* (blood purifier),[17] *sayalān-i-mani, mundij* and *Muqawwī-i-rahim* (uterotonic) etc.[18] Pharmacologically, these herbs have been proven for their anti inflammatory,[19] antioxidants,[20] anti microbial[21] etc properties.

Hence, considering the traditional claim, chemical constituents and reported activities of polyherbal unani formulation, the present study was planned to evaluate the effect of Unani formulation in *Sayalan al-Rahim.*

Materials And Methods

The present study was an open, pre and post-evaluation, non-randomized trial conducted at the out-patient Department of Ilmul Qabalat wa Amraze Niswan, NIUM, Bengaluru from 2020-2021. The study protocol was approved by the institutional ethical committee, NIUM, Bengaluru under IEC No: NIUM/IEC/2018–19/014/ANQ/06 with CTRI registration number CTRI/2020/02/023275.

Sample Size Estimation

Sample size was calculated by using formula: n= [(Zα-Zβ) σ/μ1- μ2]2. The SD and mean for reference was taken from the previous study.[22]

The Procedure of Study

Clinically diagnosed patients with *Sayalān al-Rahim* aged 18-45 years having abnormal vaginal discharge, low backache, pruritus vulvae, pain in lower abdomen, dysuria, and dyspareunia were selected for the present clinical trial. Patients with known systemic, metabolic diseases, HIV, malignancy, pelvic pathologies, STIs, trichomoniasis, pregnant, lactating women, OCP and IUCD insertion. Investigations such as CBC, ESR, CUE, RBS, VDRL, USG pelvis, and Pap smear were done for all screened participants for exclusion. The patient information sheet (PIS) containing information about the nature and objectives of the study and details of other study-related procedures was provided to each trial participant. Satisfied patient were registered for clinical trial, she was screened and assessed for clinical and biochemical parameters after taking signature on PIS.

The socio-economic status and *mizaj* were assessed by Kuppuswamy's socio-economic modified Scale[23] and temperamental scale, respectively.

Local examination of vagina of each participant was examined using a speculum to find out signs of AVD. Samples of vaginal secretion specimen were collected using a sterile swab from the upper-lateral side of the vaginal wall and smeared on two slides. The first specimen was added by normal saline to observe the possible presence of clue cells, hyphae of *Candida* and *Trichomonas vaginalis*. The second specimen was added by one drop of 10% KOH solution to carry out the whiff test and to assess the possible presence of *Candida* microscopically. Vaginal pH was assessed using pH-meter paper. Criteria to diagnose BV clinically were based on the presence of 3 out of 4 Amsel's criteria: a vaginal pH > 4.5, the presence of clue cells on wet mount test; a thin grey or white homogenous discharge, or a positive KOH "whiff test". All included patients underwent biochemical investigation (blood urea, Sr. creatinine, AST, ALT, alkaline phosphatase) before and after the trial to assess the safety of test drugs.

Intervention

Powdered prepared from equal quantity of Unani single drugs i.e. *taj, majeeth*, *gul-i-pista*, *gokharū* and *gond-i-dhāk* and mixed with equal quantity of sugar was administered orally in a dose of 5 gm twice daily with water from 5th day of menses for 21 days.

Assessment Cum Follow Up

The patient was advised to follow up every week during trial and one follow-up after 15 days of trial completion to look for recurrence. During follow-up visits, the patients were assessed in the improvement of sign and symptoms

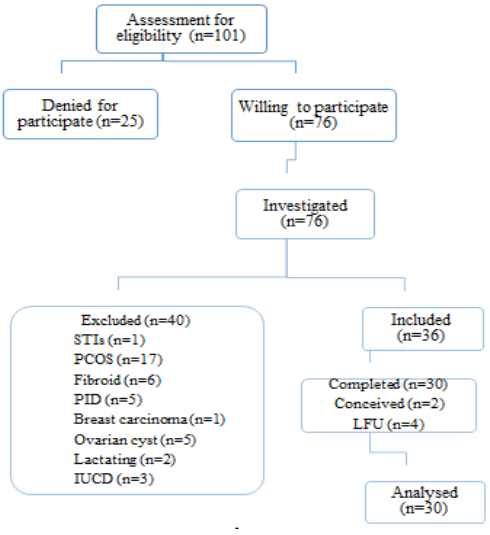

Fig. 1: Consort flow diagram.

using the same scales. Patients were also enquired for any adverse effect of drug during the study.

Initially 101 patients were screened for eligibility for the study of whom 25 patients denied and 40 patient were excluded for not meeting the inclusion criteria: STIs 1, PCOS 17, fibroid 6, PID 5, breast carcinoma 1, ovarian cyst 5, IUCDs 3, lactating 2. 36 patients who fulfilled the criteria were included in the study. 4 patients were lost to follow up due to covid 19 pandemic and 2 patients withdrawn because of pregnancy (Fig. 1).

Outcome Measures

The primary outcomes were change observed in subjective parameters (abnormal vaginal discharge, low backache, pruritus vulvae, pain in lower abdomen). Change observed in objective parameters (VSS and VAS score).[24,25] were based on improvement in vaginal discharge and VSS scale before, during and after completion of trial.

Statistical Analysis

Paired proportion test, student t-test (two-tailed, dependent) and paired t-test were used to analyses the result. The statistical software, namely SPSS 22.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel were used to generate graphs, tables etc.

Results And Discussion

Baseline Characteristics

Age

The patients with vaginal discharge were ranged between 20–40 years with a mean age 30.13 ± 5.15, showing vaginal infection in the reproductive age group. Where 53.3% were in 31–40 years and 46.7% of women were between 20–30 years of age, consistent with Vijaya D *et al.*[26] reported 30–35 years, and Abdul-Aziz *et al.*[27] reported 26–35 years. Mean age of patients reported by Hillier SL[28] 29.4 ± 6.5, and Agrawal M *et al.*[29] 30.5 ± 5.7 years.

Table 1: Baseline characteristics of *Sayalan al-Rahim* patients.

Variables	*No. of patients*	*Percentage*
Age in years		
20–30	14	46.7
31–40	16	53.3
Mean ± SD	30.13 ± 5.15	
Socio Economic Status		
Lower Middle	11	36.7
Upper Lower	17	56.7
Upper Middle	1	3.3
Upper	1	3.3
Education		
GRA	2	6.7
HSC	3	10.0
MSC	14	46.7
PSC	5	16.7
ILL	6	20.0
Diet		
Mix	29	96.7
VEG	1	3.3
BMI (kg/m^2)		
Underweight (<18.5)	0	0.0
Normal (18.5–25)	8	26.7
Overweight (25–30)	14	46.7
Obese (>30)	8	26.7
Obstetrics History-Parity		
0	2	6.7
1	4	13.3
2	14	46.7
3	7	23.3
4	2	6.7
5	1	3.3
H/O Contraception		
Absent	11	36.7
Present	19	63.3
BARR	5	16.7
TUB	14	46.7
Mizaj		
Balghami	16	53.3
Damwi	2	6.7
Safrāwi	11	36.7
Sawdāwi	1	3.3

Table 2: Effect of research drug on abnormal vaginal discharge (AVD)

Vaginal discharge	*Before treatment*	*1st Follow up*	*2nd Follow up*	*3rd Follow up*	*After treatment*	*%Difference*
No	0 (0%)	0 (0%)	0 (0%)	22 (73.3%)	21 (70%)	70.0%
Mild	0 (0%)	0 (0%)	20 (66.7%)	8 (26.7%)	7 (23.3%)	23.3%
Moderate	4 (13.3%)	25 (83.3%)	10 (33.3%)	0 (0%)	2 (6.7%)	-6.6%
Severe	26 (86.7%)	5 (16.7%)	0 (0%)	0 (0%)	0 (0%)	-86.7%
Total	30 (100%)	30 (100%)	30 (100%)	30 (100%)	30 (100%)	-

p=0.00025**, significant, Paired proportion test, Improvement of 70.0%

Table 3: Effect of research drug on low backache

Low backache	*Before treatment*	*1st Follow up*	*2nd Follow up*	*3rd Follow up*	*After treatment*	*%Difference*
Nil	3 (10%)	3 (10%)	4 (13.3%)	9 (30%)	12 (40%)	30.0%
Mild	0 (0%)	2 (6.7%)	8 (26.7%)	16 (53.3%)	12 (40%)	40.0%
Moderate	9 (30%)	19 (63.3%)	17 (56.7%)	5 (16.7%)	5 (16.7%)	-13.3%
Severe	18 (60%)	6 (20%)	1 (3.3%)	0 (0%)	1 (3.3%)	-56.7%

p =0.008** significant, Paired proportion test, Improvement of 30%

Table 4: Effect of research drug on pruritus vulvae

Pruritus vulvae	*Before treatment*	*1st Follow up*	*2nd Follow up*	*3rd Follow up*	*After treatment*	*%Difference*
No	4 (13.3%)	6 (20%)	11 (36.7%)	26 (86.7%)	28 (93.3%)	80.0%
Mild	4 (13.3%)	12 (40%)	16 (53.3%)	3 (10%)	1 (3.3%)	-10.0%
Moderate	14 (46.7%)	10 (33.3%)	3 (10%)	1 (3.3%)	1 (3.3%)	43.4%
Severe	8 (26.7%)	2 (6.7%)	0 (0%)	0 (0%)	0 (0%)	-26.7%

p < 0.001**, significant, Paired proportion test, Improvement of 80%.

Table 5: Effect of research drug on VSS scale

VSS scale	*Min-Max*	*Mean ± SD*	*Difference*	*t value*	*p-value*
Before treatment	17.00–36.00	23.53 ± 3.49	-	-	-
1st Follow up	14.00–32.00	20.33 ± 3.63	3.200	11.910	<0.001**
2nd Follow up	10.00–26.00	15.63 ± 3.20	7.900	16.874	<0.001**
3rd Follow up	3.00–17.00	9.83 ± 2.88	13.700	41.178	<0.001**
After treatment	3.00–21.00	10.33 ± 4.05	13.200	23.152	<0.001**

Socio-economic Status

In this study, the maximum patients were from upper lower class 17 (56.7%), 11 (36.7%) patients were from lower middle, 1 (3.3%) from each upper middle and upper class. These findings are comparable with that of Guntoory I *et al.*[30] and Rathod ND *et al.*[31]

Education

In this study, 6 (20.0%) were from illiterate, 5 (16.7%) from primary school, 14 (46.7%) from middle school, 3 (10.0%) from high school and 2 (6.7%) from graduate. A similar trend was observed by Guntoory I *et al.*[30] and Rathod ND *et al.*[31]

Mizāj

In this study, maximum no. of patients 16 (53.3%) possessed *balghami Mizāj,* followed by *Safrāwi* 11 (36.7%), *Damwi* 2 (6.7%) and *Sawdāwi* 1 (3.3%). It is in accordance with the theories proposed by eminent unani physicians, who have quoted that this disease is more common in individuals with the dominance of *khilt-i-balgham*. Similar finding was reported by khan M *et al.*[1] and Anjum A *et al.*[32] Maximum 14 (46.7%) of *sayalan al-rahim* patients had parity 2 which is in consonance with Vijayalakshmi D *et al.,*[26] Rathod ND *et al.*[31] and Guntoory I *et al.*[30] Maximum 14 (46.7%) patients were tubectomised,11 (36.7%) were non-contraceptive users, 5 (16.7%) were using barrier methods which is in conformance with Rathod ND *et al.,*[31] Guntoory I *et al.,*[30] and khan M *et al.*[1] (Table 1).

Amsel's Criteria

In this study, whiff test was positive in 17 (56.7%) patients, clue cells were present in 17 (56.7%) patients and the mean vaginal Pη was 5.56 ± 1.03, diagnosed cases of BV. This was in accordance to studies conducted by Spurthi *et al.*[33], which reported that 16.4% had positive whiff test, 56.4% had a vaginal pH of >4.5 and 58% had clue cells, and 55.9% patients were diagnosed BV using Amsel's criteria.

Table 6: Effect of research drug on VAS scale for LBA and LAP

Objective parameters	*Min–Max*	*Mean ± SD*	*Difference*	*t value*	*p-value*
VAS scale for LBA					
Before treatment	0.00–9.00	6.37 ± 2.36	-	-	-
1st Follow up	0.00–7.00	5.07 ± 2.00	1.300	10.140	<0.001**
2nd Follow up	0.00–7.00	3.80 ± 1.77	2.567	12.066	<0.001**
3rd Follow up	0.00-6.00	2.33 ± 1.54	4.033	12.473	<0.001**
After treatment	0.00–7.00	2.37 ± 1.87	4.000	10.511	<0.001**
VAS Scale for LAP					
Before treatment	0.00–6.00	2.43 ± 1.96	-	-	-
1st Follow up	0.00–4.00	1.43 ± 1.36	1.000	5.785	<0.001**
2nd Follow up	0.00–3.00	0.60 ± 0.89	1.833	7.090	<0.001**
3rd Follow up	0.00–1.00	0.03 ± 0.18	2.400	6.713	<0.001**
After treatment	0.00–1.00	0.03 ± 0.18	2.400	6.713	<0.001**

Table 7: Effect of research drug on safety profile

Variables	*Before treatment*	*After treatment*	*Difference*	*t value*	*p-value*
AST (IU/L)	17.37 ± 3.91	20.67 ± 10.99	-3.300	-1.503	0.144
ALT (IU/L)	25.03 ± 7.12	28.23 ± 15.11	-3.200	-1.325	0.195
Alkaline phosphate	109.40 ± 32.13	104.50 ± 29.90	4.900	0.887	0.382
Blood urea	22.77 ± 4.25	22.07 ± 4.88	0.700	0.580	0.567
Serum creatinine	0.81 ± 0.11	0.79 ± 0.11	0.018	0.804	0.428

Wet Mount Test

In this study, clue cells were present in 17 (56.7%) patients with BV at baseline whereas after treatment, only 2 (6.7%) patients had clue cells considered significant (p= 0.008**). *Candida* was present in 2 (6.7%) at baseline and after treatment no patients had *Candida* in wet mount test, suggesting strongly significant (p= <0.001**). The presence of > 20% clue cells on a wet mount is the single most reliable predictor of BV.[33]

Subjective Parameters

Vaginal Discharge

At baseline, the vaginal discharge was moderate and severe in 4 (13.3%) and 26 (86.7%) patients respectively, which was improved to no discharge in 70.0% and mild in 23.3% patients and no patient had severe vaginal discharge after treatment, with the improvement of 70%. A similar finding was reported by Khan M *et al.*[1] and Tabassum AB *et al.*[34] 76.7% improvement in two groups. Pentikis H *et al.*[35] reported 58.6% with p= <0.001. At baseline, Mean ± SD was 2.87 ± 0.35 which was reduced to 0.37 ± 0.61 after treatment with p= <0.0001** suggesting strongly significant, which is consistent with the study by Askari SF *et al.*[36] reported 2.18 ± 1.08 to 0.64 ± 0.50. Marked improvement in *Sayalan al-Rahim* is attributed to *qāṭi '-i-Sayalan al-Rahim, qabiḍ,*[37] *mumsik, musaffi khun, muqawwī* rahim[18] properties of research drug formulation (Table 2).

Low Backache

At baseline, low backache was moderate and severe in 9 (30.0%) and 18 (60%) patients respectively, which was improved to no LBA in 12 (40.0%), mild in 12 (40.0%), moderate in 5 (16.7%) and severe in 1 (3.3%) with the improvement of 30%. These finding are comparable with Tabassum AB *et al.*[34], which reported 26.7% and Khan M *et al.*[1], which reported 40% and 46.6% improvement in two groups. At baseline, Mean ± SD was 2.45 ± 0.93 which was reduced to 0.83 ± 0.83 with p= <0.0001**. It might be due to *muqawwī-i-rahim wa kamar,*[18] *musakkin-i-alam* etc.[38] properties of research drug formulation (Table 3).

Pruritus Vulvae

At baseline, pruritus vulvae were mild, moderate and severe in 8 (26.7%), 14 (46.7%) and 4 (13.34, 13.3%) which was improved to no pruritus in 28 (93.3%), mild in 1 (3.3%) and moderate in 1 (3.3%) with the improvement of 80%. Tabassum AB *et al.*[34] reported 46.6 and 40% and Khan M *et al.*[1] reported 39.9 and 16.6% improvement in two groups. Unani scholars mentioned that itching is due to balgham shor or balgham māleh, effect might be due to qābiḍ,[18,37] mumsik, musaffi khun etc.[18] properties of research drug formulation (Table 4).

Table 8: Therapeutic outcome in *Sayalan al-Rahim* patients

Therapeutic outcome	*BT*	*AT*	*p-value*
Vaginal discharge	2.87 ± 0.35	0.37 ± 0.61	<0.0001**
VSS scale	23.53 ± 3.49	10.33 ± 4.05	<0.001**

Lower Abdominal Pain

At baseline, LAP was mild and moderate in 11 (36.7%) and 10 (33.3%) which was improved to no LAP in 30 (100%). Khan M *et al.*[1] reported 23.3% test and 13.3% improvement in two groups and Tabassum AB *et al.*[34] reported 10 and 20% improvement in two groups.

Objective Parameters

Vaginal Symptoms Score Scale

In this study, the severities of symptoms and QOL before, during and after treatment were assessed by VSS. At baseline Mean ± SD of VSS were 23.53 ± 3.49 and after treatment 10.33 ± 4.05 with p= <0.001**, suggesting strongly significant which is in accordance with the study of Tabassum AB *et al.*[34]reported 9.53 ± 4.58 to 1.00 ± 1.23 with $p < 0.001$ in two groups and Anjum A *et al.*[32] reported from 33.03 ± 3.26 to 13.77 ± 6.10 (Table 5).

VAS Scale for LBA and LAP

In this study, the severity of LBA and LAP was assessed by VAS scale. At baseline Mean ± SD of VAS for LBA were 6.37 ± 2.36 and for LAP were 2.43 ± 1.96 which was reduced to 2.37 ± 1.87 and 0.03 ± 0.18, respectively (p = < 0.001** suggesting strongly significant). Similar finding was reported by Anjum A *et al.*[32] and Tabassum AB *et al.*[34] (Table 6).

Safety and Tolerability

Unani formulation was proved to be safe as all safety parameters were within normal limits (Table 7).

Therapeutic Outcome

The present study confirmed that clinical improvement of vaginal discharge with mean was 2.87 ± 0.35 and 0.37 ± 0.61 and VSS scale was 23.53 ± 3.49 and 10.33 ± 4.05 respectively. Out of 30 patients, 21 (70.0%) improved clinically, 7 (23.3%) improved partially and 2 (6.7%) patients show recurrence within 15 days with bacterial vaginosis in *Sayalan al-Rahim*. According to unani physician *barid wa yābis mizaj adwiya* like *gul-i-pista, gokharu* and *gond-i-dhak* usually having *qābiḍ, mujaffif, mumsik, musaffi khun, muqawwī rahim*[18] properties that tone up the *quwwat ghadhiya* of *rahim* and absorb excessive discharge (Table 8).

Moreover, pharmacological studies confirmed that constituents of Unani formulation contain phytochemical such as resin, tannin, sugar, mannit, starch,[39,40] saponine,[41] gallo-tannic acids, gallic acid, anthroquinones and glycosides etc.[39] which have demonstrated for biological activities such as antimicrobial,[21,40,42] antifungal,[43] anti-inflammatory[44] analgesic,[45] antioxidants,[46] wound healing, hepatoprotective,[46-49] and nephroprotective etc.[49,50] Further, astringent drugs reported to decrease the secretion due to its inhibitory effect and even tannins having antimicrobial and antioxidant properties may further useful in this condition.[1]

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