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Effect of *Arq Brinjasif* in mild pelvic inflammatory disease-A randomised controlled trial

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Abstract
Background & Objectives: Pelvic inflammatory disease (PID) is a major health problem of reproductive age women in both developing and developed countries. About 10-20 per 1000 fertile women suffers from PID. The aim of the study was to evaluate the efficacy of *arq brinjasif* in mild pelvic inflammatory disease.
Method: A standard controlled randomised single blind study was carried out at the Institute's Hospital, Bangalore. A total of 40 patients in the age group of 20-40 yrs with mild PID were randomly assigned to two equal groups to receive either *arq brinjasif* (test group) or combination of ofloxacin-ornidazole (control group) twice daily orally for 14 days. Primary outcome measures were clinical response, defined as 70% or more reduction in Visual Analogue Score (VAS) and McCormack pain scale (McPS) score after 2nd week of treatment with no clinical recurrence within 5 days. Secondary outcome measures were clinical cure, defined by absence or minimum pelvic tenderness and presence of clear vaginal discharge at the end of 4th week.
Results: Clinical response for VAS was achieved in 90% patients in test and 95% in control group with p =1.000 & for total tenderness in 75% patients in test and 95% in control group with p value=0.182. Pelvic tenderness was clinically cured in 90% patients in either group with p=1.000. Clear vaginal discharge was achieved in 95% patients in both groups with p=1.000.
Interpretation and Conclusion: Effect of *arq brinjasif* was comparable to control drug in the management of mild PID & hence, can be used as an alternate therapy.

Keywords: Pelvic inflammatory disease; *Arq Brinjasif*; Ofloxacin; Ornidazole; Visual Analogue Scale; McCormack Pain Scale

1. Introduction

Pelvic inflammatory disease (PID) is a clinical condition representing inflammation of infectious etiology of upper genital tract and related structures [1, 2]. It specifically involves at least the uterus and/or fallopian tubes [3]. It is a major health problem of reproductive age women in both developing and developed countries [1, 4] and is the main gynaecological cause of acute lower abdominal pain. Prevalence has been estimated at 9-27 per 1000 fertile women [5]. In classical Unani literature, the description of PID is mentioned under the heading of *warme rehm* (uterine inflammation*)* which is further subdivided into *warme rehm har* (acute PID) *&* *warme rehm saudavi* (chronic PID) [6, 7, 8, 9]. *Warm* is the reaction of the body to morbid matter which may be external as injury, stings, bites, bacteria or internal as deranged humours [10]. It can either be *har* (inflammatory) or *gair har* (non inflammatory). *Warm* is caused by predisposing factors which compromise faculty (*quwa)* of an organ resulting in accumulation of blood and eventually leading to swelling (tumor), warm (calor), redness (rubor) and pain (dolor) in the effected organ. The basic cause of *warm* is the defect in *quwate ghaziya* of an organ, as a result the metabolism of the effected organ becomes defective leading to accumulation of humour [7] and subsequently temperamental abnormality sets in, which eventually causes *warm* in the effected organ [11]. The prerequisites for *amle ufoonat* (infection) are site of *maddae ratoobat* (infection), adequate *hararat* (optimum temperature) and *maddae mufenah* (putrefying/infectious agent) [12]. The *warm* (inflammation) can undergo either *tehleel* (complete resolution), *dabila* (suppuration*)* like tubo-ovarian abscess or *salabat* (induration) which is chronic PID [6, 11]. In classical Unani literature, it is mentioned that *warme rehm har* manifests specific as well as associated symptoms due to anatomical proximity of uterus, which aid in diagnosis and if it is not treated adequately, it becomes *warme rehm sulb* which is difficult to treat [6, 7]. Signs of inflammation are more pronounced in sensitive organs like uterus [7, 13]. In Unani system of medicine; combination of herbal drugs is the recommended treatment for PID which is probably the most ancient "multi-drug therapy" regimen [6]. where one compound either potentiates the effect of other, or increases the bioavailability, or reduces the toxicity. *Arq brinjasif* is a compound formulation which possesses *muhallil warm* (anti-inflammatory) property [14, 15] its ingredients exhibit anti-inflammatory [15]. Anti-microbial [16] antioxidant [15, 16] and analgesic [17] properties. Hence, these constituents may work together in a dynamic way to produce therapeutic efficacy with minimum side-effects. The hypothesis tested was use of Unani formulations in one group compared with standard drug in other group will be effective in the management of PID. The present study was carried out to evaluate the efficacy and safety of *arq brinjasif* in mild pelvic inflammatory disease.

2. Materials and methods

2.1 Study design

Standard controlled randomized single blind study was carried out from Dec 2012 to March 2014 in OBG Dept. National Institute of Unani Medicine Hospital, Bangalore. Ethical clearance was obtained from the institutional ethical

committee and all participants gave written informed consent prior to study.

2.2 Participants

Total 86 patients were screened for the study, 31 patients didn't meet the inclusion criteria and 15 patients denied participation, hence were excluded. (Fig. No. 1) 40 patients were randomly allocated in two equal groups by computer generated simple randomization table [18].

2.3 Selection criteria

Married women in the age group of 20-40 yrs with c/o of lower abdominal pain < 30 days and abnormal vaginal discharge with or without low backache having clinical features of mild PID (VAS score <6 and McPS score for any quadrant <3 was taken as cut off value to define mild PID)[19] were included in the study and those with clinical symptoms of severe PID, tubo ovarian abscess, haemorrhagic ovarian cyst, appendicitis and pelvic pain > 30 days, delivery, abortion or gynaecologic surgery < 30 days, pregnant and lactating women and with h/o HIV or syphilis, systemic illnesses and malignancies were excluded from the study by performing abdomino pelvic scan, RBS, CUE, HIV, VDRL and Pap smear.

2.4 Study procedure

All patients with a history of pelvic or lower abdominal pain for < 30 days, with mucopurulent discharge per vaginum, and pelvic organ tenderness on bimanual examination were invited to participate in the study protocol. Each patient underwent a detailed clinical interview, examination, and investigation. The degree and duration of symptomatology and other details were noted in chronological order in case record form designed for the study. Patients were inquired about the history of PID, contraception and vaginal douching. Emphasis was given to education and socioeconomic status of the patient, which were assessed by Kuppuswamy's Socioeconomic Scale. The *mizaj* was assessed by using temperamental scale as described by the ancient *Unani* physicians. Patients were instructed to maintain local hygiene, to abstain from sexual intercourse or use barrier contraceptive during the study period. General physical examination was carried out to rule out any systemic diseases. Abdominal palpation was carried out to assess the direct and rebound tenderness.

P/S examination was performed to look for:

- Mucopurulent vaginal discharge.
- Obtain wet mount test to analyse the no. of WBC per HPF in vaginal discharge.
- Obtain endocervical swab specimen for culture and gram staining to detect the microorganism.

P/V examination was performed to assess pelvic organ tenderness (uterine or adnexal) and to rule out the presence of any adnexal mass.

Each patient was subjected to biochemical (SGOT, SGPT, Alkaline phosphatise, Blood urea, Serum creatinine) as well as specific investigations (Complete blood count, ESR, CRP, Wet mount test, Cervical swab culture and gram staining).

2.5 Intervention

The ingredients of *arq brinjasif* are *Brinjasif* (*Achillea millefolium*), *Badiyan* (*Foeniculum vulgare), Tukhme kasni* (*Cichorium intybus*), *Barg jhau* (*Tamarix gallica*), *Mako khushk (Solanum nigrum*) each 150gm & *Afsanteen* (*Artemisia absinthium*) 75gm were taken & *arq* was prepared according to the method as mentioned in classical Unani literature [15]. *Arq brinjasif* 60ml was administered orally twice daily for 14 days (dispensed in unlabeled bottles). In control group, combination of ofloxacin 400 mg and ornidazole 500 mg was administered orally twice daily for 14 days [20].

2.6 Blinding & compliance

To ensure blinding the control drug was emptied from blister pack into lock bags and the test drug was dispensed in unlabelled bottles. To confirm the patient compliance, only seven days treatment were given to them, advising them to return on 8th day with empty bottles to receive the remaining half of treatment.

2.7 Follow up

Patients were followed weekly once for two weeks during the trial and once in 15 days for one month after the treatment. Two patients in test and one in control group were loss to follow, and included in statistical analysis by using last observation carry forward method. Patients were also inquired for any adverse effect of the drugs during the study.

2.8 Subjective parameters

Lower abdominal pain was assessed for presence, absence or worsening. LBA was assessed as percentage reduction from the baseline. Vaginal discharge was graded according to the severity as mild, moderate and severe [21].

2.9 Objective parameters

A) Lower abdominal pain: The intensity of lower abdominal pain was objectively assessed by colored Visual Analogue Scale (VAS) [22] for pain. Before pelvic examination, patients were asked to mark on the scale according the intensity of pain. The colored Visual Analogue Scale for pain intensity was graded as:

0 -1(Green Colour): No pain to distress
2-4 (Greenish Yellow): Annoying to uncomfortable
4-6 (Yellow): Uncomfortable to dreadful
6-8 (Yellowish red): Dreadful to horrible
8-10 Red): Horrible to agonizing

B) Mucopurulent vaginal discharge: was assessed on per speculum examination.

C) Wet mount test: was considered positive if WBC ≥10 / HPF in vaginal discharge.[19] A drop of vaginal discharge was placed on a glass slide with 1-2 drops of 0.9% sodium chloride solution and examined for no of WBCs (polymorphonuclear lymphocytes) per high-power field (×400).

D) Total tenderness (abdominal and pelvic): It was assessed by modified McCormack pain scale (McPS), which is a four point tenderness scale used to assess the direct and rebound tenderness ranging from 0= tenderness absent,1=tenderness referred by the patient, 2=tenderness causing observable distress & 3=rebound tenderness. Total score was sum of individual scores for 12 abdominal and pelvic regions with a maximum score=36.[18]

E) Cervical swab specimen for culture and gram staining: was performed before & after the trial.

2.10 Outcome measures

Primary outcome measures were clinical response, defined as 70% or greater reduction in VAS and McPS score at day 14 compared to baseline and secondary outcome measures were clinical cure, defined by the absence of or minimal pelvic tenderness [23] and presence of clear vaginal discharge.

2.11 Statistical Analysis

The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc**.** Significance was assessed at 5 % level of significance. Student t test, Chi-square/ Fisher Exact test was used to analyse the data.

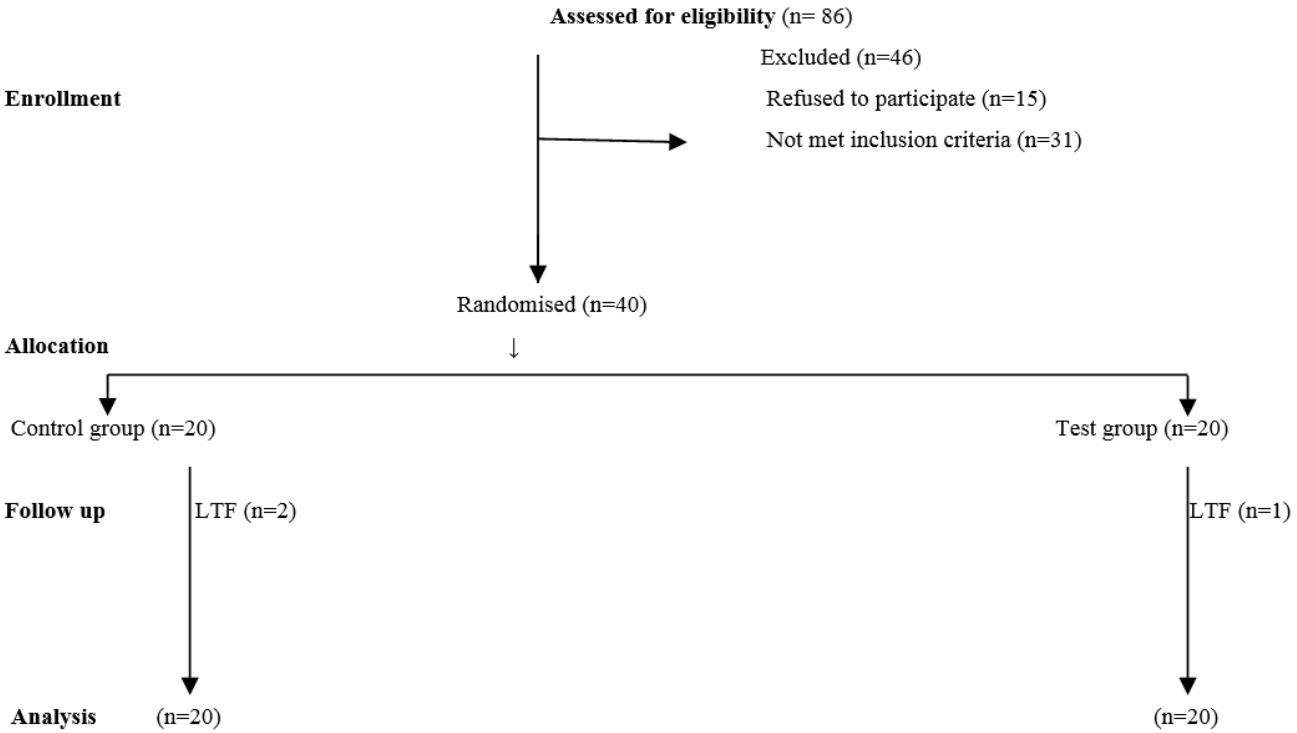

Fig 1: Consort flow chart (LTF-loss to follow up)

3. Results

Table 1: Comparison of baseline characteristics in two groups

Baseline characteristics		Test group (n=20)	Control group (n=20)	*P* value
Age (years)	Mean ±SD	27.65±4.48	27.2±4.84	*P*=0.762
Education status	Illiterate	5(25.0%)	3(15.0%)	*P*=0.429
	Literate	15(75.0%)	17(85.0%)	
SES	Lower	2(10.0%)	1(5.0%)	*P*=0.926
	Lower middle	6(30.0%)	6(30.0%)	
	Upper lower	9(45.0%)	11(55.0%)	
	Upper middle	3(15.0%)	2(10.0%)	
H/O PID	No	14(70.0%)	16(80.0%)	*P*=0.465
	Yes	6(30.0%)	4(20.0%)	
Contraception	No	14(70.0%)	16(80.0%)	*P*=0.465
	Yes	6(30.0%)	4(20.0%)	
	BC	1(5.0%)	1(5.0%)	
	IUCD	1(5.0%)	0(0.0%)	
	SP	0(0.0%)	1(5.0%)	
	TUB	4(20.0%)	2(10.0%)	
Ass. Sym.	No	5(25.0%)	5(25.0%)	*P*=1.000
	Yes	15(75.0%)	15(75.0%)	
Mizaj	*Balghami*	5(25.0%)	4(20.0%)	*P*=0.434
	Damvi	13(65.0%)	12(60.0%)	
	Safravi	2(10.0%)	4(20.0%)	

BC- barrier contraceptives**, SP**- Safe period**, TUB**- tubectomy
Data were presented as number (percentage), Student t test, Fisher exact test

Table 2: Comparison of subjective parameters in two groups

Subjective parameters		BT	After 1st week	After 2nd week	After 1st follow up	After 2nd follow up
Lower Abd Pain	Test group	20(100.0%)	19(95.0%)	3(15.0%)	2(10.0%)	2(10.0%)
	Control group	20(100.0%)	13(65.0%)	2(10.0%)	1(5.0%)	1(5.0%)
	P value	1.000	0.018*	1.000	1.000	1.000
LBA (Red in %)	Test group	19(95.0%)	19(95.0%)	14(70.0%)	13(65.0%)	12(60.0%)
	Control group	19(95.0%)	16(80.0%)	12(60.0%)	12(60.0%)	11(55.0%)
	P value	1.000	0.106	0.741	1.000	0.999
Amt of Vag. Dis Test group	Mild	1(5.0%)	6(30.0%)	10(50.0%)	15(75.0%)	18(90.0%)
	Moderate	18(90.0%)	14(70.0%)	10(50.0%)	5(25.0%)	2(10.0%)
	Severe	1 (5.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Control group	Mild	3(15.0%)	10(50.0%)	13(65.0%)	18(90.0%)	19(95.0%)
	Moderate	17(85.0%)	10(50.0%)	7(35.0%)	2(10.0%)	1(5.0%)
	Severe	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	P valve	0.605	0.333	0.523	0.407	1.0000

Abd: abdominal; **LBA:** low back ache; **Amt of Vag Dis:** amount of vaginal discharge
Data were presented as number (percentage). Chi-Square test/Fisher Exact test

Table 3: Comparison of objective parameters in two groups

Visual Analogue Scale Score		BT	After 1st week	After 2nd week	After 1st follow up	After 2nd follow up
Test group		4.45±0.51	1.65±0.881	0.25±0.64	0.15±0.63	0.15±0.63
Control group		4.40±0.60	1.25±0.97	0.15±0.49	0.1±0.48	0.1±0.48
P value		0.778	0.178	0.582	0.735	0.735
Type of Vaginal Discharge						
Test group	Leucorrhoea	8(40.0%)	2(10.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	Mucopurulent	12(60.0)	6(30.0%)	2(10.0%)	2(10.0%)	2(10.0%)
	Clear	-	12(55.0%)	18(90.0%)	18(90.0%)	18(90.0%)
Control group	Leucorrhoea	9(45.0%)	3(15.0%)	0(0.0%)	0(0.0%)	0(0.0%)
	Mucopurulent	11(55.0%)	4(20.0%)	1(5.0%)	1(5.0%)	1(5.0%)
	Clear	-	13(65.0%)	19(95.0%)	19(95.0%)	19(95.0%)
P value		0.999	0.809	0.999	0.999	0.999

McCormack Pain Scale Score		Test group	Control group	*P* value
Before Treatment	Total tenderness	8.20±1.47	8.30±1.78	0.848
	Pelvic tenderness	4.85±0.99	4.65±0.93	0.514
After 1st week	Total Tenderness	4.50±1.64	4.05±1.47	0.366
	Pelvic Tenderness	3.05±0.94	2.70±0.86	0.229
After 2nd week	Total Tenderness	2.05±1.79	1.00±1.37	0.044+
	Pelvic Tenderness	1.35±1.3	0.65±0.87	0.035+
After 1st follow up	Pelvic Tenderness	1.05±1.05	0.50±0.82	0.073
After 2nd follow up	Pelvic Tenderness	0.65±0.99	0.25±0.71	0.149
Cervical Swab Culture		**Before Treatment**	**After Treatment**	**% change**
Test group	No growth	17(85%)	20(100%)	15%
	Growth	3(15%)	0(0%)	-15%
Control group	No growth	16(80%)	20(100%)	20%
	Growth	4(20%)	0(0%)	-20%
P value		1.000	1.000	-
Gram Staining				
Test group	Organism absent	17(85%)	20(100%)	15%
	Organism present	3(15%)	0(0%)	-15%
Control group	Organism absent	16(80%)	20(100%)	20%
	Organism present	4(20%)	0(0%)	-20%
P value		1.000	1.000	-

Table 4: Comparison of outcome measures in two groups

Primary Outcome Measures	Test group (n=20)		Control group (n=20)		*P*- value
	No	%	No	%	
VAS	18	90.0	19	95.0	1.000
Total tenderness	15	75.0	19	95.0	0.182
Secondary Outcome Measures					
Vaginal Discharge	18	90.0	19	95.0	1.000
Pelvic tenderness	18	90.0	19	95.0	1.000

Data were presented as number (percentage), Chi square test

4. Discussion

Baseline characteristics

These were similar in both groups with p>0.05. The mean age of the patients was 27.65±4.48 in test group and 27.2±4.84 in control group with 45 % of patients were ≤25 years of age. This finding was in accordance with study of Ness *et al*, [1] who reported 50% of patients were < 25 years of age. McCormack *et al* [24] also reported that most of the patients with PID were in their early 20s. 80% patients were literate mostly educated to high school, 50% belonged to upper lower socioeconomic status probably due to their negligent health seeking behaviour. 25% had previous history of PID, which is compatible with the study of Ness *et al* [1] who reported 33.33% patients had previous history of PID. 75% were not using any contraceptive measure which is consistent with the study of McCormack *et al* [24]. 75% were having associated symptoms and 62.5% were having *damvi mizaj* which is in conformance with the observation of eminent Unani physician such as *Buqrat, Ibn Sina, Jurjani* [6, 7, 9] who states that this disease is caused by dominance of *khilte har* which leads to *sue mizaj maddi*, *sue tarkeeb* and *tafarruqe ittesal*, which is considered as the basic pathophysiology of *warm har* as mentioned in classical Unani literature. (Table. 1)

Subjective parameters

Improvement in lower abdominal pain was strongly significant within the group after 2nd week of trial with *P*<0.001 & the difference was non-significant on inter group comparison. This effect can be attributed to analgesic [25] and anti-inflammatory activities [26] of ingredients of the test drug. Improvement in low back ache was 35% in test and 40% in control group. Improvement in the amount of vaginal discharge was comparably equal in both groups. This effect may be exhibited to antibiotic, inflammation ameliorating and exudate desiccating effect of the test drug as it contains ingredients possessing anti-microbial, [27] anti-inflammatory and astringent activities. (Table. 2)

Objective parameters

Improvement in VAS score and abnormal vaginal discharge was strongly significant within the group after 2nd and 4th week of trial respectively with *P*<0.001. Improvement in VAS score may be credited to analgesic and anti-inflammatory activities of ingredients of test drug which probably act by inhibiting central pain receptors and inflammatory mediators due to the presence of alkaloids, tannins, flavonoids [28]. monoterpenes and sesquiterpenes [29]. Improvement in vaginal discharge can be ascribed to synergistic effect of ingredients of the test drug as they all possess antimicrobial activity. Improvement in McPS score for total tenderness and pelvic tenderness was strongly significant after 2nd and 4th week of trail respectively with *P*<0.001. This effect may be credited to antimicrobial [30], anti-inflammatory [28] and anti-oxidant [31] activities of ingredients of the test drug. Anti-inflammatory phytochemicals e.g flavonoids [28], and dicaffeoylquinic acid [32] affect the synthesis and liberation of inflammatory mediators, thus abolishing inflammation and associated tenderness. Antioxidants can attenuate cellular injury and dysfunction by scavenging reactive oxygen metabolites produced during inflammatory process [33]. No pathogenic organism was detected on cervical swab culture and gram staining after 2nd week of treatment. (Table. 3)

Outcome measures

Clinical response for VAS was achieved in 90% patients in test and 95% in control group (p =1.000) and for total tenderness, it was achieved in 75% patients in test and 95% in control group (p =0.182); Pelvic tenderness was clinically cured in 90% patients in both groups (p=1.000) and clear vaginal discharge was achieved in 95% patients in both groups (p=1.000).(Table. 4) Test drug was well tolerated with no adverse effect reported as safety profile was within normal limits.

Limitation of the study were small sample size, short follow up, lack of identification of microorganism in majority of patients. Future recommendations are Phase III trial can be carried out for generalisation of results with longer follow up to assess recurrence and long term reproductive outcome.

5. Conclusion

Arq brinjasif was effective in the management of mild PID as its ingredients possess anti-microbial, anti-inflammatory, anti-oxidant, analgesic and hepatoprotective activities due to the presence of alkaloids, tannins, flavonoids, monoterpenes, camphor, saponins, anthraquinone and terpenoids. Therefore, it can be inferred that the effect of *arq brinjasif* was comparable with the control drug; hence it can be used as an alternative therapy in the management of mild PID.

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