

## Clinical efficacy of Unani Formulation in the Management of Chronic Cervicitis-An Observational Clinical Study

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### Abstract

**Background:** Chronic Cervicitis is one of the commonest lesions of female genital tract affecting more than half of all women at some point during their adult lives and has been seen in 80% of women with any gynecological complaint.

**Objectives:** The aim of the study was to evaluate the clinical efficacy of Unani formulation in the management of chronic cervicitis.

**Methods:** An observational study was carried out at the Department of Obstetrics and Gynaecology, Nizamia General Hospital, Hyderabad. Thirty (n=30) patients of 20-45 years of age with chronic cervicitis were selected and intervened with Unani formulations prepared from

*Rheum emodi* (Safoofe-Revandchini) and *Withania somnifera* (Safoof-e-Asgand-e-Nagoori) at the dose of 8 gm twice daily for 21 days for three (3) consecutive cycles as administered as orally and local treatment in the form of intra vaginal tampon (*Humool*) prepared from *Plumbi oxidum* (Murdar Sangh) 1 gram, *Plumbo carbonas* (Safaida Kashgiri) 5 grams, *Astragalus sarcocolla* (Anzarut) 1 gram, oil of *Rosa damascena* (Gul-e-Surkh) 10 ml and *Cera flava* (Moom-e-zard) placed into vagina whole night for ten days in each cycle. Assessment of efficacy of test drugs were done by comparative study of subjective (white discharge, back ache, lower abdominal pain, dyspareunia, vulval and vaginal itching), and objective parameters (Pap smear and cervical swab culture) were assessed for improvement. Results were analyzed statistically using chi-square and student 't' test.

**Results:** This herbal formulation showed highly statistically significant improvement in all the subjective (p<0.001) and objective (p<0.001) parameters of chronic cervicitis after completion of treatment.

**Conclusion:** The study results suggest that the trials formulations are quite effective in the management of Chronic Cervicitis and hence it can be used as an alternate therapy in the management of Chronic Cervicitis. No adverse effects were noted during the complete course of the study trial.

**Keywords:** Chronic Cervicitis, *Iltehab-e-Unqurreham*, Unani Formulations.

### Introduction

Chronic cervicitis is the diffuse inflammation of the cervix and it one of the commonest lesions of female genital tract affecting more than half of all women at some point during their adult lives and has been seen in 80% of women with any gynecological complaint [1]. [It is the most common gynecological disease affecting more than half of all women at some point during their adult lives. It can be caused by infection like gonorrhoea, Chlamydia, streptococci, staphylococci, genital herpes HSV, HPV or it may be due to non-infective causes like injury to the cervix during child birth, abortion, use of hormonal contraceptives, and insertion of Intra uterine contraceptive devices (IUCDS) [2]. Risk factors for chronic cervicitis are early sexual exposure, excessive intercourse, multiple sexual partners and low socio economic status [3]. In classical Unani literature it is mentioned that chronic cervicitis occurs due to *Su-e-Mizaj*, *Su-e-Tarkeeb* and *Taffaruq-o-Ittesaal* causing hypertrophy, congestion and erosion of cervix [4, 5]. Chronic cervicitis is a major health problem which impacts on women's health both medically and socially resulting in increase healthcare cost and financial burden worldwide [6]. Untreated cervicitis can lead to various complications like PID, chronic pelvic pain, infertility, ectopic

pregnancy, cervical stenosis, cervical cancer, premature rupture of membranes (prom) and premature labour [7]. The treatment in conventional medicine includes cauterization, cryosurgery, conisation, and if above majors fail, hysterectomy is the final treatment. These treatments are effective but are associated with complications like injury to cervix, general anesthesia complications in cauterization. Copious discharge pervaginum may cause potassium loss through extensive destruction of the tissue in cryosurgery. Reactionary and secondary haemorrhage, midtrimester abortion, premature labour and cervical dystocia are the complications of conization [8]. Therefore, there is a need of alternate therapy which is to be safe, effective, easily available and free from side effects. Hence Unani formulation consists of safoof-e-revandchini and asgand were given orally which possess the properties like, anti-inflammatory (*Muhallil-e-Waram*), phlegmatic purgative (*Mukhrej-e-Balgam*), demulcent, (*Mullatif*) analgesic, (*Mussakinn-e-Alam*), deobstruent (*Muffateh Suddah*) [9]. Asgand is a uterine and nerve tonic, heals obstinate ulcers. It has anti-inflammatory anti-tumor activity, infuses fresh energy and vigor which is worn out due to any chronic disease and prevents general debility [10]. Local treatment humool (tampon) consists of

Murdar Sangh (*Plumbi oxidum*), Safaida-e-Kashgiri (*Plumbo carbonas*), Anzarut (*Astragalus sarcocolla*), Roghan-e-Gul (Rose oil) and Moom-e-Zard (*Cera-flava*). These drugs were used to bring down the inflammatory condition and swelling of the cervix, Owing to their anti-inflammatory, antiseptic healing, analgesic, resolvent, emollient effect [9, 11, 12, 13]. The objective of the study was to evaluate the efficacy of Unani formulation in the management of chronic cervicitis.

**Materials and methods**

The present study entitles “as Efficacy of Unani Formulation in the Management of Chronic Cervicitis- A Prospective Observational Study” carried out in the Dept. of Obstetrics and Gynecology, Government Nizamia Tibbi College, Charminar, Hyderabad. A total 60 patients were screened and out of them 30 patients of chronic cervicitis who has fulfilled the inclusion criteria were selected for the clinical research trial for the duration of 21 days for three (3) consecutive cycles. Informed consent was taken in English and also it was rendered in Telugu, Urdu, and Hindi as per need by the translators before start of the study. The GCP (Good Clinical Practice) guide line followed.

This study was conducted between between November, 2005 to December, 2007 and after completion of clinical trial all documents are submitted to Dept of Obstetrics and Gynecology, Government Nizamia Tibbi College for documentation.

**Selection Criteria:** Patients in the age group of 20 to 45 years with positive Pap smear (inflammatory smear) and positive cervical swab culture with complaint of white discharge, backache, lower abdominal pain with history of using oral and local contraceptives were selected and the patients with organic pelvic pathology systemic illness, and malignancy were excluded. Written informed consent was obtained from each included patients.

**Study procedure:** Patients were selected on the basis of Diagnostic criteria of chronic cervicitis which includes exudation of mucopurulent, mucoid cloudy white, curdy discharge from cervical canal, hypertrophied, congested cervix with positive Pap smear (inflammatory) and cervical swab culture. All patients were instructed not to use any medication during the trial. Assessment of Mizaj of every patient was done as per the parameters mentioned in classical Unani literature. Investigation was repeated to assess the efficacy of drugs before and after the treatment.

**Intervention:** The research drugs were given in the form of safoof orally as well as locally (humool or intravaginal tampon). Unani formulations; *Safoof-e- Revandchini* (2 grams) and *Safoof-e-Asgand* (6 grams) were administered Orally twice daily for twenty one days for three consecutive cycles. Local treatment in the form of intravaginal tampon (*Humool*) prepared from *Plumbi oxidum* (Murdarsing) 1 gram, *Plumbo carbonas* (Safaida Kashgiri) 5 grams, *Astragalus sarcocolla* (Anzarut) 1 gram, oil of *Rosa damascena* (gul-e-surkh) 10 ml and *Cera flava* (Moom-e-zard) one gram, placed into vagina whole night for ten days in each cycle.

**Assessment cum follow up:** All the patients were assessed by subjective parameters and per speculum examination once in

fifteen days for three cycles, after administration of the trial drugs.

**Outcome measures:** Primary outcome measures were restoration of normal and healthy cervix, secondary outcome measures were assessed for effectiveness of Unani therapy. The assessment of outcome was carried out by clinical assessment of subjective and objective parameters before and after treatment. Specific investigations of Pap smear and cervical swab culture were repeated after completion of treatment.

**Statistical Analysis:** Chi-square and student “t” test were used to statistical strength of the result.

**Results:** In the present study thirty patients (n=30) who has filled the inclusion criteria were selected and accomplished the study and were subjected to statistical analysis. Results were assessed after completion of treatment.

This herbal formulation showed highly statistically significant improvement in all the subjective (p<0.001) and objective (p<0.001) parameters of chronic cervicitis after completion of treatment. All results are shown in table number 1, 2, 5, 6 and 7.

**Table 1:** Showing the Age Incidence of Chronic Cervicitis and Response to the Treatment

S. No	Age group (in year)	No of patients	Percentage of incidence
1	20-25	8	26.7%
2	25-30	7	23.3%
3	30-35	9	30.0%
4	35-40	6	20.0%
5	40-45	Nil	-
6	Above 45	Nil	-
	Total	30	100%

**Table 2:** Showing Temperament of Patient

S. No	Temperament	No. of Patients	Total	Percentage
1	Sanguineous (Damvi)	5	5	16.67%
2	Choleric (Safravi)	Nil	Nil	Nil
3	Phlegmatic (Balgami)	25	25	83.33
4	Melancholic (Saudavi)	Nil	Nil	Nil

**Table 3:** Showing the Symptomatic Response Before and After Treatment

S. No	Symptoms	Complaints before treatment (no. of patients)	Complaints after treatment (no of patients)	Total No. of Patients got Cured (%)
1	White discharge	30	1	29 (96.7%)
2	Backache	30	1	29 (96.7%)
3	Lower Abdominal pain	30	1	29 (96.7%)
4	Dysmenorrhoea	30	1	29 (96.7%)
5	Dyspareunia	30	1	29 (96.7%)
6	Itching of Vulva	12 (40%)	1	29 (96.7%)
7	Itching of Vagina	12(40%)	1	29 (96.7%)

**Table 4:** Showing the Socio-Economic Status in Patients of Chronic Cervicitis

S. no	Class	No. of Patients	Percentage (%)
1	Upper Class	Nil	-
2	Middle Class	6	20%
3	Poor Class	24	80%
	Total	30	100%

**Table 5:** Showing the Presence of Organisms in Cervical Swab Culture Before and After Treatment

S. no	Cervical Swab Culture	Before Treatment	After Treatment	Response of treatment in (%)
1	Staphylococcus	22	5	77.3%
2	Streptococcus	1	Sterile Culture	100%
3	E. Coli	1	Sterile Culture	100%
4	Candida	1	Sterile Culture	100%
5	Kleibisella	-	-	-
6	Pseudomonas	-	-	-
7	HPV	1	1	0
8	Sterile	4 (13.3%)	24 (80%)	-

**Table 6:** Showing the per speculum Appearance of Cervix before and after Treatment

S. no	Cervical Pathology	Total No. of Patients	Complaint Before Treatment	Complaint After Treatment	Response of Treatment (%)
1	Hypertrophy	30	Present	1 (patient)	96%
2	Inflammation	30	Present	1 (patient)	96%
3	Congestion	30	Present	1 (patient)	96%

**Table 7:** Showing Cytological Screening in 30 Patients with Papinicolou's Smear and Response to the Treatment (See the Inference in Discussion)

S. No	Nature of Pap Smear	No. of patient	Cured	Relieved	No response
1	Inflammatory	26	23(88.5%)	2(7.7%)	1(3.8%)
2	Dysplasia	3	2(66.7%)	1(33.3%)	Nil
3	HPV infection	1	-	1 (100%)	Nil

**Table 8:** Showing the Response of the Treatment

S. No	No. of patients	Cured	Relieved	No response	Total
1	30	25(83.3%)	4(13.3%)	1(3.3%)	30

**Table 9:** Standard Mean Deviation Before and After Treatment

S. no	Before Treatment	After Treatment	Significance
1	29.13+/-16.97	16.33+/-9.67	P<0.001 (Significant)

## Discussion

In Present Research study, high incidence of chronic cervicitis was noted in 20 to 45 years of age group. Twenty four patients (80%) out of thirty were belonging to poor socio-economic status. It may be due to poor nourishment and poor health status and negligence in early treatment is one of the predisposing factors of this disease reported by Ellen JM *et al.*, [14]. Twenty five patients (83.33%) were of Balghami Mizaj (phlegmatic temperament) which correlates with the theories as proposed by Unani physicians by Zakaria Rhazi Ibn Sina, Hkm, Mohd, Azam Khan, that Phlegmatic temperament cervices uteri are more vulnerable for infections due to which inflammation of the cervix persists [4, 5]. Nine patients out of thirty (30%) had used oral contraceptive pills (OCP), Eight patients (26.67%) had used condoms, Six patients (20%) had used intrauterine contraceptive devices (IUCD), Three patients (10%) were tubectomised, and Four

patients (13.13%) had not used any contraceptives measures. This shows that using oral and local contraceptives may be one of the factors that are responsible for increased incidence of chronic cervicitis is supported by Harrison HR *et al.* [15].

**Subjective parameters:** All the subjective parameters like white discharge, low backache, lower abdominal pain, vulval and vaginal itching were present before treatment. The above complaints subsided after completion of treatment (Orally & Locally) up to three cycles.

**Objective parameters:** before treatment all the thirty patients with chronic cervicitis showed inflammatory Pap smear. They were intervened with oral and local treatment up to three cycles. ( $p < 0.001$  significant). In cervical swab culture before treatment Twenty two patients (77.33%) showed staphylococcus organisms, one patient had showed streptococcus, (3.33%), one patient (3.33%) showed E-coli, one patient (3.33%) showed Candida albicans, one patient (3.33%) showed HPV and culture was sterile in four patients (13.33%). Twenty six patients had inflammatory Pap smear. Out of which 23 patients got cured after intervention of treatment. Two patients did not turn for post treatment cytological study though they got completely cured they assumed 7.7% treatment. One patient with inflammatory Pap smear showed no response to the treatment. This patient had lax vagina due to which the genital tract inoculating repeatedly and it may be one of the factor for poor response to the treatment in this patient. Three cases of mild dysplasia were registered with positive inflammatory smear before treatment. After treatment showed normal cytology. One patient with mild dysplasia did not turn for post treatment cytological study. She assumed that (33.33%) treatment response as the Pap smear after treatment turned from dysplasia to inflammatory in second cycle of the treatment only. One patient of HPV infection got relieved completely. The analysis

of oral drug formula showed that the ingredients of this *Safoof* have mainly anti-inflammatory effects [9]. It excretes sticky, dominant and altered humors and moderates the viscosity of humors. General tonic effects, nervine sedative, anti-tumor activity, infuses fresh energy and vigor which worn out due to any chronic disease [9, 10, 11, 12, 13, 16]. This maintains the hormonal balance, support the integrity of uterine tissue, blood vessels and capillaries. Relax the muscles and control inflammation [17, 18]. This result correlates well with the theories as proposed by Unani physicians regarding the use of anti-inflammatory, healing, demulcent, emollient, phlegmatic and bilious purgative drugs in patients of chronic cervicitis.

### Conclusion

The study has revealed that the test drugs were used to bring down the inflammatory condition and swelling of the cervix, due to their anti-inflammatory, anti-septic, healing, analgesic, resolvent, emollient effect and as protective to wounds and ulcers. On the basis of this above observation it can be concluded that this drugs are very effective in the management of chronic cervicitis.

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