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 Tuqme khatmi has been Discharge selected out from various available drugs in sailan ur raham. Aim: To evaluate the effect of Tuqme 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 tuqme khitmi 5gms with Shahed and marham of tuqme 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.

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.3 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). 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.

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. Dyspareunia has been reported as well. In addition, the related symptoms, LBA and abdominal discomfort, post coital bleeding should be evaluated. In classical Unani literature, Iltehabe-unqur-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 tanth 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.

Various single and compound formulations are mentioned in Unani literature, which are effective in iltehabe-unqur-al-Rahim such as Isra, Marhame Henna, Safuf-e-Mundi, Murdar Sang, Khatmi, Aarade-Jao, Mako Khushk, Raswat, Majoon Mochras, Marhame Basaltiong etc. 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.
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. The drug is finely powdered as per standard preparation. About 40gms of Shahad was packed for 1 week and 40ml of shahad for a week was dispensed for 3 weeks. Saufit of Tukhm-e-Khitmi was given for humul at bed time for 21 days after completion of menstrual periods.

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), _wajaal mafasil_ (arthritis), _qaidan dj_ (colitis), _zatter riya_ (pneumonia), _warme shob_ (bronchitis), etc. chemical constituents contains Pectins, Hypolactatin-8-glucoside, fericul acid, p-hydroxybenzoic acid, salicylic acid, p-hydroxyphenylacetic acid, vanillic acid. Scopoletin, Isoquerctin, 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 _safaf_ was packed for 1 week and 40ml of _shahad_ for a week was dispensed for 3 weeks. _Safaf_ of _Tukhm-e-Khitmi_ 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) score and LBA, lower abdominal pain was assessed using Vaginal Analogue Scale (VAS). Score separately. SF12 Score for health-related quality of life in cervicitis patients.

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.[11-17]

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. et al. 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(43.3%).[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>
<thead>
<tr>
<th>Characteristics</th>
<th>No. of patients (n=30)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age in years</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21-30</td>
<td>12</td>
<td>40.0</td>
</tr>
<tr>
<td>31-40</td>
<td>14</td>
<td>46.7</td>
</tr>
<tr>
<td>41-50</td>
<td>4</td>
<td>13.3</td>
</tr>
<tr>
<td><strong>S.E Status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>Lower Middle</td>
<td>6</td>
<td>20.0</td>
</tr>
<tr>
<td>Upper Lower</td>
<td>16</td>
<td>53.3</td>
</tr>
<tr>
<td>Upper Middle</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td><strong>BMI (Kg/m²)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;18.5</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>18.5-25</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>25-30</td>
<td>13</td>
<td>43.3</td>
</tr>
<tr>
<td>&gt;30</td>
<td>9</td>
<td>30.0</td>
</tr>
<tr>
<td><strong>Age of menarche</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11-12</td>
<td>13</td>
<td>43.3</td>
</tr>
<tr>
<td>13-15</td>
<td>17</td>
<td>56.7</td>
</tr>
<tr>
<td><strong>Mizaj</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Balghani</td>
<td>24</td>
<td>80.0</td>
</tr>
<tr>
<td>Damvi</td>
<td>6</td>
<td>20.0</td>
</tr>
</tbody>
</table>

Mizaj
In this study maximum patients, 24(80.0%) possessed balghani mizaj followed by 6(20.0%) damvi mizaj, none of the patients had safrâvi 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 mizaj.[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(40.0%) 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 amean of 2.37±0.56 and 0.37±0 after treatment respectively.[20] B Ameri et al. were observed 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.[20] 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] mujaffi-i-qurooh,[26,27] qabiz,[28] dafi-i-ta’fiun, 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 $1.62\pm0.81$ and $0.3\pm0.46$ before and after intervention respectively, with $p<0.0001$. Anees S. et al. reported 100% of patients complaining of LBA before treatment in which 66.7% got relieved after treatment. Which is correlating with present study.

The improvement in LBA might be due to research formulation having muqawwi-i-rahim, musakkin-i-dard, mohallil-i-waram al-rahim, munavvim (sedative), mulattif (demulcent) etc., 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. The improvement in LAP might be due to research formulation having muqawwi-i-rahim, musakkin-i-dard, mohallil-i-warm al-rahim, munavvim (sedative), muqawwi-i-rahim 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. 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 $p<0.0001$. The improvement in CB might be due to research formulation having mujaffi-i-qurooh, gabiz, musakkin-i-dard, dafi-i-ta'ffun, muqawwi-i-rahim, munavvim etc., properties. (Table 5).

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 $p<0.0001$. The improvement in dyspareunia might be due to research formulation having muqawwi-i-rahim, musakkin-i-dard, mohallil-i-waram al-rahim, munavvim sedative, musakkin-i-dard, properties. (Table 6).

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, 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 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.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>VAS</th>
<th>BT</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>AT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nil</td>
<td>0(0%)</td>
<td>0(0%)</td>
<td>3(10%)</td>
<td>18(60%)</td>
<td>22(73.3%)</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>16(53.3%)</td>
<td>16(53.3%)</td>
<td>18(60%)</td>
<td>11(36.7%)</td>
<td>8(26.7%)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>9(30%)</td>
<td>10(33.3%)</td>
<td>8(26.7%)</td>
<td>1(3.3%)</td>
<td>0(0%)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>5(16.7%)</td>
<td>4(13.3%)</td>
<td>1(3.3%)</td>
<td>0(0%)</td>
<td>0(0%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>30(100%)</td>
<td>30(100%)</td>
<td>30(100%)</td>
<td>30(100%)</td>
<td>30(100%)</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>SF-12</th>
<th>BT</th>
<th>AT</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;300</td>
<td>2(6.7%)</td>
<td>0(0%)</td>
</tr>
<tr>
<td>300-400</td>
<td>15(50%)</td>
<td>0(0%)</td>
</tr>
<tr>
<td>&gt;400</td>
<td>13(43.3%)</td>
<td>30(100%)</td>
</tr>
<tr>
<td>Total</td>
<td>30(100%)</td>
<td>30(100%)</td>
</tr>
</tbody>
</table>

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±0.32BT and 0.13±0.34AT respectively with p= <0.001**the effect might be due to research formulation having mohallil-i-warām al-rahim,[19,24] muqawwi-i-rahim, musakkin-i-dard,[23] Mūjaffīf-i-qūrooh,[25,27] qābiz, mūrakkhi,[28] dāfī-i-ta’ffun, mūnāvvim (sedative), mūlattīf (demulcent) mūsaffī (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-warām al-rahim,[21,24] mūnāvvim (sedative), mūlattīf (demulcent) etc.[18] properties. 24(80%) improvement in LAP with mean±SD 1.0±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-warām al-rahim,[21,24] mūnāvvim (sedative), mūrakkhi, mūlattīf etc.[18] properties. 100% improvement in CB with mean±SD 0.3±0.42 to 0.0±0 BT and AT respectively with P= <0.0001**, the effect might be due to research formulation having Mūjaffīf-i-qūrooh,[25,27] qābiz, mūrakkhi,[28] dāfī-i-ta’ffun, muqawwi-i-rahim, musakkin-i-dard,[39] mohallil-i-warām al-rahim,[21,32] mūnāvvim (sedative), mūrakkhi, mūlattīf etc.[18] properties. 100% improvement in dyspareunia with mean±SD 0.37±0.67 to 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,[20] mohallil-i-warām al-rahim,[21,24] mūnāvvim (sedative), mūrakkhi, mūlattīf etc.[18] properties.

**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. Similar 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 etc., were due to qabis, habis, mūjaffīf, dāfī taffun, mūhālli warām 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.

**Conclusion**

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

**Acknowledgement**

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work. It is a pleasure to thank Dr. KP Suresh biostatistician and scientist, National Institute of Veterinary Epidemiology and Disease informatics (NIVEDI) for performing the statistical analysis.

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National Institute of Unani Medicine.

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: Hypertrophioid; W: Watery; Muc: Mucoid; SES: Socioeconomic status; UL: Upper lower; UM: Upper middle; LM: Lower middle; U: Upper; L: Lower; I: Iiliterate; 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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SUMMARY

The improvement in cervicitis was credited to the effect of research formulation which possess properties like mohallil waram, mutattif, mutafteh, musaffi, habis, mulayan. 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, p-coumaric acid, ferulic acid, p-hydroxybenzoic acid, salicylic acid, p-hydroxyphenylacetic acid, 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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