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Efficacy of Unani Formulation in the Management of Chronic Cervicitis-A Prospective Observational Study

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Abstract

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.

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

An observational study was carried out at the Department of Obstetrics and Gynecology, 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 mucilage of *Linum usitatissimum* (5 grams Tukhm-e-Kataan) and *Ricinus communis* (10 ml Roghan-e- Bedanjeer) for ten days in each cycle. Pap smear and cervical swab culture were performed before and after treatment. Assessment of efficacy of test drugs was done by comparative study of subjective and objective parameters were assessed for improvement. 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.

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, *Ittehab* *Unqurreham*, Unani Formulations

1. 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, conization, 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 per vaginum 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*), *Muffateh suddah* (de obstruent) [9]. Asgand is a uterine and nervine 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]. Rogan-e-bedanjeer (Castor oil) is anti inflammatory analgesic, purgative of all *Akhlat* [11]. Tukhme Kataan is (*Linum Usitissimum Linn*) demulcent, emollient, counter irritant for deep-seated inflammation, relaxes the tissue and thereby relieves the tension [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. Before starting upon the project, a comprehensive protocol was checked out and submitted for ethical clearance from the institutional ethical committee of Government Nizamia Tibbi College. After ethical clearance enrolling patients for the study. 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 complete 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 mucilage of *Luab-e-Tukme Kataan* (5 grams) and *Rogan-e-Bedanjeer* (10ml) 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 was 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)	Cured	Relieved	No. response	Total	Percentage
1	20-25	7	-	-	7	23.3%
2	25-30	8	-	-	8	26.7%
3	30-35	9	-	-	9	30.0%
4	35-40	5	-	-	5	16.7%
5	40-45	1	-	-	1	3.3%
6	Above 45	-	-	-	-	-
	Total	30	-	-	30	100%

Table 2: Showing the Symptomatic Response Before and After Treatment

S. No	Symptoms	Complaints before treatment	Complaints after treatment	Patients got relief (%)
1	White discharge	30	Nil	100%
2	Backache	30	Nil	100%
3	Lower Abdominal pain	30	Nil	100%
4	Dysmenorrhoea	30	Nil	100%
5	Dyspareunia	30	Nil	100%
6	Itching of Vulva	04(13.3%)	Nil	100%
7	Itching of Vagina	04(13.3%)	Nil	100%

Table 3: Showing the Socio-Economic Status In Patients of Chronic Cervicitis

S. no	Class	No. of Patients	Total	Percentage (%)
1	Upper Class	-	-	-
2	Middle Class	9	9	30%
3	Poor Class	21	21	70%
	Total	30	30	100%

Table 4: 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	12	Sterile Culture	100.0
2	Streptococcus	1	Sterile Culture	100.0
3	E. Coli	7	Sterile Culture	100.0
4	Candida	1	Sterile Culture	100.0
5	Kleibsella	1	Sterile Culture	100.0
6	Pseudomonas	1	Sterile Culture	100.0
7	Sterile	7 (23.3%)	23 (76.7%)	-

Table 5: Showing the per speculum Appearance of Cervix before and after Treatment

S. no	Cervical Pathology	No. of Patients	Before Treatment	After Treatment	Response of Treatment (%)
1	Hypertrophy	30	Present	Subsided	100%
2	Inflammation	30	Present	Subsided	100%
3	Congestion	30	Present	Subsided	100%

Table 6: Showing Cytological Screening in 30 Patients with Papinicolou's Smear and Response to the Treatment

S. no	No of Patients Before Treatment	Nature of Pap Smear Before treatment	Nature of Pap Smear After treatment	No. of Patients Cured	Percentage (%)
1	30	Inflammatory	Normal Cytology	30	100%

Table 7: Standard Mean Deviation Before and After Treatment

S. no	Before Treatment	After Treatment	Significance
1	33.6+ 10.06	15.97+ 8.35	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 one patients (70%) out of thirty were belonging to poor socio-economic status showing in Table no. 3. 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 (80%) 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]. Thirteen patients out of thirty (43.33%) had used oral contraceptive pills (OCP), Four patients (13.33%) had used condoms, four patients (13.33%) had used intrauterine contraceptive devices (IUCD), six patients (20%) were tubectomised, and three patients (10%) 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 twelve patients (40%) showed staphylococcus organisms one patient had showed streptococcus, (3.33%), seven patients (23.33%) showed E-coli one patient (3.33%) showed Candida albicans, one patient (3.33%) showed

kleibsella, one patient (3.33%) showed pseudomonas, and culture was sterile in seven patients (23.33%). 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, 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 is very effective in the management of chronic cervicitis.

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