

# Efficacy and Safety of Aspaghol (*Plantago ovata* Forssk.) in the Management of Warm-e-Unq-ur-Reham (Cervicitis): A Single-Blind Randomized Placebo-Controlled Trial

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**Abstract:** *Background:* Cervicitis (Warm-e-Unq-ur-Reham) affects >50% of reproductive-age women globally, with an OPD incidence of 35–85%. Conventional antibiotic therapy is limited by resistance and recurrence. Aspaghol (*Plantago ovata* Forssk.), classified as Barid wa Ratab in Unani pharmacology, has classical indication in cervicitis owing to its Mohallil-e-Auram (anti-inflammatory) and Mulayyin (demulcent) properties. *Methods:* A single-blind, randomized, placebo-controlled trial was conducted on 44 women of reproductive age with clinically confirmed cervicitis (n=22 per group). The intervention group received Sufoof-e-Isapgol 5 g orally twice daily and intravaginal Humul (mucilage pessary) for 10 days per cycle over 3 consecutive menstrual cycles. Outcomes were assessed by symptom relief (white discharge, lower abdominal pain, backache) and per speculum findings (inflammation, hypertrophy, congestion). Statistical analysis used chi-square and Fisher's exact tests. *Results:* The intervention group showed highly significant improvement in white discharge (81.8%), lower abdominal pain (86.4%), and backache (77.3%), all p<0.001. Cervical inflammation resolved in 86.4% (p<0.001) and hypertrophy in 77.3% (p=0.017). The placebo group showed negligible improvement (≤9.1%; p>0.05). No adverse effects were recorded. *Conclusion:* Aspaghol is a safe, effective, and cost-efficient Unani alternative for the management of cervicitis, demonstrating statistically significant superiority over placebo.

**Keywords:** Cervicitis, Warm-e-Unq-ur-Reham, *Plantago ovata*, Aspaghol, Unani Medicine, Randomized Controlled Trial, Intravaginal Pessary

## 1. Introduction

Cervicitis refers to inflammation of the uterine cervix and represents one of the most prevalent gynecological disorders in women of reproductive age. Studies estimate a lifetime incidence exceeding 50%, with chronic cervicitis accounting for 35–85% of gynecology OPD presentations.<sup>1</sup> The condition carries significant morbidity including pelvic inflammatory disease, infertility, adverse pregnancy outcomes, and an established role as a co-factor in cervical intraepithelial neoplasia and HIV transmission.<sup>2</sup>

Conventional management relies on antibiotics, antifungals, and antivirals, yet is constrained by antimicrobial resistance, high recurrence rates, incomplete symptom resolution, and cost. These limitations motivate exploration of evidence-based traditional alternatives.<sup>3</sup>

In Unani medicine, cervicitis is termed Warm-e-Unq-ur-Reham. Classical authorities including Ibn Sina and Hakeem Ajmal Khan attributed it to excess Dam and Safra humors generating a hot, moist temperament and prescribed drugs of cold and dry temperament (Barid wa Yabis) in accordance with the principle of Ilaj bil Zid (treatment by opposites).<sup>4</sup> Aspaghol (*Plantago ovata* Forssk., family Plantaginaceae), assigned a Barid 3° and Ratab 2° Mizaj, is classically indicated for cervicitis due to its anti-inflammatory (Mohallil-e-Auram), soothing (Musakkin), and demulcent (Mulayyin) actions. Modern pharmacology confirms a high arabinoxylan

mucilage content responsible for mucosal protection and anti-inflammatory activity.<sup>5</sup>

Despite this classical and pharmacological rationale, no randomized controlled trial has evaluated Aspaghol specifically for cervicitis. This study was therefore designed to generate clinical evidence for its efficacy and safety.

## 2. Materials and Methods

**Study design:** Single-blind, randomized, placebo-controlled clinical trial.

**Setting:** PG Department of Qabalat-o-Niswan (QON), OPD & IPD, Govt. Nizamia Tibbi College and General Hospital, Charminar, Hyderabad, Telangana, India. Study duration: 18 months.

Sample size was calculated using the formula  $n = Z^2p(1-p)/e^2$ , with  $Z=1.28$  (80% power),  $p=0.5$ ,  $e=0.05$  on a population of 60, yielding  $n=44$  (22 per group). All participants were randomized equally; participants were blinded to group allocation.

**Inclusion criteria:** Married women of reproductive age with clinical features (white discharge, pelvic pain, dyspareunia, contact bleeding) and per speculum evidence of cervicitis (congestion, hypertrophy, mucopurulent discharge) confirmed by inflammatory Pap smear.

**Exclusion criteria:** Pregnancy, suspected malignancy, uterine pathology (fibroid, prolapse, endometritis), inability to attend for 3 months.

**Treatment protocol- Group A (Intervention):** (i) Sufoof-e-Isapgol 5 g orally twice daily; (ii) Intravaginal Humul (pessary) prepared from Luab-e-Isapgol (mucilage of Plantago ovata seeds soaked overnight) inserted at mid-cycle for 10 consecutive days, repeated over 3 menstrual cycles. Group B (Placebo): identical inert oral and intravaginal preparations in the same schedule.

Outcome parameters: Subjective — white vaginal discharge, lower abdominal pain, low backache. Objective — per speculum findings (cervical inflammation, hypertrophy, congestion, discharge, Nabothian cysts). Investigations: haemoglobin, WBC, ESR, VDRL, and cervical Pap smear performed at baseline and on follow-up. Statistical analysis: Chi-square and Fisher's exact tests (SPSS); p<0.05 considered significant.

### 3. Results

#### 3.1 Demographic and Baseline Profile

**Table 1:** Demographic and Baseline Clinical Profile of Study Participants (n=44)

Variable	Category	Group A — Aspaghol n (%)	Group B — Placebo n (%)
Age (years)	20–35	14 (63.6%)	14 (63.6%)
	36–40	8 (36.4%)	8 (36.4%)
Socioeconomic	Lower income	14 (63.6%)	14 (63.6%)
	Middle income	8 (36.4%)	8 (36.4%)
Parity	Nulliparous	3 (13.6%)	3 (13.6%)
	Multiparous (1–5)	17 (77.3%)	18 (81.8%)
	Grand multiparous (≥6)	2 (9.1%)	1 (4.6%)
Menstrual cycle	Regular	18 (81.8%)	17 (77.3%)
	Irregular	4 (18.2%)	5 (22.7%)
Mizaj (Unani temperament)	Damavi	10 (45.5%)	8 (36.4%)
	Safravi	8 (36.4%)	8 (36.4%)
	Balghami	4 (18.2%)	6 (27.3%)

Both groups were well-matched at baseline. Multiparous women predominated (79.5% combined), highlighting repeated cervical trauma as a risk factor. The preponderance

of Damavi and Safravi Mizaj is consistent with the hot temperament of cervicitis as described in Unani nosology.

**Table 2:** Baseline Laboratory Investigations (n=44)

Investigation	Group A n (%)	Group B n (%)	Total n (%)
Hb <11 gm% (anaemia)	16 (72.7%)	17 (77.3%)	33 (75.0%)
WBC 4500–11000 /mm <sup>3</sup> (normal)	20 (90.9%)	21 (95.5%)	41 (93.2%)
ESR >15 mm/hr (elevated)	14 (63.6%)	15 (68.2%)	29 (65.9%)
Pap smear- inflammatory	22 (100%)	22 (100%)	44 (100%)
VDRL- non-reactive	22 (100%)	22 (100%)	44 (100%)

Elevated ESR (65.9%) and universal inflammatory Pap smear confirmed chronic cervicitis at baseline. Anaemia (75%) reflects the socioeconomic profile of the cohort.

#### 3.2 Effect of Treatment

**Table 3:** Symptomatic Response After Treatment- Both Groups

Symptom	Group A — Aspaghol (n=22)			Group B — Placebo (n=22)		
	Cured	Relieved	p-Value	Cured	Relieved	p-Value
White Discharge	18 (81.8%)	2 (9.1%)	<0.001**	2 (9.1%)	0 (0%)	0.317 NS
Lower Abd. Pain	19 (86.4%)	1 (4.5%)	<0.001**	1 (4.5%)	0 (0%)	0.445 NS
Low Backache	17 (77.3%)	3 (13.6%)	<0.001**	1 (4.5%)	0 (0%)	0.445 NS

\*\* p<0.001 Highly Significant; NS = Not Significant (p>0.05). Chi-square / Fisher's exact test.

**Table 4:** Post-Treatment Per Speculum Findings- Both Groups

Cervical Finding	Group A Healed n (%)	p-Value	Group B Healed n (%)	p-Value	Significance
Inflammation	19 (86.4%)	<0.001	0 (0%)	1	Highly Sig.**
Cervical Hypertrophy	17 (77.3%)	0.017	0 (0%)	1	Significant*
Discharge	15 (68.2%)	0.134	1 (4.5%)	0.311	NS
Congestion	11 (50.0%)	1	0 (0%)	1	NS
Nabothian Cysts	0 (0%)	<0.001	0 (0%)	1	NS (none healed)

\* p<0.05 Significant; \*\* p<0.001 Highly Significant; NS = Not Significant. Fisher's exact test.

### 4. Discussion

The findings of this trial establish that Aspaghol (Plantago ovata) is significantly superior to placebo in alleviating both

the symptoms and clinical signs of cervicitis. The demographic profile- predominantly young multiparous women (79.5%) from lower socioeconomic backgrounds, with Damavi and Safravi Mizaj- is consistent with published

epidemiological data and Unani pathophysiological descriptions of Warm Haar (hot inflammation).<sup>6</sup>

The therapeutic mechanism is attributable to the arabinoxylan mucilage content of *Plantago ovata* seeds. Upon hydration, this polysaccharide forms a protective viscous gel that coats and soothes the inflamed cervical mucosa when applied intravaginally, reducing irritation, discharge, and inflammatory exudate.<sup>7</sup> This Mulayyin (demulcent) action directly counteracts the Hararat and excess discharge underlying cervicitis, conforming to the Unani principle of Ilaj bil Zid. The oral route simultaneously modulates systemic inflammation through the mucilage's anti-inflammatory arabinoxylan fractions.<sup>8</sup>

Cervical inflammation resolved in 86.4% and hypertrophy in 77.3% of intervention patients, confirming objective tissue-level efficacy rather than mere symptomatic palliation. The partial responses of discharge (68.2%; NS) and congestion (50%; NS) suggest that complete vascular and secretory resolution may require longer treatment duration. The non-response of Nabothian cysts is expected, as these are mature walled-off retention cysts representing resolved pathology-structurally beyond the reach of anti-inflammatory pharmacotherapy without surgical excision.

No adverse effects were recorded in any patient, affirming the classical Unani safety profile of Aspaghol and its suitability as a first-line, non-antibiotic option — particularly relevant in an era of rising antimicrobial resistance. Cost-effectiveness and cultural acceptability further strengthen its applicability in low-resource settings.<sup>9</sup>

## 5. Conclusion

Aspaghol (*Plantago ovata* Forssk.) demonstrates statistically significant efficacy in the management of Warm-e-Unq-ur-Reham (Cervicitis), with highly significant improvement in white discharge, lower abdominal pain, backache, and cervical inflammation. It is safe, well-tolerated, affordable, and culturally accessible, validating its classical Unani pharmacological claims through a rigorous randomized controlled design. Larger multicentric trials with extended follow-up and comparison against standard antibiotic regimens are recommended to consolidate these findings and guide integrative clinical practice.

**Conflict of Interest:** None

**Funding:** Institutional thesis research (self-funded)

**Ethics:** IEC, Govt. Nizamia Tibbi College & General Hospital, Hyderabad. Written informed consent obtained from all participants.

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