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Original Article

Effect of *Althea officinalis* Linnaeus *(Tuqme khatmi)* in Cervicitis *(Iltehabe unqur rehm)* - An Open Observational Clinical Study

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ABSTRACT

Introduction: Cervicitis *(Iltehabe unqur rehm)* is characterized by inflammation of the cervix. Patients may present with complaints of abnormal vaginal discharge, post coital bleeding, dyspareunia, lower backache and lower abdominal pain. In Unani system of medicine *Tukhme khatmi* has been Discharge selected out from various available drugs in *sailan ur raham*. **Aim:** To evaluate the effect of *Tukhme khatmi (Althea officinalis* Linnaeus) in cervicitis. **Materials and Methods:** Clinically diagnosed patients (n=30) married women between age group of 18-45 yrs with regular menses were included considering selection criteria. *Safuf* of *tukhme khitmi* 5gms with *Shahed* and *marham* of *tukhme khitmi* will be prepared as per standard preparation. *Safuf* twice daily orally and *Humul* at bed time for 21 days after menses with weekly follow up. Subjective and objective parameters were assessed. Primary outcome and Secondary outcome were assessed for Improvement in Abnormal Vaginal LBA, LAP, CB, dyspareunia, VSS score, VAS and SF-12 for QOL and for any adverse effect safety profile was done. **Results:** there was a significant improvement in abnormal vaginal discharge with a mean of 2.37±0.56 BT and 0.37±0 AT with $p<0.0001$ and other associated sign and symptoms of cervicitis. VSS with a mean of 1.80±0.48 BT and 0.03±0.182 AT shows significant change with $p<0.0001$ after intervention. QOL was markedly improved. **Conclusion:** Considering the above result *tuqme khitmi* is effective in alleviating symptoms of cervicitis. It can serve as an alternative treatment without any side effects and it is also cost effective. Further research is needed in large sample size for longer duration.

Keywords: Cervicitis, *Warme unqur rehm, Tuqme khatmi, Humul,* VSS, VAS, SF-12.

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INTRODUCTION

Cervicitis is an inflammation of the uterine endocervix's columnar epithelium. Acute or chronic symptoms can occur, with infectious causes causing acute symptoms and non-infectious agents causing chronic symptoms.[1] The disease's clinical range includes anything from asymptomatic cases to patients with mucopurulent cervical discharge and systemic symptoms. Regardless of how they appear on the surface, any of these circumstances could result in life-threatening outcomes such as pelvic inflammatory disease (PID).[2] As a result, it's vital for the doctor to identify the symptoms as soon as feasible, investigate and make a diagnosis, and begin effective treatment as soon as possible.[3]

The most common age group is sexually active women aged 15 to 24. Purulent or mucopurulent vaginal discharge, as well as intermenstrual or post-coital hemorrhage, are common symptoms.[4,5] Dyspareunia has been reported as well. In addition, the related symptoms, LBA and abdominal discomfort, post coital bleeding should be evaluation. In classical Unani literature, *Iltihabe -unuq-al- Rahim* is of three type's *waram harr*, *barid* and *sulb*. The *waram* is *harr* and it may be due to inflammation or *sue mizaj*. The other causes are retention of matter (*madda*) as in *ihtibas tamth* and during puerperium and *insabab-e-safra* and *sawda*. The main symptoms are vaginal discharge (*sayalan-al- rahim*) and low back ache pain in lower abdomen post coital bleeding.[6]

Various single and compound formulations are mentioned in Unani literature, which are effective in *iltehabe–unqur-al-Rahim* such as *Irsa, Marhame Henna, Sufuf-e-Mundi, Murdar Sang, Khatmi, Aarade-Jao, Mako Khushk, Raswat, Majoon Mochras, Marhame Basaliqon* etc.[6,7] In this study *Khatmi* (*Althea officinalis* Linn.) has been selected based on its ingredients and as per the indications and Hypothesized, by which this drug may found to be effective in alleviating the inflammation as well as it helps in anti-microbial activity. Hence, an open observational clinical study was envisaged.

MATERIALS AND METHODS

Study Population

A observational clinical study, with a sample size of 30. From 2020 to 2021 from the department of Ilmul Qabalat wa Amraze Niswan, at hospital, NIUM, Bengaluru.

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The duration of the study was one and a half years. The method of collection of data was History Taking and Clinical examination.

Inclusion criteria

Women between 18-45 years of age, Cervicitis is diagnosis through P/S examination (Hypertrophy, congestion, redness and Nabothian cyst on cervix), Vaginal discharge, low backache, lower abdominal pain, Inflammatory changes in Pap smear.

Exclusion criteria

Patients with PID, Malignancy, Benign lesion, Systemic diseases (HTN, DM,), STDs, and on contraceptives, Pregnancy and lactation.

Study design

An observational clinical study.

Study duration

One and half year from December 2020-February 2022.

Sample size

30 patients.

Ethical clearance

Ethical clearance is obtained by Institutional Ethical Committee vide No: NIUM/IEC/2019-20/014/ANQ/06. And CTRI registration done vide no. CTRI/2021/02/031404.

Informed consent

All the participants gave written informed consent before the study starts.

Drug Identification

Was done at FRLHT Bengaluru with an a/c no.03711450000072.

Chromatography of stud Drug *Althea officinalis* Linnaeus (*Tuqme khatmi*) done by HPTLC method using CAMAG apparatus: *Althea officinalis*_20220705_145730

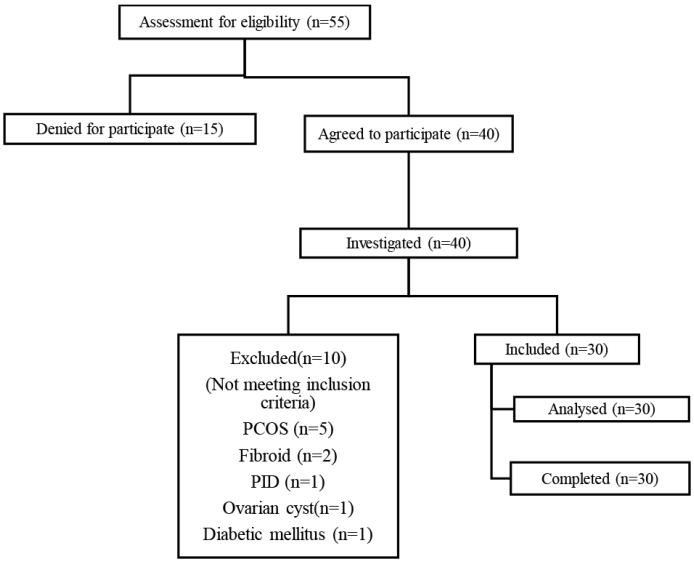
Std. Prep.: 10mg sample soaked in methanol overnight. Mobile phase: toluene: etyhl acetate (48.5:1:5) wavelength: 220nm. The sharp peak indicates presence of respective standards are present, this indicates the purity level of these three standards are good.

Selection criteria

Women between 18-45 years of age. Having symptoms of Abnormal Vaginal discharge, low backache, lower abdominal pain post coital bleeding, dyspareunia, inflammatory changes in Pap smear were included. Patients with PID, Malignancy, Benign lesion, Systemic diseases like HTN, DM, STDs, and contraceptive Pregnancy and lactation were excluded.

Study procedure

The Inclusion criteria fulfilled patients were included in study. Participants were asked to provide details on their demographic data. Menstruation cycle with the medical history. In each patient, history is evaluated and a complete physical examination was performed including gynaecological examination. Personal details, history clinical examination, investigations, per vaginal examinations were recorded in case record form structured for the study.



Flow diagram.

Criteria for selection of drugs

Tukhm-e-khatmi possesses the properties like anti-inflammatory, antimicrobial, styptic, astringent, antispasmodic, laxative, fungicidal, immune modulator, demulcent and soothing diuretic. *Khatmi* has been used for several centuries to treat inflammatory disorders like *warme reham* (metritis), *warme pistan* (mastitis), *warme ama* (enteritis), *wajaul mafasil* (arthritis), *qaulanj* (colitis), *zatur riya* (pneumonia), *warme shoib* (bronchitis), etc[8] chemical constituents contains Pectins, Hypolaetin-8-glucoside, ferulic acid, p-hydroxybenzoic acid, salicylic acid, p-hydroxyphenylacetic aicd, vanillic acid. Scopoletin, Isoquercitrin, ellagitannins, gallic acid L-Aspartic Acids, L-Asparagine, L-Glutamic acids etc.,

Method of preparation

The best quality of *tuqme khitmi* was provided by the pharmacy of NIUM and was further authenticated by FRLHT Bengaluru. With an a/c no. 03711450000072. The drug is finely powdered as per standard preparation. About 40gms of *safuf* was packed for 1 week and 40ml of *shahad* for a week was dispensed for 3 weeks. *Sufuf* of *Tuqm-e-Khitmi*[9] *5gms* with *Shahed* 5ml orally and *marham* of *tuqme khitmi* was given for *humul* at bed time for 21 days after completion of menstrual periods.

Initial assessment and laboratory screening

Baseline laboratory investigations like haemoglobin, percentage, total leucocytic count, differential leucocytic count, erythrocyte sedimentation rate, random blood sugar urine routine was done to exclude the general diseases. Ultrasonography of pelvis was done to exclude pelvic pathology in each case. Pap smear was done to exclude genital malignancy and Inflammatory smears or bacterial vaginosis were included. Safety profile Blood Urea, Serum Creatinine, AST, ALT and Alkaline Phosphatase, was done before and after the intervention for the safety of test drug. Assessment of Patients were followed during trial, start on 5th day of menses and continue upto 21 days the trial follow-up by Weekly. During this period, Abnormal Vaginal Discharge was assessed, using scales Vaginal Symptom Scale (VSS)[10] score and LBA, lower abdominal pain was assessed using Vaginal Analogue Scale (VAS).[11] Score separately. SF12 Score for health-related quality of life in cervicitis patients.[12]

Patient were also enquired for any adverse effect of research drugs during the study period.

Subjective parameters

Abnormal vaginal discharge, Dyspareunia, Low abdominal pain, low backache, Post coital bleeding.

Objective parameters

Vaginal symptom score scale (VSS) for vaginal discharge, and visual analogue scale (VAS) for low back ache and low abdominal pain. SF12 Score for health-related quality of life in cervicitis patients.

Outcome measures

It is assessed by change in subjective and objective parameters.

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.[13-17]

RESULTS AND DISCUSSION

The present study entitled "Effect of *Tuqme Khitmi* in cervicitis- An open observational clinical study" was effective in treating the symptoms of cervicitis. In the present study it was demonstrated that Mean±SD before and after treatment were 1.93±0.52 and 0.13±0.34 with p <0.0001, considered as highly significant. And achieved no discharge in 86.7% and mild discharge in 31.3% of patients after treatment. 70% had no Low back ache with a mean of was1.6±0.81 and 0.3±0.46 before and after treatment respectively with p<0.0001, considered as highly significant. No adverse effect of unani research drug was reported during the study.

Baseline data has been represented in (Table 1)

Age

A similar study conducted by Jeanne M. *et al.* observed 40% patients were from > 30 years of age. Ameri B *et al.* reported with a mean age 32.1±8.5 of cervicitis.[18] *Warm al-raham* also classified according to age by Ansari S. *et al.* mentioned that most commonly occurs in 31-40 years of age.[23] Hashmi S. *etal.* reported majority of the women were between the age group of 20-40.[19]

Socioeconomic status

Similar study conducted by S. Ansari *et al.* and MS Kaveri. *et al.* showed that majority of patients 19 (63.3%) and 40(33.3%) respectively were from lower middle and middle class.[20,21] while Hashmi S. *et al.* showed that the majority of patients were from Upper lower 13(43.33).[19]

Education

The study conducted by Ansari S. *et al.* showed that majority of patients 11 (36.7%), were from primary school 7(23.3%) were in secondary school.[20] whereas Hashmi S. *et al.* and Zahid S. *et al.* reported that majority of patients were from Illiterate 15(50) followed by primary school 04(13.33), middle school 06(20) and 04(13.33) were from high school.[19]

Body mass index

A study by Ameri B, *et al.* reported maximum patients had 67(55.4) normal BMI, followed by 35(28.9) overweight, 15(12.4%) obese and 4(3.3%) hadlow BMI.[18]

Table 1: Baseline Demographic data.

Characteristics	No. of pateints (n=30)	%
Age in years		
21-30	12	40.0
31-40	14	46.7
41-50	4	13.3
S.E Status		
Lower	3	10.0
Lower Middle	6	20.0
Upper Lower	16	53.3
Upper Middle	5	16.7
Education		
Primary and secondary School	20	66%
High School	5	16.7
Intermediate	4	13.3
Graduate	1	3.3
BMI (Kg/m^2)		
<18.5	3	10.0
18.5-25	5	16.7
25-30	13	43.3
>30	9	30.0
Age of menarche		
11-12	13	43.3
13-15	17	56.7
Mizaj		
Balghami	24	80.0
Damvi	6	20.0

Mizaj

In this study maximum patients, 24(80.0%) possessed *balghami* mizaj followed by 6(20.0%) *damvi* mizaj, none of the patients had *safrāvi* and *saudavi mizaj*. It is in accordance with the theories proposed by eminent unani physician, who have quoted that this disease is more common in individual with dominance of *khilt-i-balgham*. Similar finding was reported by Ansari *et al.* 25 (83.3%) patients were from *balghami mizāj*.[20]

Age of menarche

In this study, majority 17(56.7%) of the patients were attained menarche of 13-15 years of age followed by 13(30.0%) at 11-12 years.

Abnormal vaginal discharge

Similar study conducted by Ansari S. *et al.* reported all patients had vaginal discharge before treatment and 63.3% patients were improved with a mean of 2.37±0.56 and 0.37±0 after treatment respectively.[20] B Ameri *et al.* wereobserved 58.7% patient had abnormal vaginal discharge.[18] Anees S. *et al.* reported 100% patients were complaining of vaginal discharge in which(86.6%) patients got relieved.[22] The improvement in vaginal discharge might be due to research formulation having *mohallil-i-warmal-rahim*,[23,24] *muqawwi-i-rahim*,*musakkin-i-dard*,[25] *mujaffif-i- qurooh*,[26,27] *qabiz*,[28] *dafi-i-ta'ffun*, *musaffi*(blood purifier) etc.[18] properties. (Table 2).

Low backache

The findings of present study are comparable with S. Ansari *et al.* reported 3(10%) patients had mild LBA, 26(86.7%) moderate and 1(3.3%) had severe and 90% patients were improved with a mean of 1.6±0.81 and 0.3±0.46 before and after intervention respectively, with $p<0.0001$.[20] Anees S. *et al.* reported 100% of patients complaining of LBA before treatment in which 66.7% got relieved after treatment.[22] Which is co-relating with present study.

The improvement in LBA might be due to research formulation having *muqawwi-i- rahim*, *musakkin-i-dard*,[25] *mohallil-i-warm al- rahim*,[23,24] *munavvim* (sedative), *mulattif* (demulcent) etc.,[18] properties. (Table 3).

Lower abdominal pain

Similar finding was reported by Anees S. *et al.* 25(83.3%) patients were complaining of LAP in which 21(70.0%) patients got relieved.[22] The improvement in LAP might be due to research formulation having *muqaww-i-rahim*, *musakkin-i-dard*,[18] *mohallil-i-warm al- rahim*,[23,24] *munavvim* (sedative), *murakhkhi, mulattif* etc.[18] properties. (Table 4).

Contact bleeding

The study by Ansari S. *et al.* reported 25(83.4%) had contact bleeding. with mild in 14(46.7%), moderate in 9(30%) and severe in 2(6.7%) patients and After treatment, 96.7% of patients were improved and 3.3% with mild contact bleeding with mean 1.27±0.83 to 0.03±0.18 with $p<0.0001$.[20]

The improvement in CB might be due to research formulation having *mujaffif-i- qurooh*,[26,27] *qabiz, murakkhi*,[28] *dafi-i-ta'ffun*, *muqawwi-i-rahim*, *musakkin-i- dard*,[25] *mohallil-i-waram al-rahim*,[23] properties. (Table 5).

Table 2: Abnormal vaginal discharge in cervicitis patients studied.

AVD	BT	F1	F2	F3	AT
0	0(0%)	1(3.3%)	2(6.7%)	14(46.7%)	26(86.7%)
1	5(16.7%)	16(53.3%)	25(83.3%)	16(53.3%)	4(13.3%)
2	23(76.7%)	11(36.7%)	3(10%)	0(0%)	0(0%)
3	2(6.7%)	2(6.7%)	0(0%)	0(0%)	0(0%)
Total	30(100%)	30(100%)	30(100%)	30(100%)	30(100%)

Table 3: Lower backache in cervicitis patients studied.

LBA	BT	F1	F2	F3	AT
0	0(0%)	0(0%)	2(6.7%)	16(53.3%)	21(70%)
1	15(50%)	16(53.3%)	17(56.7%)	13(43.3%)	9(30%)
2	10(33.3%)	9(30%)	10(33.3%)	1(3.3%)	0(0%)
3	5(16.7%)	5(16.7%)	1(3.3%)	0(0%)	0(0%)
Total	30(100%)	30(100%)	30(100%)	30(100%)	30(100%)

Table 4: Lower abdominal pain in cervicitis patients studied.

LAP	BT	F1	F2	F3	AT
0	11(36.7%)	11(36.7%)	12(40%)	18(60%)	24(80%)
1	8(26.7%)	8(26.7%)	13(43.3%)	12(40%)	6(20%)
2	10(33.3%)	10(33.3%)	5(16.7%)	0(0%)	0(0%)
3	1(3.3%)	1(3.3%)	0(0%)	0(0%)	0(0%)
Total	30(100%)	30(100%)	30(100%)	30(100%)	30(100%)

Table 5: Contact bleeding in cervicitis patients studied.

CB	BT	F1	F2	F3	AT
0	27(90%)	29(96.7%)	29(96.7%)	30(100%)	30(100%)
1	2(6.7%)	1(3.3%)	1(3.3%)	0(0%)	0(0%)
2	1(3.3%)	0(0%)	0(0%)	0(0%)	0(0%)
3	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Total	30(100%)	30(100%)	30(100%)	30(100%)	30(100%)

Table 6: Dyspareunia in cervicitis patients studied.

Dyspareunia	BT	F1	F2	F3	AT
0	22(73.3%)	25(83.3%)	25(83.3%)	30(100%)	30(100%)
1	5(16.7%)	4(13.3%)	5(16.7%)	0(0%)	0(0%)
2	3(10%)	1(3.3%)	0(0%)	0(0%)	0(0%)
3	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Total	30(100%)	30(100%)	30(100%)	30(100%)	30(100%)

Table 7: Vaginal symptoms scale in cervicitis patients studied.

VSS	BT	F1	F2	F3	AT
Nil	0(0%)	1(3.3%)	3(10%)	18(60%)	29(96.7%)
Mild	7(23.3%)	19(63.3%)	26(86.7%)	12(40%)	1(3.3%)
Moderate	22(73.3%)	10(33.3%)	1(3.3%)	0(0%)	0(0%)
Severe	1(3.3%)	0(0%)	0(0%)	0(0%)	0(0%)
Total	30(100%)	30(100%)	30(100%)	30(100%)	30(100%)

Dyspareunia

Similar study was conducted by Ansari S. *et al.* reported 70% of patients with mild, moderate 46.7% and 23.4% severe dyspareunia respectively where 96.6% patients were relieved**,** with mean 0.93±0.734 to 0.03±0.18 with $p<0.0001$.[20] (Table 6).

The improvement in dyspareunia might be due to research formulation having *muqawwi- i-rahim*, *musakkin-i-dard*,[25] *mohallil-i-waram al-rahim*,[23,24] *munavvim*(sedative), *murakhkhi, mulattif* etc.[18] properties.

Vaginal symptoms scale

Present study was assessed before, during and after treatment, by VSS. At baseline, VSS score (for vaginal discharge) was categorized from mild, moderate, severe in 1(3.3%), 22(73.3%), 1(3.3%) patient before treatment. And 1(3.3%) had mild and 29(96.7%) had no vaginal symptom score respectively with a difference of 96.7% after treatment with an improvement of 96.7% (Table 7).

Visual analogue scale

In present study the severity of LBA and LAP was assessed by VAS Scale. At baseline 5(16.7%) patients had severe, 9(30%) had moderate VAS scale score and 16(53.3%) had mild VAS score. After treatment 8(26.7%) had mild, 22(73.3%) had no LBA and LAP with $p<0.001$% considered highly significant. (Table 8).

QOL by SF-12 score

The mean± SD before intervention was 382.73± 52.33 and after it was 910.17±56.30 with $p<0.0001$ which is extremely significant and improvement of 43.3% in >400 score. (Table 9).

Table 8: Visual analogue scale in cervicitis patients studied.

VAS	BT	F1	F2	F3	AT
Nil	0(0%)	0(0%)	3(10%)	18(60%)	22(73.3%)
Mild	16(53.3%)	16(53.3%)	18(60%)	11(36.7%)	8(26.7%)
Moderate	9(30%)	10(33.3%)	8(26.7%)	1(3.3%)	0(0%)
Severe	5(16.7%)	4(13.3%)	1(3.3%)	0(0%)	0(0%)
Total	30(100%)	30(100%)	30(100%)	30(100%)	30(100%)

Table 9: Assessment of SF-12 in cervicitis patients studied.

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

Outcome

In this study there is highly significant change seen in primary and secondary outcome. 26(86.7%) improvement seen in vaginal discharge with mean ±SD 1.93±0.52BT and 0.13±0.34AT respectively with *p*= <0.001**the effect might be due to research formulation having *mohallil-i-waram al- rahim*,[23,24] *muqawwi-i-rahim*, *musakkin-i-dard*,[25] *Mujaffif-i-qurooh*,[26,27] *qabiz, murakkhi*,[28] *dafi-i-ta'ffun*, *munavvim* (sedative), *mulattif* (demulcent) *musaffi* (blood purifier) etc.[18] properties.

21(70%) improvement in LBA with mean±SD 1.6±0.81BT and 0.3±0.46AT respectively with *p* = <0.0001**the effect might be due to research formulation having *muqawwi-i-rahim*, *musakkin-i-dard*,[20] *mohallil-i-waram al-rahim*,[23,24] *munavvim* (sedative), *mulattif* (demulcent) etc.[18] properties.

24(80%) improvement in LAP with mean±SD1.0±0.95 to0.2±0.41 BT and AT respectively (*P*=<0.0001**) the effect might be due to research formulation having *muqawwi-i-rahim*, *musakkin-i-dard*,[20] *mohallil-i-waram-al rahim*,[23,24] *munavvim* (sedative), *murakhkhi, mulattif* etc [18] properties.100% improvement in CB with mean ± SD 0.13±0.42 to 0.0±0 BT and AT respectively with *P*=<0.0001**, the effect might be due to research formulation having *Mujaffif-i-qurooh*,[26,27] *qabiz, murakkhi*,[29] *dafi-i-ta'ffun, muqawwi-i-rahim*, *musakkin-i-dard*,[30] *mohallil-i-waram al-rahim*,[31,32] properties.100% improvement in dyspareunia with mean±SD 0.37±0.67to 0.0±0.0 BT and AT respectively (*P*=<0.0001**) the effect might be due to research formulation having *muqawwi-i-rahim*, *musakkin-i-dard*,[25] *mohallil-i-waram al- rahim*,[23,24] *munavvim* (sedative), *murakhkhi, mulattif* etc.,[18] properties. Similar study was conducted by S Ansari *et al.* reported improvement in vaginal discharge from 2.37±0.57 to 0.37±0.49 *p*<0.0001, LBA 1.93± 0.37 to 0.1±0.31 P<0.0001, Contact bleeding 1.27 ± 0.83 to 0.03±0.18 *P*<0.0001 and Dyspareunia 0.93±0.74 to 0.03±0.18 *P*<0.0001.[20] It was assessed by VSS and VAS. Mean±SD of VSS was 1.80±0.48 to 0.03±0.182 with *p* valve <0.0001 considered as highly significant. Mean±SD of VAS 1.63±0.76to0.27±0.45with *p* value< 0.0001% considered highly significant. QOL was assessed by SF-12 scale score with mean±SD was 382.73± 52.33 BT and 910.17±56.301 AT with *p* value< 0.0001% considered highly significant (Table 10).

Table 10: Outcome in cervicitis patients studied.

Outcome	Mean±SD		*P* Value
	BT	AT	
Primary outcome			
AVD	1.93±0.52	0.13±0.34	<0.0001
LBA	1.6±0.81	0.3±0.46	<0.0001
LPA	1.0±0.95	0.2±0.41	<0.0001
CB	0.13±0.42	0.0±0	<0.0001
DYP	0.37±0.67	0.0±0	<0.0001
Secondary outcome			
VSS	1.80±0.48	0.03±0.182	<0.0001
VAS	1.63±0.76	0.27±0.45	<0.0001
Sf-12	382.73± 52.33	910.17±56.301	*P*< 0.0001

Interpretation

Significant reduction in primary and secondary outcome parameters were noted.

Strength of the study

This study was an open single centered observational study. Where treatment was given both orally and locally as *hamūl* of research drug which is directly affected the vaginal discharge, congestion and hypertrophied of cervix. There was good compliance to management.

Limitations of the study

The main limitation of this study was with small sample size, short duration of intervention, short follow up. Laboratory test will not verify the efficacyof result was not performed.

Future recommendation

Use of research unani drug orally and as *hamūl* for longer duration, on large sample size of patients with long follow up for better therapeutic outcome. RCT's with oral and *hamūl* of same research drug with standard treatment i.e., cauterization either electro-cautery or cryo-cautery is recommended.

CONCLUSION

The present study was carried out to prove the efficacy of *tukhme khitmi* in *warme unqur rahim* (Cervicitis) in the form of *hamūl* and orally. The improvement in vaginal discharge, congestion of cervix, hypertrophy of cervix and other associated symptoms Viz, LAP, LBA, dyspareunia, may be due to *qabis, habis, mujaffif, dafe taffun, muhallile waram* properties of the unani drug. Pharmacological studies shows that research drug exhibit anti-microbial, anti-inflammatory, analgesic, antiseptic, anti-oxidant and anti-ulcer ameliorated the sign and symptoms of cervicitis. However, no adverse effect of the research unani drug was reported during the trial. It can be inferred that the research drugs have affected on the clinical parameters through its effect on cervicitis.

On the basis of above observation, it can be concluded that this drug is very effective in relieving the symptoms and sign of cervicitis. The drug is cost effective easily available and well tolerated by the patients without having any side effects.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

VSS: Vaginal symptoms scale; **VAS:** Vaginal analogue scale; **LAP:** Lower abdominal pain; **LBA:** Lower abdomen pain; **CB:** Contact bleeding; **AT:** After treatment; **BT:** Before treatment; **Cong:** Congested; **HYP:** Hypertrophied; **W:** Watery; **Muc:** Mucoid; **SES:** Socioeconomic status; **UL:** Upper lower; **UM:** Upper middle; **LM:** Lower middle; **U:** Upper; **L:** Lower; **I:** Illiterate; **D:** Damvi; **B:** Balghami; **BT:** Before treatment; **AT:** After treatment; **F1:** First follow up; **F2:** Second follow up; **F3:** Third follow up; **HB:** Hemoglobin; **RBS:** Random blood sugar; **AST:** Aspartate transaminase; **ALT:** Alanine transaminase; **USG:** Ultra sonography; **NS:** Normal study; **BLD. U:** Blood urea; **ALK.Phos:** Alkaline phosphates; **S.CRE:** Serum creatinine; **CUE:** Complete urine examination; **IMS:** Inflammatory smear; **LFU:** Last follow up.

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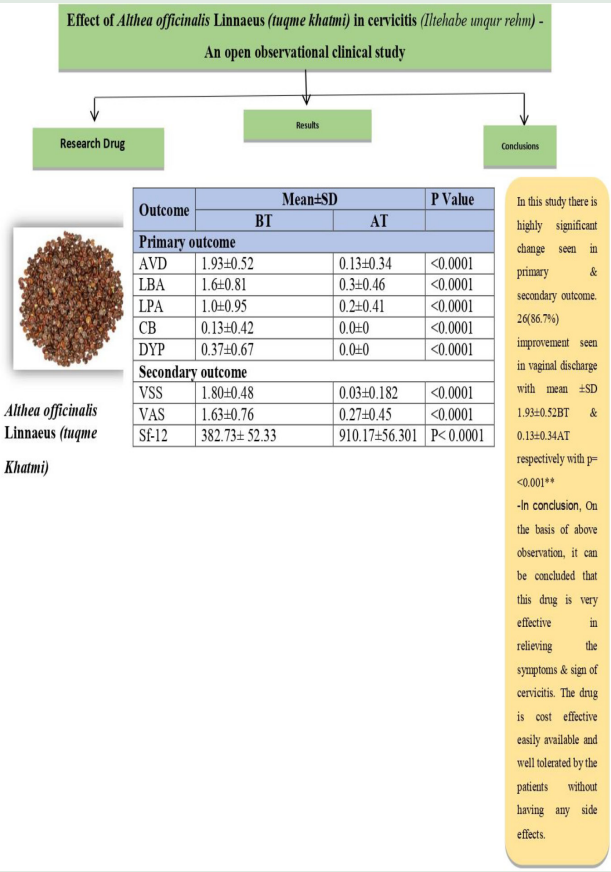
GRAPHICAL ABSTRACT



SUMMARY

The improvement in cervicitis was credited to the effect of research formulation which possess properties like *mohallil waram, mulattif, mufatteh, musaffi, habis, mullayan*. Pharmacological studies shows that the research drugs exhibit antimicrobial, anti-inflammatory, anti-oxidant, anti-cancer, analgesic activities. Further *tuqme khatmi* shows the presence of more quantity of Flavonoids Hypolaetin-8-glucoside, Isoquercitrin, kaempferol, caffeic, pcoumaric acid, ferulic acid, p-hydroxybenzoic acid, salicylic acid, p-hydroxyphenylacetic aicd, vanillic acid. Coumarins like Scopoletin, herniarin, warfarin and Tannins, Isoquercitrin, ellagitannins, gallic acid etc. which helps in treating *Iltehabe unqur al Rahim* It can be inferred that the research drugs have effect on *Iltehabe unqur al Rahim* and relieving the symptoms. No adverse effects were observed in the research drugs used. Hence the research drug possesses the anti-inflammatory, Immunomodulatory effects and antimicrobial activity which locally helps in relieving the signs and symptoms of cervicitis.

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