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Effectiveness of an Unani Formulation as Topical Medication in Cervical Ectopy-An Open Observational Study

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Abstract

***Background and objectives**: Cervical ectopy is one of the commonest gynaecological conditions met in day-to-day clinical practice. 80-85% of women suffer from cervical ectopy during the reproductive age. The objective designed for the study was to evaluate the efficacy of an Unani formulation as topical medication in cervical ectopy (Quruh al rahim).*

***Method**: An open labelled observational study was carried out in the Department of Ilmul Qabalat wa Amraze Niswan, National Institute of Unani Medicine, Hospital, Bengaluru. Diagnosed cases (n=30) of cervical ectopy were included in the study. Patients with abnormal cervical cytology, pelvic inflammatory diseases, systemic diseases, steroidal contraceptives, pregnancy & lactation were excluded. Research drug comprises of Murr (Commiphora myrrha), Safeda (Lead carbonate), Anzaroot (Astragalus sarcocola), Mom (Beeswax) and Roghane gul (Rose oil). Ointment of these drugs was prepared & 6g was applied with an applicator per vaginum over the eroded cervical area daily once at bedtime for 2 weeks. Primary outcome measure (cervical ectopy) and secondary outcome measures (vaginal discharge and low backache) were assessed for improvement. Data were analyzed using paired Student't' test.*

***Results**: Improvement in grading of cervical ectopy was achieved in 46.7% patients with 20% improvement in healing of cervical ectopy (P=0.0054). Improvement in vaginal discharge was achieved in 90% patients with relieve in 83.4% (P<0.001). Improvement in low backache was achieved in 70% patients with relieve in 46.7% (P=0.005).*

***Interpretation and conclusion**: Research drug show potent wound healing action due to the presence of active antiulcer ingredients. No adverse effect of the research drug was reported during the trial. Hence, research drug serves as an effective alternative in patients with cervical ectopy.*

***Keywords**: Quruh al rahim; Cervical ectopy; Research drug; Vaginal discharge; Low back ache; Ointment.*

Introduction

Cervical ectopy is one of the commonest gynecological conditions seen in OPD's [1,2] and 80-85% of women suffer from cervical ectopy during the reproductive age [1,3-12]. Many a times, it is an accidental finding in an asymptomatic woman coming for routine gynaecological examination [2,3,10]. Though it is not fatal, but if left untreated may leads to infertility & predispose to cervical cancer, which is considered as frequent cancer among women in India [13]. Pathologically, it is the replacement of the

stratified squamous epithelium of the ectocervix by the columnar epithelium of the endocervix [2,4,5,8,14-17]. Predisposing factors for cervical ectopy are early sexual exposure [18], multiple sexual partners [2,18], presence of STI's [7,8,17-19] lower genital tract infections, low socioeconomic status, poor personal hygiene, poor health awareness etc. [2]. Etiology includes cervical trauma during delivery, abortion, and sexual intercourse [12] use of contraception either barrier or steroidal etc. [10,15,18]. Although it is benign but may be troublesome due to its chronicity and nature of recurrence.

Unani physicians mentioned that quruh al rahim (cervical ectopy) [20-29], is caused by either external factors like uterine injury by direct trauma or instrumentation, drug induced i.e. local use of haad drugs (in the form of humool or farzaja) [20-30] or internal factors like difficult labour**,** mismanagement of labour, flow of acute yellow bile towards the uterus causing gradual erosion of cervix, rupture of inflammatory swelling or pustules [20,26-30]. The patient may present with intense pelvic pain, abnormal vaginal discharge [20,21,23,26-28,31], excessive tiredness etc. [20,21,23,25-27]. On examination, qarha on unqur rahim is visible on inspection & even palpated as rough surface on bimanual examination [22,30].

The treatment option available in conventional medicine for cervical ectopy is surgical treatment like electro or cryocautery, which though effective, but have their own complications like cramping pain during procedure, copious discharge per vaginum, PID, risk of secondary hemorrhage, cervical stenosis, infertility etc. [1,3,832]. Hence, the need for alternate treatment arises which is to be safe, effective & free from side effects.

In Unani system of medicine, several drugs are available for healing of cervical ectopy as a local treatment in the form of humool [20-27] which are safe and cost effective. Research drug comprises of Murr (Commiphora myrrha), Safeda (Lead Carbonate), Anzaroot (Astragalus sarcocola), Mom (Beeswax) and Roghane gul (Rose oil) [21]; ointment was prepared and 6g was applied with applicator per vaginum over the eroded cervical area daily [3] once at bedtime for 2 weeks. The research drug exhibit muhallile waram (anti-inflammatory), mujaffif (desiccant), mudammile quruh (healing of wound),qabid (astringent), musakkin (analgesic),dafi-i-ta'ffun (antiseptic) properties [33-36]. Moreover, extract of Commiphora myrrha proved pharmacologically to have anti-inflammatory, antimicrobial, sedative and cytotoxic activities due to the presence of steroids, flavonoids, terpenoids, lignans and carbohydrates [37-39]. Lead Carbonate proved to have sedative and haemostatic properties [40]. Crude extract of Astragalus showed antiviral, anti-inflammatory, anticancer, antioxidant activities due to the presence of saponins, flavonoids and polysaccharides [41,42]. Therefore, research drug might be helpful in healing of cervical ectopy due to strong antiulcer & antioxidant activities. The study was designed to test the hypothesis ''Unani formulation may be effective in healing of quruh al rahim". The objective designed for the study was to evaluate the efficacy of an Unani formulation as topical medication in quruh al rahim.

Methodology

Study design and setting

An open labeled observational study was carried out in the Dept. of Ilmul Qabalat wa Amraze Niswan, National Institute of Unani Medicine Hospital, Bengaluru in a duration of one and a half year.

Selection criteria of patients

Married women in age group of 20-40 years with cervical ectopy on speculum examination, vaginal discharge and normal or inflammatory changes in pap smear were included in the study and those with abnormal pap smear, frank growth on cervix, Pelvic inflammatory disease, steroidal contraceptives and IUCD, Systemic illnesses (UTI, DM, TB) and STD's (Syphilis, HIV), pregnant and lactating women were excluded from the study.

Study procedure

Total 133 patients were screened for the study from OPD and IPD of the Institute's hospital. 30 patients fulfilling the inclusion criteria were enrolled in the study after obtaining the written informed consent from them. The clinical study was started after the approval by Institutional ethical committee, under IEC No.: NIUM/IEC/2015-16/010/ANQ/02. Detailed history was elicited from each included patient, regarding nature and duration of vaginal discharge, its

association with low backache and pruritis vulva, its relationship with menstrual cycle. Complete physical examination including pelvic examination was performed in all patients. Each patient underwent initial investigation such as CUE, CBP, ESR, RBS, VDRL, HIV, USG pelvis and pap smear to exclude UTI, TB, DM, STD's (Syphilis, HIV), and malignancy respectively. Assessment of socioeconomic status, mizaj (temperament), vaginal discharge [43], low backache [44,45] and cervical ectopy [15] was recorded in each patient. All information was reported on case record form structured for the study. After meticulous evaluation of patients with clinical interview, they were provided with intervention.

Sample size estimation

Sample size was calculated for single group with pre and post assessment for grading of cervical ectopy as indicator. From the previous study mean area of cervical erosion was 2.05 with SD of 0.59 [16]. The effective size set was ~0.5 i.e. 10% reduction. For this effective size, the sample was calculated from the formula [46]:

$n=2[(Z\alpha - Z\beta)\ SD/\mu1- \mu2]^2$

and validated from thumb rule for calculation of sample size i.e. (SD/ μ1- μ2)2 × 20 180 for 95% confidence limit. It was found to be 29.9~30. So, the size was fixed at 30 in the group.

Intervention

Murr, safeda, anzaroot was taken in equal quantity, finely powdered and ointment was prepared with mom and roghanegul[21]as per the method mentioned in classical Unani text as follows: Roghane gul-1 liter was heated and wax-500 gm was dissolved and mixed thoroughly, then fine powder of murr, safeda and anzaroot (each 1 kg) were added, stirred well and allowed to cool till it forms a soft and semi-solid mass [29,47,48]. Ointment 6 g was applied with applicator per vaginum on the eroded cervical area daily once at bedtime for 2 weeks & healing was observed.

Compliance to treatment

Compliance with medicine was monitored on subsequent follow up visit by examining the container in which medicine was dispersed at earlier visit.

Parameters for evaluation of efficacy of test drug

Subjective parameters

Vaginal discharge: It was assessed with severity as
Mild: No staining or moistness of underclothes
Moderate: Underclothes are soiled and require changing.
Severe: Requires the wearing of some extra absorbent pad [43].

Low backache: The intensity of low back ache was assessed by colored Visual Analogue Scale (VAS) for pain. It is a 10 cm line labeled scale which has 'no pain' or 'zero' on left side and 'worst possible pain' or 'ten' on the right side. The colored scale was taken to ease the patients in marking the intensity of the pain. Before pelvic examination, patients were asked to mark on the scale according to the severity or intensity of pain. VAS score was assessed at base line and at every follow up.

The colored Visual Analogue Scale for pain intensity was graded as:
0-1(Green Color): No pain to distress.
2-4 (Greenish Yellow): Annoying to uncomfortable.
6-8 (Yellow): Uncomfortable to dreadful.
6-8 (Yellowish red): Dreadful to horrible.
8-10 (Red): Horrible to agonizing [44,45].

Objective parameter

Cervical ectopy: Scale used for assessment of cervical ectopy was categorized in 3 grades based on ectropion size.
Grade I - when ectopy covers 1/3rd area of cervix.
Grade II- when ectopy covers 1/3rd to 2/3rd area of cervix.
Grade III- when ectopy covers>2/3rd area of cervix [45].

Assessment and follow up

Patients were followed once in a week for two weeks during treatment and once in two weeks for one month after treatment. At each visit, vaginal discharge, low backache and grading of cervical ectopy were assessed and noted on CRF and Pap smear was done at the last follow up visit. Patients were advised to maintain personal hygiene and avoid intercourse during the trial.

Assessment of efficacy

Primary outcome measure: Improvement in grading of cervical ectopy.
Secondary outcome measures: Improvement in vaginal discharge and low backache
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. Student t test (two tailed, dependent) has been used to find the significance of study parameters on continuous scale within each group. Paired Proportion test has been used to find the significance of proportion in paired data. The Statistical software namely SPSS 18.0, 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. [49,50] (Figure 1).

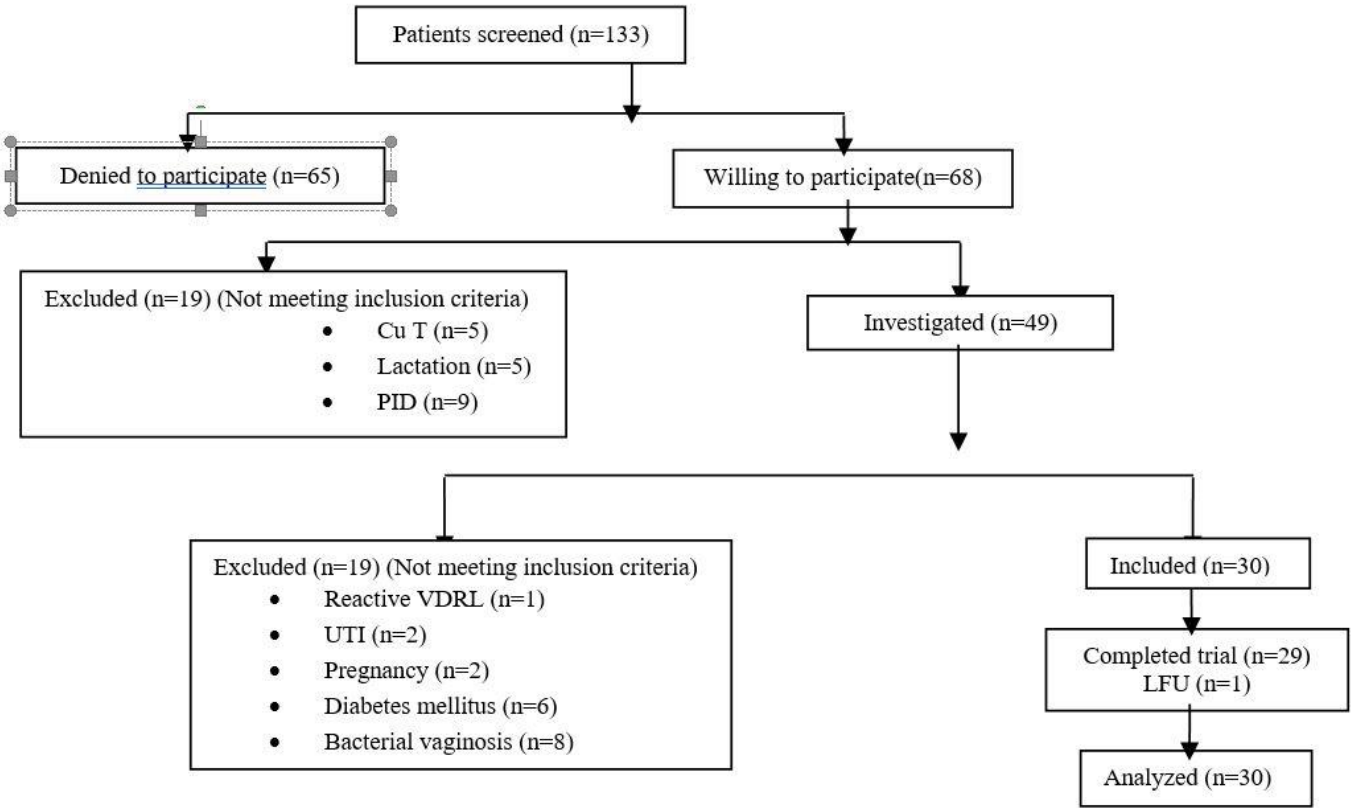

Figure 1: Trial flow chart of participant (LFU: Lost to follow up).

Results and Discussion

Main findings

In the present study, it was demonstrated that improvement in grading of cervical ectopy was achieved in 46.7% patients with 20% improvement in healing of cervical ectopy (P=0.0054). Improvement in vaginal discharge was achieved in 90% patients with relieve in 83.4% (P<0.001). Improvement in low backache was achieved in 70% patients with relieve in 46.7% (P=0.005). Significant improvement in vaginal discharge and low backache was probably due to healing of cervical ectopy, which causes relieve in these symptoms. No adverse effect of research drug was reported during the trial.

Demographic data

Age

Majority of the patients (53.3%) were in the age group of 31-40 years & remaining 46.7% in 20-30 years of age. Patil et al [13] reported 39.2% in 31-40 yrs. Latafat et al. [51] reported 40% and 44% in two groups in 31-35 years, Matiluko et al. [52] reported 30% in 36-40 years, Hashmi et al. [53] and Mirza S. et al [54] reported 40% & 37.8% in 26-30 years respectively. The result of present study correlates with the above studies. Evidence suggests that cervical ectopy is common in women of reproductive age group [7,16,18]. Mean age of patients was 31.07 ± 3.30, which is in accordance with the study of Jindal et al. [1] reported 31.32 and 33.7 in two groups, Al- Kaseer reported [55] 27.1 ± 5.9, Cekmez et al. [56] reported 34.4 ± 4.3, Hua et al [9] reported 35.1 ± 4.39 and 33.9 ± 4.02 in two groups respectively.

Socioeconomic status

In present study, 36.7% patients were belonging to upper middle class, 33.3% to lower middle class; and 30% to upper lower class. Hashmi et al. [53] 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 [54] reported 42.2% patients in upper lower class, 40% in lower middle, 11.1% in upper middle & 6.7% in upper class. Singh et al [8] & Shivanna et al [57] reported 72% and 75% patients respectively from low SES. Gautam et al. [32] reported majority of the patients belong to lower middle class. Kumar et al. [58] and Bengal et al [2] 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 predisposes to poor nutrition, poor personal hygiene leading to infection which may cause cervical ectopy [2,59].

Literary status

Most of the patients had low educational level i.e., 36.7% patients had primary school education, while 33.3% were illiterate, 20% & 10% had education up to secondary and higher secondary school respectively. Mirza S. et al [54] reported 20% illiterate, 33.3% had middle school education, 10% each in primary school and high school & 13.3% graduate. Hashmi et al. [53] reported 44.44% illiterate, 20% had middle school education & 13.3% had education in each primary, secondary and higher secondary. Gautam et al. [32] reported 40% of the patients had high school education. Al-Kaseer et al [55] reported low educational level among patients of cervical ectopy.

Mizaj

Most of the patients, 66.7 % possessed damwi mizaj, while 33.3% had balghami mizaj, none of the patients had safrawi or saudawi mizaj, which is in consonance with the studies of Hashmi et al. [53] reported 66.67 % patients with damwi mizaj, Mirza et al. [54] reported 53.3% with damwi mizaj. 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 gets secondarily infected, it result in rupture of this swelling which in turn leads to ulcer formation [21,60,61].

Table 1: Demographic data.

Demographic data	No. of patients (n=30)	%
Age in years		
20-30	14	46.7
31-40	16	53.3
Mean age in years	31.07±3.30	
Socio economic status		
Lower Middle	10	33.3
Upper Middle	11	36.7
Upper Lower	9	30
Literary status		
Illiterate	10	33.3
Primary	11	36.7
Secondary	6	20
High Secondary	3	10
Mizaj		
Balghami	10	33.3
Damwi	20	66.7
Pelvic ultrasonography		
No abnormality detected	23	76.6
PID	4	13.3
Cervicitis	3	10
Data are presented as number (percentage), Student t test (two tailed, dependent)		

Pelvic Ultrasonography

no abnormality was detected in 76.66% patients, though 13.3% had pelvic inflammatory disease & 10 % had cervicitis on pelvic ultrasonography. hashmi et al [53] reported no abnormality in 60% patients, pelvic inflammatory disease in 3.3%, bulky uterus in 20%, pcod in 13.3% and 3.33% each had bulky ovaries and functional cyst (Table 1).

Pap Smear

Before treatment, it was normal in 33.3% patients and inflammatory in 66.7%, while after treatment it was normal in 53.3% patients and inflammatory in 46.7% patients with improvement of 20%. Shivanna et al. [8] reported inflammatory smear in 70%, normal in 8.4%, and unsatisfactory in 16.5% patients before treatment, whereas smear was inflammatory in 16.6%, normal in 75% and unsatisfactory in 8.3% patients after treatment. Improvement in pap smear might be due to antimicrobial, antifungal, antiviral, anti-inflammatory effect of research drug [37,40,41,62-67] (Table 2).

Table 2: Effect of research drug on pap smear.

Pap smear	BT	AT	% Difference
Normal	10(33.3%)	16(53.3%)	20.00%
Inflammatory	20(66.7%)	14(46.7%)	-20.00%
	Data are presented as number (percentage), Student t test (two tailed, dependent)		

Subjective Parameters

Vaginal Discharge

At baseline, 96.7% patients were complaining of vaginal discharge. During treatment, on 1st& 2nd follow up, it persists in 73.3% & 43.3% and was absent in 26.7% & 56.7% patients respectively. After treatment, on 1st& 2nd follow up, it persists in 16.7% & 13.3% & was absent in 83.3% & 86.7% patients respectively. At baseline, vaginal discharge was mild, moderate & severe in 53.3%, 40% & 3.3% patients respectively. During treatment, on 1st follow up vaginal discharge was mild & moderate in 56.7% & 16.7% patients respectively, whereas none of the patients had severe vaginal discharge; on 2nd follow up, vaginal discharge was mild in 43.3% patients while none of the patients had moderate or severe vaginal discharge. After treatment, on 1st follow up, vaginal discharge was mild & moderate in 13.3% & 3.3% patients respectively, though no patient had severe vaginal discharge; on 2nd follow up, vaginal discharge was mild & moderate in 10% & 3.3% patients respectively and none of the patients had severe discharge. After treatment, vaginal discharge was improved in 83.4% patients with P<0.001, considered as highly significant, which is consistent with the study of Gupta et al. [68] Monroy et al. [14] and Anees et al. [69] studies who reported vaginal discharge in 100% patients before treatment and relief in 86.6% after treatment. Cekmez et al. [56] reported vaginal discharge in 91.9% patients with complete relief in 89.5%. Kamini et al. [6] reported 93.45% and Hashmi et al. [53] reported 100% improvement in vaginal discharge. Moreover, research drug possesses muhallile waram, daffi-i- taffun, anti-microbial, anti-fungal, anti-viral activities, which might resolve the inflammation after eliminating the infection and thus improves the vaginal discharge [37,40,41,62-67] (Table 3A).

Table 3A: Effect of research drug on vaginal discharge.

Vaginal discharge	Before Treatment	During Treatment		After Treatment		% Difference
		1st FU	2nd FU	1st FU	2nd FU	
Absent	1(3.3%)	8(26.7%)	17(56.7%)	25(83.3%)	26(86.7%)	83.40%
Present	29(96.7%)	22(73.3%)	13(43.3%)	5(16.7%)	4(13.3%)	-83.40%
Mild	16(53.3%)	17(56.7%)	13(43.3%)	4(13.3%)	3(10%)	-43.30%
Moderate	12(40%)	5(16.7%)	0(0%)	1(3.3%)	1(3.3%)	-36.70%
Severe	1(3.3%)	0(0%)	0(0%)	0(0%)	0(0%)	-3.30%

Low Backache

After treatment, compared to baseline low backache was improved in 46.7% patients with P=0.005, considered as highly significant. Anees et al. [69] reported 100% patient's with complaining of low back pain and relief in 66.7%. Sharma P. et al [16] reported

50%, Mirza et al. [54] reported 53.3%, Hashmi et al. [53] reported 30%, Kamini [6] reported 64 %, and Al-Kaseer. et al [55] reported 65% improvement in low backache. Mean ± SD of low backache at baseline, 1st & 2nd follow up during & after treatment was 1.43 ± 1.22, 0.97 ± 1.16, 0.60 ± 1.04, 0.37 ± 0.67, 0.30 ± 0.60 respectively with P<0.001, considered as highly significant, which is in accordance with the studies of Kamini et al. [6] reported1.26 ± 0.4 and 0.46 ± 0.4, Sharma et al. [16] reported 1.90 ± 0.60 and 0.95 ± 0.60 & Gautam et al. [32] reported 1.12 ± 0.169 and 0.75 ± 0.619 as Mean ± SD of low backache before and after treatment. Moreover, research drug possesses muhallile waram, musakkin, anti-inflammatory, analgesic, sedative activities which might resolve the inflammation and hence improves low backache [37,40,41,62-67] (Table 3B).

Table 3B: Effect of research drug on low backache.

Low Backache	Before Treatment	During Treatment		After Treatment		% Difference
		1st FU	2nd FU	1st FU	2nd FU	
0	9(30%)	14(46.7)	21(70%)	22(73.3%)	23(76.7%)	46.70%
1	7(23.3%)	8(26.7%)	3(10%)	5(16.7%)	5(16.7%)	-6.60%
2	7(23.3%)	4(13.3%)	3(10%)	3(10%)	2(6.7%)	-16.60%
3	6(20%)	3(10%)	3(10%)	0(0%)	0(0%)	-20.00%
4	1(3.3%)	1(3.3%)	0(0%)	0(0%)	0(0%)	-3.30%
Total	30(100%)	30(100)	30(100%)	30(100%)	30(100%)	-
Mean±	1.43±1.22	0.97±1.6	0.60±1.04	0.37±0.67	0.30±0.60	-
SD		0.001**	<0.001**	<0.001**	<0.001**	

Objective Parameter

Cervical ectopy

At base line, cervical ectopy was observed in 100% patients, which remains constant in 80% patients after treatment. Cervical ectopy was in grade I in 46.7% patients, grade II in 40% & grade III in 13.3%; during treatment, on 1st follow up, it was in grade I in 46.7% patients, grade II in 40% and grade III in 10%; on 2nd follow up, it was in grade I in 46.7% patients, grade II in 33.3% and grade III in 6.7%. After treatment, on 1st follow up, 46.7% patients had cervical ectopy in grade I, 36.7% in grade II and none of the patient had cervical ectopy in grade III; on 2nd follow up, 46.7% patients had in grade I, 33.3% in grade II and none of the patient had grade III cervical ectopy. Thus, healing of cervical ectopy was achieved in 20.0% patients with P=0.0054, considered as highly significant. Shivanna et al. [8] 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. [16] reported improvement in 65.85% patients, Cekmez Y. et al [56] reported in 95.9% patients after 6weeks. Gautam et al. [32] reported improvement in 53.4% patients after 7 days. Hence, complete healing of cervical ectopy was observed in 20% patients only after 2 weeks of treatment. Moreover, research drug possesses mujaffif, mudamille quruh, qabid, antiulcer, antioxidant & wound healing activities, which might be helpful in healing of cervical erosion [37,40,41,62-67] (Table 4).

Table 4: Effect of research drug on cervical ectopy.

Cervical Ectopy	Before Treatment	During Treatment		After Treatment		% Difference
		1st FU	2nd FU	1st FU	2nd FU	
Absent	0(0%)	1(3.3%)	4(13.3%)	5(16.7%)	6(20%)	20.00%
Present	30(100%)	29(96.7%)	26(86.7%)	25(83.3%)	24(80%)	-20.00%
Cervical ectopy grading						
Grade-I	14(46.7%)	14(46.7%)	14(46.7%)	14(46.7%)	14(46.7%)	0.00%
Grade-II	12(40%)	12(40%)	10(33.3%)	11(36.7%)	10(33.3%)	-6.70%
Grade-III	4(13.3%)	3(10%)	2(6.7%)	0(0%)	0(0%)	-13.30%
Data are presented as number (percentage), paired proportion test. Cervical ectopy improved to 20.0%, P=0.0054**, highly significant						

Primary Outcome Measure

Cervical ectopy

Improvement in grading of cervical ectopy was observed in 46.7% patients & no improvement in 53.3% patients after 2 weeks of treatment. Hashmi et al. [53] reported cure in 26.66% patients after 9 weeks of treatment. Shivanna et al [8] reported in 60% patients after 1week and in 40% after 3 weeks of local application of albothyl solution. Jindal et al. [1] reported 92% & 76% respectively in two groups (electrocautery/cryocautery) after 4-6 weeks. Cekmez et al [56] reported in 95.9% patients after 6 weeks of cryocautery. Hua et al [9] reported cure in 89.8% & 91.5% patients after 12 weeks in PRP & laser groups respectively.

Secondary Outcome Measures

Vaginal discharge

Improvement in vaginal discharge was noted in 90% patients; while it persists in 10% patients after 2 weeks of treatment, which is in agreement with the studies of Hua et al [99] reported 89.7% in PRP group and 94.3% in laser group after 12 weeks; Anees et al. [69,70] reported 86.6% after 1 week, Jindal et al. [1] reported 100% and 92% in two groups after 4-6weeks of treatment.

Low backache

Improvement in low back ache was noted in 70% patients, while it remains constant in 30% patients after 2 weeks of treatment, which matched well with the study of Jindal M [1] reported relief in 96% & 76% in two groups after 4-6weeks of treatment (Table 5).

Table 5: Effect of research drug on outcome measures.

Outcome measures		No. of patients (n=30)	%
Primary outcome measure			
Cervical ectopy	No	16	53.3
	Yes	14	46.7
Secondary outcome measures			
Vaginal discharge	No	3	10
	Yes	27	90
Low backache	No	9	30
	Yes	21	70
Data are presented as number (percentage), Student t test (two tailed, dependent)			

Strength of the study

This study was first of its kind; where treatment was given as topical medication in ointment form which was applied with the applicator directly over the eroded cervical area.

Limitations of the study

Small sample size, short duration of intervention, short follow up, colposcopy was not done during the study.

Future recommendation

Use of research drug as topical medication for longer duration (6-8 weeks) on large number of patients with long follow up for better therapeutic outcome, to conduct RCT's with topical application of research drug with standard treatment i.e., cauterization either electro cautery or cryo cautery and future trial with use of research drug as topical medication is recommended in patients with abnormal cervical cytology or cervical intraepithelial neoplasm.

Conclusion

Thus, research drug was effective in healing of cervical ectopy and relieving the associated symptoms as marked improvement in outcome measures was observed with just two weeks of intervention in ointment form. Research drugs possess muhallile waram, mujaffif, mudammile quruh, dafi-i-ta'ffun, qabid, musakkin properties. Moreover, pharmacological studies shows that research drug exhibit anti-microbial, anti-inflammatory, antioxidant, anti-cancer, anti-ulcer, analgesic, wound healing activities. Further murr, anzaroot, roghanegul, mom contains flavonoids, saponins (glycosides), carbohydrates, alkaloids (terpenoids, steroids) etc., which are considered as the active principle of anti-ulcer activity. Flavonoids are group of Polyphenolic compounds having anti-ulcer genic, anti-inflammatory, anti-bacterial, antioxidants properties which provide strength to the mucosal barrier & promote the ulcer to heal fast. The wound healing activity of ointment

might protect against microbial invasion by providing better tissue formation. Further, the ointment probably enhanced the rate of wound healing & tissue epithelization. Finally, it can be inferred that research drug shows potent wound healing action, and thus serves as an effective alternative in patients with cervical ectopy.

Clinical Trial Registration

No/2018/03/012668.

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Conflict of interest

The authors declared that there is no conflict of interest.

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