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Efficacy of Unani Formulation in Cervical Ectopy (Quruhal Rahim) - An Open Observational Study

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ABSTRACT

Introduction: Cervical ectopy (*quruhal Rahim*) is a benign and common gynaecological condition in India with 19% of the total population. About 80-85% of women suffer from Cervical Erosion. Cervical erosion is diagnosed by per speculum examination. Considering these facts *methi, alsi,babuna*, *nakhuna*, *karamkalla*, has been selected to evaluate the efficacy in the form of *Abzan* in *Quruhal Rahim*.

Objective: To evaluate the efficacy of *Abzan* in *Quruhal rahim* with *unani formulation.*

Methods: This is an open observational clinical study in clinically diagnosed woman (n=30) in the age group of 18-45 yrs having symptoms of vaginal discharge, normal or inflammatory changes in pap smear were included and patients with malignancy, Pelvic inflammatory disease, systemic illnesses & Sexually transmitted disease, oral contraceptive Pills and Intrauterine contraceptive device, pregnancy and lactation were excluded. *Joshanda* of *methi* 5gms, *alsi* 5gms, *babuna* 3gms, *nakhuna* 5gms, *karmkalla* 10 gms in 2 litres of warm water. After menses use daily one time for sitz bath for 15minuts for 21 days. The primary and secondary outcome was assessed. Cervical ectopy by arbitrary grading scale and SF-12 for Quality of life were health-related quality of the life is measured by SF-12 Questionnaire. To provide easily interpretable scales for physical and mental health.

Results: Vaginal discharge mean score before and after treatment is 2.37±0.57 and0.367±0.49 respectively with p<0.0001. In cervical erosion, grading means score before and after treatment is 1.7±0.65 and 0.47±0.58 respectively with a p<0.0001. Highly significant improvement is found in subjective and objective parameters.

Conclusion: This data suggests that the test drugs were safe, effective in improving and relieving symptoms of cervical erosion. Further, research in a larger sample size for longer duration is recommended.

Key Words: *Quruhalrahim*, Cervical ectopy, Abzan, Arbitrary grading scale, SF-12 for QOL, Vaginal discharge

INTRODUCTION

Cervical erosion is also known as cervical ectopy. It is a benign lesion and a common gynaecological condition seen in outpatient departments.[1,2] About 80-85% of women suffer from cervical erosion.[3] It is the commonest finding in routine pelvic examinations during the fertile age group 1.[1] Pathologically cervical erosion is a condition where squamous epithelium of the ectocervix is replaced by the columnar epithelium of the endocervix.[3] The exposed columnar epithelium looks red because of the blood vessels just below the surface.[4] A single layer of glandular cells that reside in close association with the underlying vascular cervical stroma appear. It is thin and vascularized epithelium fragile tissue. With easy access to the blood and lymphatic systems, there are decreased mucosal barriers to sexually transmitted infections (STIs), including HIV. Prior observational epidemiological studies have suggested that cervical ectopy can increase the risk of acquiring diseases like chlamydia trachomatis, human papillomavirus, and cytomegalovirus, but not Neisseria gonorrhoea.[5]

The common causes of ectopy are trauma by multiple childbirths, tampon use of intrauterine contraceptive device chemicals, infections, hormones (oral contraceptive pills) or carcinoma etc. Cervical ectopy is more common in women of lower socioeconomic groups, poor general hygiene, early marriage and multiple pregnancies.[6] Clinically, the patient may present with vaginal discharge, low backache, contact bleeding in the form of post-coital bleeding or intermenstru-

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al bleeding, dyspareunia, etc.[7] Cervical erosion is diagnosed by per speculum examination. It reveals a bright red area surrounding and extending beyond the external os in the ectocervix. The outer edge is demarcated. It may be smooth or having small papillary folds. It is neither tender nor bleeds to touch.[7] It is asymptomatic and physiological then needs no treatment but when it is symptomatic and infected then the treatment is needed.[3,7] Cryo-cauterization, electrocoagulation and cautery with laser is the treatment of choice. Side effects like prolonged excessive mucoid discharge per vagina, seldom cervical stenosis, accidental burns, bleeding and recurrence are associated with this treatment.[6] In classical Unani literature which is caused by external factors such as wound due to trauma, instrumentation, the drug which is caused by external factors such as wounds due to trauma, instrumentation, drug-induced i.e use of *haad* drugs in the form of *humool,* or internal factors like difficult labour or mismanagement of labour, sometimes, it may be because of acute yellow bile causing gradual erosion of cervix due to its acute nature or inflammation and rupture of pustules.[8,9] In symptoms like backache, pelvic pain, abnormal vaginal discharge, excessive tiredness etc. Use of (relaxant) drugs is harmful while *qabiz* (astringent) drugs are beneficial in its treatment.[8-10]

Unani system of medicine has several drugs available for healing of cervical ectopy as a local treatment in the form of a sit bath, which is safe and cost-effective. In present study research drug comprises of *Methi* (*Trigonella foenum graeceum*) 5 gms, *alsi (Linum usitatissimum*) 5gms*, babuna* (*Matricaria chaemomilla)* 3gms*, nakhuna ((Trigonella uncata*) 5gms*, karmkalla ka dant'hal* (*Brassica oleracea)*10 gms *Joshanda* is prepared in 2 lots of warm water. After menses use daily one-time for*sitz bath* for 15minuts for 21 days.[11] In unani system of medicine various drugs with medicinal properties like *munzij, muhallilawram* (anti-inflammatory), *jaali* (detergent), *muqawiebadan, mushil* (laxative), *mujaffif, mudammilquruh, dafi-i-taffun, mullayan, mussakin*etc are used locally to treat this disease.

MATERIALS AND METHODS

Study design: An open observational study.

Study duration: One and a half years from March 2019 to January 2020

Study centre: OBG Dept. National Institute of Unani Medicine Hospital, Bangalore.

Sample size: 30 patients

Ethical clearance No.: Ethical clearance was obtained from the institutional ethical committee vide no NIUM/IEC/2017-18/013/ANQ/05; and CTRI registration done vide no.CTRI//2019/03/024426.

Informed consent: all participants gave written informed consent before study

Drugs Identification: was done at *FRLHT Bengaluru.* with an acc. No. 5510-5514

Participants: Total 60 patients were screened for the study, 10 patients refused participation and 20 patients didn't meet the inclusion criteria, hence were excluded. 30 patients were allocated in- an open observational study.

Selection criteria: Married women between the age group of 18-45 yrs. Having symptoms of vaginal discharge, low backache, dyspareunia, post-coital bleeding, normal or inflammatory changes in pap smear were included and patients with malignancy, PID, systemic illnesses like Hypertension, diabetes mellitus & STIs, OC Pills and IUCD's, pregnancy and lactation were excluded.

Study procedure: The patients fulfilling the inclusion criteria were enrolled after explaining the study in detail and receiving informed consent. In each patient, history was evaluated and a complete physical examination including breast, abdominal examination and per vaginal examination was performed. Personal details, history, clinical features and investigations were recorded in the Case record form structured for the study.

Criteria for selection of drug: the research drug possess properties like *muhallilewaram*, *mujaffif*, *mudammilequruh*, *dafi-i- ta'ffun,qabid, musakkin*, [12-17] properties. Moreover, pharmacological studies show that research drug exhibit anti microbial, anti-inflammatory, anti oxidant, anti-cancer, anti-ulcer, analgesic, hepatoprotective wound healing activities.[13,14,18-20,] Further *methi, alsi, nakhoona, baboona, karamkalla*contains flavonoids, saponins (glycosides), alkaloids (terpenoids, steroids) arachidonic acid, ethanol, histamine, leukotriens, polysaccharides, saponins (glycosides), carbohydrates, tannins, triglisoraletc; [13,14,18,] which are considered as the active principle of anti-ulcer activity. Flavonoids are a group of a polyphenolic compound having anti-ulcerogenic, anti-inflammatory, anti-bacterial, antioxidants properties[4] which provide strength to the mucosal barrier & promote the ulcer to heal fast. [20]The wound healing activity of Unani formulation as *abzan* might protect against microbial invasion by providing better tissue formation. Further, it enhances the rate of wound healing & tissue epithelization[4] Thus, research Unani formulation is anticipated to be effective in the healing of cervical ectopy and relieving the associated symptoms.

Method of preparation

The best quality of methi, alsi, babuna, nakhuna, and karmkalla was provided by the pharmacy of NIUM, and was further authenticated by *FRLHT Bengaluru.* with an acc. No. 5510-5514. All the drugs were finely powdered. Drugs were weighed and mixed. The powdered drugs were dispatched in

plastic self-lock bags. To avoid any confusion regarding dosages one lock bag was used to dispatch 28gm of the drug for a single day which was to be used daily for one measure for sitz bath. So every patient was given 7 packets of the drug for one week at each visit and continued for 3 weeks.

Route of administration: Locally

Initial assessment and laboratory screening

1. Baseline Laboratory investigations like haemoglobin percentage, total leucocyte count, differential leucocyte count, erythrocyte sedimentation rate, Veneral Disease Research Laboratories test and random blood sugar were done to exclude general diseases. Ultrasonography of pelvis was done to exclude pelvic pathology. Pap smear was done to exclude genital malignancy in each case.
2. Assessment of the extent of erosion was graded as 0, 1, 2 and3; as follows. Grade 0: No erosion Grade 1: covering 1/3rdof cervix Grade 2: from 1/3rd to 2/3rd area of the cervix, and Grade 3: overs 2/3rd of the cervix. The assessment was done before treatment, at each follow up during treatment and after treatment. Patients were also enquired for any side effects during the trial.
3. Assessment of Health-related quality of life (HRQol) was assessed by the SF-12 questionnaire.
4. Assessment of low backache is done by using the Visual Analogue Scale (VAS)
5. Assessment of vaginal discharge was graded from 0 to 4 grade: score: 1-No discharge; 2- Mild (No staining or moistness of undergarments); 3-Moderate (stain on undergarments); Score:4- severe (using pads).
6. Dyspareunia and post-coital bleeding were based on the arbitrary four-point scale (0= None,1=Mild,2= Moderate, 3= Severe).

Treatment was subsequently started in patients fulfilling the inclusion criteria.

Intervention

Joshanda of *methi* (Trigonella foenum graceum) 5gms, *alsi* (Linum usitatissium graceum) 5gms, *babuna* (Matricaria chaemomilla) 3gms, *nakhuna* (Trigonella uncata) 5gms, *karmkalla ka danthal* (Brassica oleracea) 10gms was prepared by soaking the drugs in 400ml of water for the whole night. Next day in the morning the soaked drugs with water was boiled until it was concentrated to 180 ml. Abzan were prepared according to the standard method of preparation. It was used for 15minuts daily for 21 days after menses. Assessment of erosion and health-related quality of life (HRQol) was done at baseline, each follow up during treatment (weekly) and after treatment (once in 15 days for a month). Patients were also enquired for any side effects during the trial. Patients were advised to maintain personal hygiene and avoid intercourse during the treatment.

Subjective parameters

Vaginal discharge, low backache, contact bleeding, dyspareunia

Objective parameters:

1. Changes in Cervical ectopy assessed by the arbitrary grading scale
   (Direct visual assessment of the appearance of cervix, healing of erosion and vaginal discharge).
2. SF-12 score to assess for QOL

Outcome measures:

Primary outcome measure: changes in white discharge and low backache.

Secondary outcome measure: Improvement in cervical ectopy grading and SF-12 (12 items short-form survey) Health Questionnaire score (Figure 1).

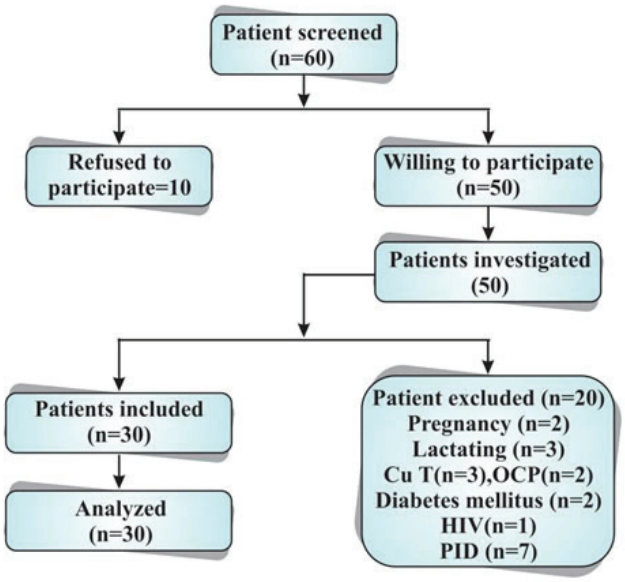

Figure 1: Study design.

Statistical analysis

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. 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 have been used to generate graphs, tables etc.[22,23]

RESULTS AND DISCUSSION

Demographic characteristics

Age: Majority of the patients (63.3%) were in the age group of 31-40 years & remaining 30% were in 21-30 years and 6.7% in 41-50 years of age. Hashmi et al[24], Mirza et al[25], Patil et al 26 and Latafat et al.[27] 40% and 44% in two groups in 31-35 yrs, reported 39.2% in 31-40 yrs., reported 40% &37.8% in 26-30 yrs. respectively. The result of present study correlates with the above studies. Evidence suggests that cervical ectopy is common in women of reproductive age group.[4,7] Mean±SD of age of patients was 33.93±5.37, which is in accordance with the study of Jindal et al.[2] who reported 31.32 and 33.7 in two groups, Al- Kaseer reported[28] 27.1 ± 5.9, Cekmez et al.[29] reported 34.4±4.3.

Socioeconomic status: In present study, 23.3% patients belongs to upper middle class, 63.3% to lower middle class; and 13% to lower class. Hashmi S et al.[24] reported 43.3% patients in upper lower, 36.6% in upper middle, 16.6% in lower middle and 13.3% in lower class. Mirza et al.[25] reported 42.2% patients in upper lower class, 40% in lower middle, 11.1% in upper middle & 6.7% in upper class. Shivanna et al. [30] reported 72% and 75% patients respectively from low Socioeconomic status. Gautam et al.[31] reported majority of the patients belong to lower middle class. Bengal et al.[32] reported that maximum patients having cervical ectopy belong to low socioeconomic class, low literacy level, poor personal hygiene and poor health awareness. Literature report says that low socio economic status predispose to poor nutrition, poor personal hygiene leading to infection which may cause cervical ectopy.[32,33]

Literary status: Most of the patients had low educational level i.e.; 36.7% patients had primary school education, while 13.3% were illiterate, 23% & 16.7% had education up to secondary and higher secondary school while graduate and post graduate are 6.7% and 3.3 % respectively. Mirza et al.[25] reported 20% illiterate, 33.3% had middle school education, 10% each in primary school and high school & 13.3% graduate. Hashmi S et al.[24] reported 44.44% illiterate, 20% had middle school education & 13.3% had education in each primary, secondary and higher secondary. Gautam et al.[31]reported 40% of the patients had high school education. Al-Kaseer et al.[28] reported low educational level among patients of cervical ectopy.

Occupation: In this study house wife are more affected than the working class. Out of 30 patients 73.3% of patients are of house wife affected with cervical erosions where as 26.7% are working women.

Dietetic habit: In this study out of 30, 20 (66.7%) patients are of mix diet. Whereas 10 (33.3 %) are vegetarian. In *Unani* system of medicine importance has been given to dietetics in health and disease.[34] *Unani* physicians mentioned certain foods which are to be taken and to be avoided according to age, season, place, and *mizaj* of the person. The temperament of meat is *har*, when consumed in excessive quantity; it causes increase production of *khilte dam*, and can lead to *amrazedamvi*. As, mentioned earlier that cervical erosion with cervicitis is a *damvi marz*,[35] it may be assessed that non vegetarian diet has its impact on this disease as per the *mizaj* and *akhlat* theory.

***Mizaj*:** Most of the patients, 86.7 % possessed *damwimizaj,* while 13.3% had *balghamimizaj*, none of the patients had *safrawi* or *saudawimizaj,* which is in consonance with the studies of Hashmi et al.[24] reported 66.67 % patients with *damwimizaj*, Mirza et al.[25] reported 53.3% with *damwimizaj*. Moreover, it coincides well with the theories of eminent Unani Scholars in etiopathogenesis of *quruh*, who states that *hararat* and *ratubat* are essential component of *ufunat* which forms an inflammatory swelling and when it get secondarily infected, it result in rupture of this swelling which in turn leads to ulcer formation.[10,36.]

Table 1: Baseline characteristics.

Age in years	No. of patients (N=30)	%
21-30	9	30.0
31-40	19	63.3
41-50	2	6.7
Mean ± SD: 33.93±5.37 P > 0.10		
Socio Economic Status		
Lower	4	13.3
Lower Middle	19	63.3
Upper Middle	7	23.3
Occupation		
H.W.	22	73.3
Others	8	26.7
Diet		
Mixed	20	66.7
Veg	10	33.3
Literary status		
Ill	4	13.3
Prim	11	36.7
Sec.	7	23.3
Hr. Sec.	5	16.7
Graduate	2	6.7
Post G.	1	3.3

Subjective parameters

Vaginal discharge: At baseline, all patients were complaining of vaginal discharge. During treatment, on 1st & 2nd follow up, it persists in 96.3% and was absent in 3.3% patients respectively. After treatment, it persists in 36.7% with mild

discharge. & was absent in 63.3%.At baseline, vaginal discharge was mild, moderate & severe in 3.3%, 56.7% & 40% patients respectively. During treatment, on 1st follow up vaginal discharge was mild & moderate and severe in 3.3% , 70% and 26.7% patients respectively, whereas none of the patients had severe vaginal discharge; on 2nd follow up, vaginal discharge was not present in 3.3% and 26.7% and 70% patients had mild and moderate vaginal discharge respectively. After treatment, vaginal discharge was mild in 36.7% & absent in 63.3% patients, though no patient had moderate and severe vaginal discharge. After treatment, vaginal discharge with mean of 2.37±0.57 and 0.367±0.49 before and after intervention with P<0.001, considered as highly significant, which is consistent with the study of Gupta P et al.,[37] Monroy OL[38] & Anees S, [39] studies who reported vaginal discharge in 100% patients before treatment and relief in 86.6% after treatment. Cekmez Y et al.[29]reported vaginal discharge in 91.9% patients with complete relief in 89.5%.Kamini D[3] reported 93.45% and Hashmi S et al.[24]reported 100% improvement in vaginal discharge. Moreover, research drug possess *muhallilewaram, daffi-i- tafun,* anti-microbial, anti-fungal, anti-viral activities, which might resolve the inflammation after removing the infection and thus improves the vaginal discharge (Table 2).[14,16,17,19,40-43]

The unani formulation was most successful in managing white discharge as all 30 patients presenting with vaginal discharge were having no discharge after the treatment. Other associated symptoms of cervicitis like low backache, lower abdominal pain, and dyspareunia were significantly relieved. Pharmacological studies reported that *methi, alsi, babuna, nakhuna*and *karamkalla*[12] are proved for antimicrobial effect that may have inhibit the growth of organism and also these drugs are having anti-inflammatory property.[18,40,45] The improvement in these symptoms is most probably because of the effect of the test drugs having *musaffikhoon*, *muhallil, dafetaffun, qabiz, mujaffifqurooh* properties and *baridwayabismiz.*[46] As discussed earlier in etio-pathogenesis *zoefequwateghazia* is one of the main causes of *saylanurrahim* that leads to this disease and *baridwayabismizaj* of drugs tone up the *quwateghazia* of *rahim*[10] and thereby rectifying the quality and quantity of *khilte dam.* Further, astringent drugs have been reported to decrease the secretions, which may have inhibitory effect.

Table 2: Assessment of Vaginal Discharge in cervical erosion patients studied.

Vaginal Discharge	Before Treatment	I Follow up	II Follow up	III Follow up	After Treatment	% Difference
Nil	0(0%)	0(0%)	1(3.3%)	2(6.7%)	19(63.3%)	63.3%
Mild	1(3.3%)	1(3.3%)	8(26.7%)	24(80%)	11(36.7%)	33.4%
Moderate	17(56.7%)	21(70%)	21(70%)	4(13.3%)	0(0%)	-56.7%
Severe	12(40%)	8(26.7%)	0(0%)	0(0%)	0(0%)	-40.0%
Total	30(100%)	30(100%)	30(100%)	30(100%)	30(100%)	-
Mean±sd		BT 2.37±0.56			AT 0.37±0.49	
P value			P<0.0001			

Test used: Paired proportion test

Low backache: After treatment, compared to baseline low backache was relieves in 90% patients with mean of 1.93±0.37 and 0.1±0.36 before and after intervention respectively, with P<0.0001 considered as highly significant. Anees[39] reported 100% patient's with complaining of low back pain and relief in 66.7%. Mirza et al[25] reported 53.3%, Hashmi et al.[24] reported 30%, Kamini[3] reported 64 %, and Al-Kaseer et al.[28] reported 65% improvement in low backache. low backache at baseline, after treatment was nil, mild, moderate, and severe, ie 90%, 10%,0%,0% respectively with P<0.001, considered as highly significant, which is in accordance with the studies of Kamini et al.[3] reported1.26±0.4 and 0.46±0.4, Sharma et al.[44]reported 1.90±0.60 and 0.95±0.60 & Gautam et al.[31]reported 1.12±0.169 and 0.75±0.619 as Mean ±SD of low backache before and after treatment. Moreover, research drug possess *muhallilewaram, musakkin,* anti-inflammatory, analgesic, sedative activities which might resolve the inflammation and hence improves low backache (Table 3).[14,16,17,19,40-43]

Table 3: Assessment of Low Backache of in cervical erosion patients studied.

Low Backache	BT	I-FU	II-FU	III-FU	AT	% Difference
Nil	0(0%)	0(0%)	1(3.3%)	13(43.3%)	27(90%)	90.0%
Mild	3(10%)	6(20%)	26(86.7%)	17(56.7%)	3(10%)	0.0%
Moderate	26(86.7%)	24(80%)	3(10%)	0(0%)	0(0%)	-86.7%
Severe	1(3.3%)	0(0%)	0(0%)	0(0%)	0(0%)	-3.3%
Total	30(100%)	30(100%)	30(100%)	30(100%)	30(100%)	-
Mean±SD			BT 1.93±0.37		AT 0.1±0.31	
P value			P<0.0001			

Test used: Paired proportion test

Dyspareunia: Dyspareunia in 70% of patients with mild and moderate 46.7% and 23.4% respectively was observed. Whereas 30% of patients are free of dyspareunia. In first follow-up of treatment 36.7% are free with dyspareunia in mild and 20%in moderate dyspareunia patients. Where as in second follow up 46.7% patients were free of dyspareunia where as 53.3% were having mild dyspareunia. Where as in third follow up it is improved to 80% with dyspareunia free and 20% with mild Dyspareunia. The mean is 0.93±0.734and 0.03±0.18 before and after treatment respectively with p<0.0001 which is highly significant. After treatment 96.7% patients are free of this symptom with a % difference of 66.7, and 3.3% with mild dyspareunia with a% difference of -43.4 (Table 4).

Table 4: Assessment of Dyspareunia in cervical erosion patients studied.

Dyspareun-ia	BT	I-FU	II-FU	III-FU	AT	% Difference
Nil	9(30%)	11(36.7%)	14(46.7%)	24(80%)	29(96.7%)	66.7%
Mild	14(46.7%)	13(43.3%)	16(53.3%)	6(20%)	1(3.3%)	-43.4%
Moderate	7(23.3%)	6(20%)	0(0%)	0(0%)	0(0%)	-23.3%
Severe	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0.0%
Total	30(100%)	30(100%)	30(100%)	30(100%)	30(100%)	-
Mean±sd			BT 0.93±0.74		AT 0.03±0.18	
P value			P<0.0001			

Test used: Paired proportion test

Contact bleeding: In this study out of 30 patients 25 (83.4%) had contact bleeding. with mild in 14(46.7%), moderate in 9 (30%) and severe in 2 (6.7%) patients. In first follow up of treatment one severe case of contact bleeding responded well. Where as in second follow up 43.3% are free of contact bleeding. Whereas 46.7% had mild type and 6.7% had moderate and 3.3% has severe contact bleeding. In third follow up 70% got relieved totally from contact bleeding and only 26.7% had mild contact bleeding and 3.3% had moderate bleeding in patients of cervical erosion. The mean is 1.27±0.83 and 0.03±0.18 before and after intervention with p<0.0001 which is highly significant. After treatment 96.7% of patients are free of contact bleeding and 3.3 % with mild contact bleeding. This show the effect of *abzan* of unani formulation as mentioned in unani literature (Table 5).

Table 5: Assessment of Contact bleeding in cervical erosion patients studied.

Contact Bleeding	BT	I-FU	II-FU	III-FU	AT	% Difference
Nil	5(16.7%)	5(16.7%)	13(43.3%)	21(70%)	29(96.7%)	80.0%
Mild	14(46.7%)	14(46.7%)	14(46.7%)	8(26.7%)	1(3.3%)	-43.4%
Moderate	9(30%)	10(33.3%)	2(6.7%)	1(3.3%)	0(0%)	-30.0%
Severe	2(6.7%)	1(3.3%)	1(3.3%)	0(0%)	0(0%)	-6.7%
Total	30(100%)	30(100%)	30(100%)	30(100%)	30(100%)	-
Mean±SD			BT 1.27 ± 0.83		AT 0.03±0.18	
P value					P<0.0001	

Test used: Paired proportion test

Objective parameters

Cervical ectopy grading: At base line, cervical ectopy was observed in 100% patients, which remains in 43.3% patients after treatment. Cervical ectopy was in grade I in 40% patients, grade II in 50% & grade III in 10%; during treatment, After treatment, on 1st follow up, 40% patients had cervical ectopy in grade I, 3.3% in grade II and none of the patient had cervical ectopy in grade III; Thus, cervical ectopy was reduced in 43.3% and cured in 56.7% patients with P=0.0054, considered as highly significant. The mean is 1.7±0.66 and 0.47±0.58 before and after intervention with p<0.0001 which is highly significant. Shivana et al.[30] reported healing of cervical ectopy in 60% patients after 7 days, 30% after 14 days and 10% after 21 days of treatment. Sharma et al.[44] reported improvement in 65.85% patients, Cekmez et al.[29] reported in 95.9% patients after 6 weeks. Gautam et al[31]reported improvement in 53.4%patientsafter 7days. Hence, complete healing of cervical ectopy as observed in 20% patients only after 2 weeks of treatment. Moreover, research drug possess *mussakin, muhallil- i- auram mullayan, mujaffif, mudammillequruh, qabid,* antiulcer, antioxidant & wound healing activities,

which might be helpful in healing of cervical erosion (Table 6).[14,16,17,19,40-43]

Table 6: Assessment of Grading of cervical erosion patients studied.

Grade	Before Treatment	After Treatment	% Difference
0	0(0%)	17(56.7%)	56.7%
1	12(40%)	12(40%)	0.0%
2	15(50%)	1(3.3%)	-46.7%
3	3(10%)	0(0%)	-10.0%
Total	30(100%)	30(100%)	-
Mean±sd	1.7 ±0.66	0.47±0.58	
P value		P<0.0001	

Test used: Paired proportion test

QOL by SF-12 score: Cervical erosion with its symptoms has a broad impact on HRQoL and puts a heavy economic burden on society.[47] The mean± SD before intervention was 382.73± 52.33 and after it was 910.17±56.30 with mean difference 0f 910.17 and p value <0.0001. It shows strongly significant improvement in the quality of life (Table.7).

Table 7: Assessment of SF-12 in cervical erosion patients studied.

SF-12	BT	A T	% difference
<300	2(6.7%)	0(0%)	-6.7%
300-400	15(50%)	0(0%)	-50.0%
>400	13(43.3%)	30(100%)	56.7%
Total	30(100%)	30(100%)	-
Mean±sd	382.73± 52.33	910.17±56.301	
P< 0.0001			

Test used: Paired proportion test

Primary outcome measures

Vaginal discharge: the mean of vaginal discharge before and after treatment is 2.37±0.57and 0.37±0.49 respectively with a P<0001**.** Improvement in vaginal discharge was nted in 90% patients; while it persist in 10% patients after 2 weeks of treatment; Anees S[31]reported 86.6% after 1 week, Jindal M [2] reported 100% and 92% in two groups after 4-6weeks of treatment (Table 8).

Low backache: The mean± sd of low back ache before intervention was 1.93±0.37and after it was 0.1±0.36 with mean difference 0f 90.0% and p value <0.0001. Absence of low back ache was noted in 90% patients, where it was in mild in 10% of patients after 3 weeks of treatment, which correlating with the study of Jindal M [2] reported relief in 96% & 76% in two groups after 4-6weeks of treatment (Table 8).

Dyspareunia: The mean is 0.93±0.74and 0.03±0.18 before and after treatment respectively with p<0.0001 which is highly significant. This study shows dyspareunia is absent in the 96.7% of patients with mild in 3.3%.. In first follow-up of treatment 36.7% are free with dyspareunia 43.3 in mild and 20%in moderate had dyspareunia. Where as in second follow up 46.7% patients were free of dyspareunia where as 53.3% were having only mild dyspareunia. In third follow up in80% were dyspareunia free and 20% with mild Dyspareunia. After treatment 96.7% patients are free of this symptom with a % difference of 66.7, and 3.3% with mild dyspareunia with a% difference of -43.4. It show that unani formulation having *muhallileawram, jail, mussakinealam* etc. properties helps in relieving pain (Table 8).

Contact bleeding: The mean is 1.27±0.83 and 0.03±0.18 before and after intervention with p<0.0001 which is highly significant. In this study patients with contact bleeding, mild in 14(46.7%), moderate in 9(30%) and severe in 2(6.7%) patients. In first follow up of treatment one severe case of contact bleeding responded well. In second follow up43.3% are free of contact bleeding. Whereas 46.7% had mild type and 6.7% had moderate and 3.3% has severe contact bleeding. In third follow up 70% got relieved totally from contact bleeding and only 26.7% had mild contact bleeding and 3.3% had moderate bleeding. After treatment 96.7% of patients are free of contact bleeding and 3.3 % are with mild contact bleeding with % difference of 80.0% (Table 8). This show the effect of *abzan* of unani formulation as mentioned in unani literature.

Secondary outcome measure

Cervical ectopy grading: complete healing of cervical ectopy was observed in56.7% patients & no improvement in 43.3% patients after 3 weeks of treatment. The mean is 1.7±0.65 and 0.47±0.58 before and after intervention with p<0.0001 which is highly significant. Hashmi S et al.[24] reported cure in 26.66% patients after 9 weeks of treatment. Shivanna S et al.[30] reported in 60% patients after 1week and in 40% after 3 weeks of local application of albothyl solution. Jindal M et al.[2] reported 92% & 76% respectively in two groups (electro cautery/ cryocautery) after 4-6weeks. Cekmez et al.[29]reported in 95.9% patients after 6 weeks of cryocautery (Table 8).

QOL by SF-12 score: The eight domains of SF-12 measures are as follows: physical functioning role: role limitations due to physical health, role limitation due to emotional problems, energy /fatigue, emotional wellbeing social functioning, pain general health.[47]The mean± sd before intervention was 382.73± 52.33 and after it was 910.17±56.30 with mean difference 0f 910.17 and p value <0.0001. It shows strongly significant improvement in the quality of life. Cervical erosion with its symptoms has a broad impact on HRQoL and puts a heavy economic burden on society (Table 7). Hence the unani formulation makes a strongly significant change in SF-12 score hence improvement in quality of life (Table 8).

Table 8: Assessment of primary and secondary outcome in cervical erosion patients

Outcome	BT	AT	P value
Primary outcome			
Vaginal discharge	2.37±0.57	0.37±0.49	p<0.0001
LBA	1.93± 0.37	0.1±0.31	P<0.0001
Contact bleeding	1.27 ± 0.83	0.03±0.18	P<0.0001
Dyspareunia	0.93±0.74	0.03±0.18	P<0.0001
Secondary outcome			
Cervical erosion grading	1.7 ±0.65	0.47±0.58	P<0.0001
SF-12	382.73± 52.33	910.17±56.30	P<0.0001

Interpretation; significant reduction in primary and secondary outcome parameters.

DISCUSSION

The present study entitled "Efficacy of *Abzan* with Unani formulation in *Quruhal Rahim* - An open observational study" was effective in the healing of cervical erosion and relieving the symptoms. In the present study, it was demonstrated that complete healing of cervical ectopy was achieved in 56.7% of patients with mean of 1.7±0.66 & 0.47±.57before and after respectively. Vaginal discharge was improved in 63.3% patients with mean of 2.37±0.56 and 0.37±0after treatment respectively (Table 1 and 2). While it persists in mild form in 36.7%. Low backache was relieved in 90% patients, and remains 10% in mild form, with mean of 1.93±0.37 and 0.1±0.36 (Table 3). Highly significant improvement in vaginal discharge and low backache was might be due to healing of cervical ectopy, which cause relief in these symptoms. No adverse effect of research unani formulation was reported during the study.

Hence, marked improvement in outcome measures with just 3 weeks of intervention with research unani formulation as topical application was due to the effect of research drug which possess *muhallilewaram*, *mujaffif*, *mudammilequruh*, *dafi-i-ta'ffun, qabid, musakkin*, [12,13,14,15,16,17] properties. Moreover, pharmacological studies shows that research drug exhibit anti microbial, anti-inflammatory, anti oxidant, anti cancer, anti ulcer, analgesic, hepato protective wound healing activities.[13,14,18,19,20] Further *methi, alsi, nakhoona, baboona, karamkalla* contains flavonoids, saponins (glycosides), alkaloids (terpenoids, steroids) arachidonic acid, ethnol,histamine, leukotriens, polysachorides, saponins (glycosides), carbohydrates, tannins, triglisoraletc,[13,14] which are considered as the active principle of anti ulcer activity. Flavonoids are group of polyphenolic compound having anti ulcerogenic, anti inflammatory, anti bacterial, antioxidants properties[4] which provide strength to the mucosal barrier & promote the ulcer to heal fast.[21] The wound healing activity of unani formulation as *abzan* might protect against microbial invasion by providing better tissue formation. Further, the it enhance the rate of wound healing & tissue epithelization.[4]

Thus, research unani formulation was effective in healing of cervical ectopy and relieving the associated symptoms. Moreover, significant improvement would be expected if duration of treatment was at least 6-8 weeks. Hence, it can be inferred that research unani formulation shows potent wound healing action, the recovery of wound might be due to the presence of chemical constituents which might favored wound healing action. Hence, it serves as an effective alternative in patients with cervical ectopy, particularly in those patients who are either not willing for cryotherapy or in whom cryotherapy is contraindicated.

This study was first of its kind; where treatment was given as *abzan* form which directly affects the eroded cervical area. However, small sample size, short duration of intervention, short follow up, colposcopy was not done during the study are some limitations.

Future recommendation:

- Use of research unani formulation as *abzan* for longer duration (6-8 weeks) on large number of patients with long follow up for better therapeutic outcome.
- To conduct RCT's with *abzan* of research formulation with standard treatment i.e.r electrocautery or cryo cautery.
- Future trial with use of this research formulation in patients with abnormal cervical cytology or Cervical intraepithelial neoplasia

CONCLUSION

It can be inferred that *Abzan* of unani formulation is effective in healing of cervical erosion and the inflammatory response due to associated cervicitis. It was found to be safe drugs when used as *abzan* for 21 days. Thus, the formulation may be effective and safe for the management of cervical ectopy. Hence, it serves as an effective alternative in patients with cervical erosion.

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REFERENCES

1. Kumari RC, Singh BK. Role of Udumbaradi Tail in the management of a vaginal discharge due to Cervical erosion: A case report. Int J Res Ayur Pharm 2013;4(4):631-633.
2. Jindal M, Kaur S, Sharma S, Gupta KB, Pandotra P. What is better: cryocautery or electrocautery for cervical erosion? Int J Reprod Contracept Obstet Gynecol 2014; 3(3):715-719.
3. Kamini D, Meena.P. Kampillakadighrita in Garbhashaya Greeva Gata Vrana (Cervical Erosion). IJARP 2012;3(2):203-209.
4. Solanki SK, Sharma S. Role of Kshara Karma in the Management of Cervical Erosion. Ayurpharm Int J Ayur Alli Sci 2016;5(6):77-82.
5. Kartik K, Venkatesh, Uvin S. Assessing the relationship between cervical ectopy and HIV susceptibility: implications for HIV prevention in women. Am J Reprod Immunol 2013;69:68-73.
6. Yogesh M, Hetal B, Shachi P. Effect of Udumber-Sar in Garbhashaya Grivamukhagata Vrana (Cervical erosion)- A case study. IJAAR GAU J. Int J Appl Ayur Res 2017 Oct;3(4):781-784.
7. Dutta DC. Text Book of Gynecology 7th Edn. New Delhi: Jaypee Brothers Medical Publishers Ltd. 2016. Pg. 217-218.
8. Khan A. Al Akseer (Urdu trans. by Kabeeruddin). 1st ed. New Delhi: Idarae Kitabul Shifa; 2011:788-90.
9. Razi ABZ. Al Hawi Fil Tib. Vol IX. New Delhi: CCRUM; 2001:10,12,24,25,36,42 ,47,50,
10. Ibn Sina. Al Qanoon Fil Tib (Urdu trans. by Kantoori GH).Vol III. New Delhi: Idarae Kitabul Shifa; 2010:1092,125-126.
11. Qamari MH. Ghana Mana. 1st ed. New Delhi: Markazi Council Barai Tehqeeq Tibbe Unani; 2008: 414-415.
12. Halim MA. Mufradate Azizi. New Delhi: Central Councill Research for Unani Medicine, 2009. p.49.
13. Swaroop A, Jaipuriar AS, Gupta SK, Bagchi M, Kumar P, Preuss HG, et al. Efficacy of a novel fenugreek seed extract (Trigonellafoenum-graecum, FurocystTM) in polycystic ovary syndrome (PCOS). Int J Med Sci 2015;12(10):825.
14. Umer KH, Zeenat F, Ahmad W, Ahmad I, Khan AV. Therapeutics, phytochemistry and pharmacology of Alsi (Linumusitatissimum Linn): An important Unani drug. J Pharmacog Phytochem 2017;6(5):377-383.
15. Khan ZJ, Khan NA, Naseem I, Nami SA. Therapeutics, phytochemistry and pharmacology of Tukhm-e-Katan (Linumusitatissimum L.). Int J Adv Pharm Med Bioallied Sci 2017; 2017:1-15.
16. Rashid N, Dar PA, Ahmad HN, Rather SA. Alsi (Linum Usitatissimum (Linn.): A potential multifaceted Unani drug. J Pharmacog Phytochem 2018;7(5):3294-3300.
17. Hakim A. Tajudlin. Ahmed G. Jahan N. Evaluation of anti-infllammatory activity of the pods of iklil-ul-Malik (Astraogalushamosus. Linn). Indian J Natl Prod Reso 2010;(I):34-37.
18. Jabeen A, Khan AA, Alam T, Maaz M, Mohmad SH. J Pharmac Sci Innov 2014;3(5):401-409.
19. Umer KH, Zeenat F, Ahmed W. Khan VK. Theraputics phytochemistry and pharmacology of Iklilul Malik (Astragalus hamosus Linn) A natural unani remedy. Int J Herb Med 2017;5:1-4.
20. Khan MA. Asmaul Advia (Edited hy S. Z. Rehman). Aligarh: Publication Division. AMU: 2002:45
21. Gur CS, Onbasilar I, Atilla P, Genc R, Cakar N, Gurhan ID, et al. In vitro growth stimulatory and in vivo wound healing studies on cycloartane-type saponins of Astragalus genus. J Ethnopharmacol 2011;134: 844-850.
22. Bernard Rosner. Fundamentals of Biostatistics, 5th Edition, Duxbury, 2000;pg 80-240.
23. Suresh KP, Chandrasekhar S. Sample Size estimation and Power analysis for Clinical research studies. J Human Reprod Sci 2012;5(1):7-13.
24. Hashmi S, Begum W, Sultana A. Efficacy of *Sphaeranthusindicus* and cream of *Lawsoniainermis* in cervical erosion with cervicitis. Eur J Integr Med 2011;3:183-185.
25. Mirza S, Naaz SA, Alim SM, Rahman A. Analgesic, anti-inflammatory and anti-microbial activities of Irsa (*Irisensata):* A clinical study on the patients of Iltehabe Unqur-Reham (Cervicitis). IJPPR 2015;3(4): 66-72.
26. Patil P, Sharma P. Colposcopic evaluation of cervical erosion in symptomatic women. Int J Reprod Contracept Obstet Gynecol 2017;6(6):2207-2211.
27. Latafat T, Siddiqui MMH, Jafri SAH. A Clinical study of marhamdakhlion on chronic cervicitis and cervical erosion; Ancient Sci Life 1992;11(3&4):158-162.
28. Al-Kaseer EA. Epidemiological characteristics of women with cervical erosion in Al-Sader city, Baghdad, Iraq. J Fac Med Baghdad 2010; 52(2):157-158.
29. Cekmez Y, Sanlikan F, Gocmen A, Vural A, Turkmen SB. Is cryotherapy friend or foe for symptomatic cervical ectopy? Med Princ Prac 2016;25:8-11.
30. Shivanna BS, Shivanna L, Kulkarni P. Comparative study of efficacy of cryosurgery and Albothyl® solution in the management of cervical erosion in a rural hospital. J Dent Med Sci 2014;13(9):106-109.
31. Gautam A, Rajan S, Rajan S, Sharma E. A clinical study of Kusthadi Varti in Karnini Yonivyapada w.s.r. to cervical erosion. Int J Curr Res 2017;9(12):62140-62143.
32. Bangal VB, Patil NA, Gavhane SP, Shinde KK. Colposcopy guided management of cervical erosions in Rural population. Sch J App Med Sci 2014;2(1):261-265.
33. Koteswari M, Rao N, Renuka IV, Devi CP. A study of Pap smear examination in women complaining of leucorrhea. J Dent Med Sci 2015;14(1):37-42.
34. Zulkifle M, Ansari AAH, Shakir M, Kamal Z, Alam T. Management of non-healing leg ulcers in Unani system of medicine. Int Wound J 2012; 366-372.
35. Qadry JS. Pharmacognosy. 16th ed. New Delhi: JS. Offset Printers; 2014: 170.
36. Ibn Rushd. Kitabul Kullyat. (Urdu trans.). New Delhi: CCRUM; 1980.pg.79-81.
37. Gupta P, Sharma S. Clinical evaluation of the efficacy of Kashara Karma with ApamargaKashara and Jyatyaditailapichu in the management of cervical erosion (Karniniyonivyavada).WJCPMT. 2015; 1(3): 43-49.
38. Monroy OL, Aguilar C, Lizano M, Talonia FC, Cruz RM, Zavaleta LR. Prevalanceof human papillomavirus genotypes and mucosal IgA anti-viral responses in women with cervical ectopy. J Clin Virol 2010;47:43-48.

39. Anees S, Mustafa S. Clinical study for the efficacy of Unani formulation in the management of vaginal discharge associated with cervicitis (Iltehabe unqurrehm). IABCR 2017;3(4):127-129.
40. Tanvir A, Izharul H, Aisha P, Nazamuddin M, Shaista P. Hulba (Trigonella foenum graecum): The common Indian spice full of medicinal values. Int J Preclin Pharmac Res 2014;5(1):41-46.
41. Idris AM. Methi (Trigonella fenum graceum): A Multifunctional Herbal Drug. JHMR. 2018,3(26):1-8.
42. Dharajiya D, Jasani H, Khatrani T, Kapuria M, Pachchigar K, Patel P. Evaluation of antibacterial and antifungal activity of fenugreek (Trigonella foenum graecum) extracts. Int J Pharm Pharm Sci 2016;8(4):212-217.
43. Miraj s, Alesaidi S. A systemic review study of the therapeutic effects of Matricaria recuitta chamomile (chamomile). Electr Physic 2016;8(9):3024.
44. Sharma P, Sharma S, Nariyal V. A clinical study to evaluate efficacy of Snuhi Kshara and Dhatakyadi Tail Pichu in the management of Karnini Yonivyapad w.s.r. to cervical erosion. Int Ayur Med J 2016;4(9):2793-2798.
45. Hussain SM. Herbal unani Medicine all India; Unani Tibbi conference New Delhi 53
46. Kabeeruddin M. Makhzanul Mufradat. New Delhi. Aijaz publication house: 2007:74-75, 76-77, 93-94, 398-399.
47. Larson CO, Schlundt D, Patel K, Hargreaves M, Beard K. Validity of the SF-12 for use in a low-income African American community-based research initiative (REACH 2010). Prev Chronic Dis Public health Res Pract Policy 2008;5(2):01-11.