

Effect of mocharas (*Bombax malabaricum*) and habbulaas (*Myrtus communis*) in uterovaginal prolapse: randomized open clinical trial

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Abstract

Background & objectives: Uterovaginal prolapse is the protrusion of a pelvic organ beyond its normal anatomical confines. It is a silent disorder with a huge impact on women's quality of life. It is symptomatic in 10% of women which usually require surgery; however milder stages of prolapse are commonly asymptomatic and surgical intervention is not indicated. The aim of the study was to evaluate the effectiveness of *Mocharas* (*Bombax malabaricum*) and *Habbulaas* (*Myrtus communis*) in first and second degree uterovaginal prolapse.

Methods: A randomized open clinical trial was carried out at the Institute's Hospital, Bangalore. Patients (n=40) with 1st & 2nd degree uterovaginal prolapse in the age group of 30-60 years were randomly allocated in two equal groups (A & B). In Group A, 4 gm *mocharas* powder was administered orally with milk twice daily and in both groups, local treatment in the form of sitz bath (*abzan*) with decoction of *habbulaas* 12 gm once daily was given for 8 weeks. Main outcome measure was improvement in Pelvic Organ Prolapse Quantification (POPQ) system, Pelvic Floor Distress Inventory Questionnaire (PFDIQ), Pelvic Floor Impact Questionnaire (PFIQ). Data were analyzed with student's t-test, chi square test and fisher exact test.

Results: Significant improvement ($P<0.001$) was observed in total scores of PFDIQ and PFIQ within each group though the difference was non-significant on inter group comparison. No significant change in POPQ system was reported in both groups ($P>0.05$).

Interpretation and conclusion: Test drugs *mocharas* and *habbulaas* are effective in improving the quality of life of women assessed by PFDIQ and PFIQ but fail to improve the degrees of prolapse assessed by POPQ system.

Keywords: Uterovaginal Prolapse; *Mocharas*; *Habbulaas*; Pelvic Organ Prolapse Quantification System; Pelvic Floor Distress Inventory Questionnaire; Pelvic Floor Impact Questionnaire

1. Introduction

Uterovaginal prolapse is defined as the descent of intrapelvic organs such as the uterus, bladder, urethra and rectum due to deficiencies in pelvic support system [1] In classical literature of Unani Medicine, uterine prolapse is mentioned as "a condition in which the uterus descends below into the vagina or outside the introitus from its normal level" [2] Uterine prolapse is predominantly caused by the accumulation of *balghame lazij* in *ribatate rehm* which causes its weakness leading to *khurooje rehm*. Moreover, it usually occurs in old age women having excessive *rutubat* in their body [2, 3, 4] Multiple mechanisms have been hypothesized as contributors to the development of prolapse, but none fully explain the origin and natural history of this process. Epidemiologic studies indicate that vaginal birth and aging are two major risk factors for the development of uterovaginal prolapse.⁵ However, half of all women over the age of 50 suffer from at least one type of prolapse,^[6] with 10–20% seeking medical aid for their problem. [7] UVP has significant negative impact on woman's quality of life, ranging from physical discomfort, psychological and sexual complaints to occupational and social limitations [8] Although some women are treated conservatively with medications, pessaries, physiotherapy or behavioral therapy; surgical interventions are required in advanced cases of prolapse [9] Though in Unani system of medicine, there are reports of many single drugs and

compound formulations useful in uterovaginal prolapse but the scientific validation is lacking behind. *Mocharas* and *habbulaas* were selected as research drugs possessing the properties like *qabiz*, *habis*, *mujaffif* and *muqawwie rehm* [3, 4] these drugs contain tannin [10, 11, 12] having strong astringent property [13] which may coagulates the protein and may helps the prolapse to revert back to its normal position [12, 14]

The hypothesis tested was drugs given in both the groups are likely to be effective in the management of uterovaginal prolapse. The study was planned with an objective to explore the efficacy and safety of these drugs on uterovaginal prolapse using scientific validated tools like PFDIQ, PFIQ & POPQ system.

2. Materials and methods

2.1 Study design

Randomized open clinical trial was carried out from November 2012 to April 2014 in the Dept. of Obstetrics and Gynaecology, National Institute of Unani Medicine Hospital, Bangalore. The study was started after obtaining the ethical clearance from Institutional ethical committee.

2.2 Participants

Total (n=96) patients were assessed for eligibility, out of which (n=56) were not enrolled as 28 patients denied participation and another 28 were excluded. (Fig. No. 1)

Patients (n=40) who matched the inclusion criteria were randomly allocated in two equal groups using computer generated randomization program [15].

2.3 Eligibility criteria

Patients were eligible if they present with complaints of mass per vaginum and urinary incontinence from 3-6 months duration and were aged between 30-60 years. Exclusion criteria include UTI, uncontrolled hypertension and diabetes mellitus, venereal diseases, HIV, genital malignancy and pelvic pathology. Eligible women were screened at Gynec OPD to confirm the uterovaginal prolapse.

2.4 Procedure of study

Eligible patients were enrolled in the study after obtaining the written informed consent and detailed history was elicited from each included patient. Risk factors like multiparity, home deliveries, big babies, obesity, heavy weight lifting etc were enquired. Clinical examination was done to look for built, BMI, waist circumference and vitals were recorded. *Mizaj* was assessed as per the parameters mentioned in classical Unani literature and socioeconomic status with modified Kuppuswamy’s Socioeconomic Status Scale and recorded in CRF structured for the study.

Speculum examination

Patient was examined for stress test and positive stress test is suggestive of uterovaginal prolapse [16]. The degree of uterovaginal prolapse was evaluated by examining the patient in a supine position with head end elevated to 45 degrees; an appropriately sized Sim’s speculum was inserted in the vagina to view the cervix or vaginal cuff. While the patient is performing the Valsalva maneuver, the speculum was slowly removed. The extent to which the cervix or the vaginal vault follows the speculum through and out of the vagina was noted. To examine the anterior vaginal wall, the posterior vaginal wall was retracted with the vaginal retractor and the extent of any anterior vaginal prolapse during the Valsalva maneuver was noted and vice versa [17] Staging of uterovaginal prolapse was done according to Pelvic Organ Prolapse Quantification system [18] Patients were subjected to biochemical investigation like LFT & RFT to evaluate the safety of research drugs. All participating patients were provided with PFIQ and PFDIQ questionnaire at first visit and asked to complete the questionnaires at every visit.

2.5 Intervention

Test drugs *mocharas (Bombax malabaricum)* and *habbulaas (Myrtus communis)* [3, 4] were purchased from local crude drug market of Bangalore city, identified by Dept. of *Ilmul Advia* NIUM, Bangalore. In Group A, 4 gm *mocharas* powder was administered orally with milk [19] twice daily and in both groups (A & B), local treatment in the form of sitz bath

(*abzan*) with decoction of *habbulaas* 12 gm [3, 4, 20] once daily (12 gm of drug boiled in 1 liter of water & then mixed in 4 liter of plain water) was given for 8 weeks. Patients of either group were instructed to perform Kegel’s exercise during the study period. Drug compliance was assessed at each visit by examining the packets in which medicines was dispensed at prior visit.

2.6 Assessment cum Follow up

Patients were followed once in 2 weeks for 8 weeks during treatment and once in 2 weeks for 4 weeks after treatment. During this period, PFDIQ, PFIQ and stages of POPQ system were assessed. Patients were also enquired for any adverse effect of drug during the study period. LFT and RFT were repeated after completion of trial.

2.7 Objective Parameters

- A) Pelvic Floor Distress Inventory Questionnaire (PFDIQ):
- B) Pelvic Floor Impact Questionnaire (PFIQ): [21, 22]
- C) Pelvic Organ Prolapse Quantification System: [18, 23, 24]

2.8 Main outcome measure

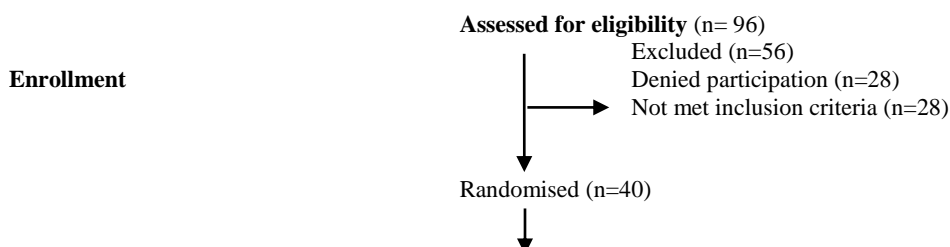
The main outcome measure was improvement in objective parameters (PFDIQ, PFIQ & POPQ). Regarding PFDIQ & PFIQ, a change of 45 points (15%) or more in the summary score of the PFDIQ-20 and a change of 36 points (12%) or more in the summary score of the PFIQ-7 would be considered as “clinically important” in patients undergoing surgery for pelvic floor dysfunction. Changes in score less than this may not be clinically important, even if statistically significant. [25] As the inclusion criteria in present study was restricted to second degree prolapse so clinically important change in mean score of those patients who felt better was modified accordingly to 30 point change in PFDIQ-20 summary score and 24 point change in PFIQ-7 summary score. While in POPQ system, improvement was assessed by change in stage in each visit.

2.9 Sample size estimation

With the help of previous studies, sample size was calculated for present study with 0.05 level of significance and power of 70% with standard deviation of 0.5. [26] It was calculated to 77, but due to time constraint the sample size was restricted to 40.

2.10 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 analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc. Student t test, Chi-square/ Fisher Exact test was used to analyse the data. Significance was assessed at 5% level of significance with confidence interval of 95%.



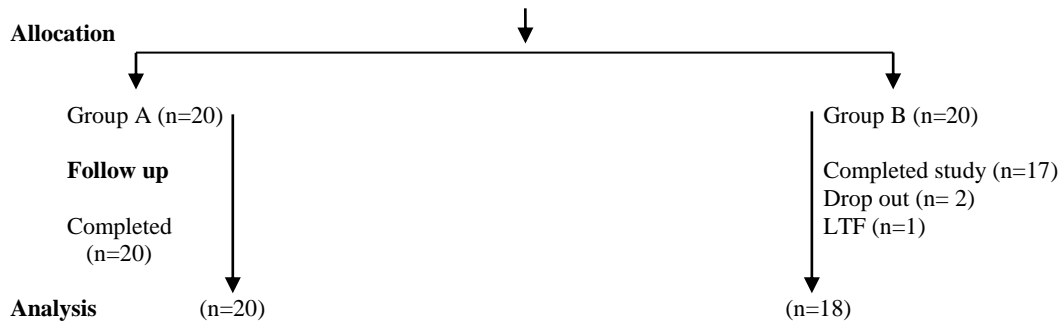


Fig 1: Consort flow diagram (LTF-loss to follow up)

3. Results

Table 1: Comparison of demographic data in two groups

Baseline characteristics		Group A (n=20)	Group B (n=20)	P value
Mean Age (years)		40.90±6.22	37.75±5.82	0.107
Socioeconomic status	Lower	0(0.0%)	1(5%)	0.868
	Lower Middle	12(60%)	10(50%)	
	Upper Lower	8(40%)	8(40%)	
	Upper Middle	0(0.0%)	1(5%)	
Mean BMI		28.32±5.85	27.93±5.65	0.831
Mizaj	Balghami	7(35%)	9(45%)	0.578
	Damvi	7(35%)	3(15%)	
	Safravi	5(25%)	7(35%)	
	Saudavi	1(5%)	1(5%)	
Mean Parity		3.75±2.09	2.85±0.98	0.124
Nature of delivery	CS	1(5%)	1(5%)	1.000
	FTND	19(95%)	19(95%)	
Mean birth weight		2.99±0.52	3.25±3.37	>0.05

Data were expressed in Mean ±SD and number (percentage). Student t-test independent and Fisher Exact test.

Table 2: Comparison of stress test in two groups

Stress test		Before treatment	After treatment	% change
Group A(n=20)	Absent	1(5%)	13(65.0%)	+60.0
	Present	19(95%)	7(35.0%)	-60.0
		20	18	
Group B(n=18)	Absent	0	13(72.2%)	72.2%
	Present	20(100.0%)	5(27.8%)	-72.2%
P value		<0.001**	<0.001**	-

Group A: improvement of 60% is significant with P<0.001**

Group B: Improvement of 72.2% is significant with P<0.001**

Objective parameters

Table 3: Comparison of Total of Pelvic Floor Distress Inventory in two groups

Total of Pelvic Floor Distress Inventory	Group A	Group B	P value
Test before Treatment	74.05±30.08	67.39±20.02	0.415
Test at 1 st Fortnight	72.07±30.61	63.93±22.13	0.341
Test at 2 nd Fortnight	59.78±25.72	51.90±22.87	0.327
Test at 3 rd Fortnight	41.92±20.13	38.77±16.79	0.606
Test at 4 th Fortnight	31.14±20.27	29.97±15.45	0.844
Test at 1 st Follow Up	30.93±20.24	29.53±15.46	0.817
Test at 2 nd Follow Up	31.45±20.91	30.26±15.58	0.848
P value	<0.001**	<0.001**	-

Data were expressed as Mean ±SD. Student t test independent and dependent, ** strongly significant

Table 4: Comparison of Total of Pelvic Floor Impact Questionnaire in two groups

Total of Pelvic Floor Impact Questionnaire	Group A	Group B	P value
Test before Treatment	107.32±45.42	105.38±34.39	0.879
Test at 1 st Fortnight	104.43±46.17	98.08±37.23	0.635
Test at 2 nd Fortnight	79.03±41.26	76.84±36.73	0.864
Test at 3 rd Fortnight	56.46±32.37	54.42±22.51	0.829
Test at 4 th Fortnight	41.55±34.69	39.07±13.43	0.783
Test at 1 st Follow Up	39.97±36.07	37.39±13.25	0.789
Test at 2 nd Follow Up	40.72±38.30	38.48±13.02	0.825
P value	<0.001**	<0.001**	-

Data were expressed as Mean ±SD. Student t test independent and dependent, ** strongly significant

Table 5: Comparison of POPQ System in two groups

POPQ System		Group A (n=20)		Group B (n=18)		P value
		No	%	No	%	
Test before Treatment	Stage 0	0	0.0	0	0.0	0.407
	Stage I	5	25.0	2	10.0	
	Stage II	15	75.0	18	90.0	
Test at 1 st Fortnight	Stage 0	0	0.0	0	0.0	0.407
	Stage I	5	25.0	2	10.0	
	Stage II	15	75.0	18	90.0	
Test at 2 nd Fortnight	Stage 0	0	0.0	0	0.0	0.407
	Stage I	5	25.0	2	11.1	
	Stage II	15	75.0	16	88.9	
Test at 3 rd Fortnight	Stage 0	1	5.0	0	0.0	1.000
	Stage I	5	25.0	5	27.8	
	Stage II	14	70.0	13	72.2	
Test at 4 th Fortnight	Stage 0	1	5.0	0	0.0	1.000
	Stage I	5	25.0	5	27.8	
	Stage II	14	70.0	13	72.2	
Test at 1 st Follow Up	Stage 0	1	5.0	0	0.0	1.000
	Stage I	5	25.0	5	29.4	
	Stage II	14	70.0	12	70.6	
Test at 2 nd Follow Up	Stage 0	1	5.0	0	0.0	1.000
	Stage I	5	25.0	5	29.4	
	Stage II	14	70.0	12	70.6	

Data were expressed as number (percentage). Fisher exact test

Table 6: Comparison of main outcome measures in two groups

Improvement in Objective Parameters		Group A (n=20)		Group B (n=18)		P Value
		No	%	No	%	
PFDIQ	No improvement	6	30.0	7	38.9	0.734
	Improvement	14	70.0	11	61.1	
PFIQ	No improvement	1	5.0	0	0.0	1.000
	Improvement	19	95.0	18	100.0	
POPQ System	No improvement	18	90.0	15	83.3	0.653
	Improvement	2	10.0	3	16.7	

Data were expressed as number (percentage). Fisher Exact test

4. Discussion

Demographic data

These were statistically similar in both groups ($P>0.05$). Mean age of women in Group A and B were 40.90 ± 6.22 and 37.75 ± 5.82 years, respectively ($P=0.107$) which is consistent with the studies of El-Gharib et al [27]. Most of the patients belonged to lower middle class which is in accordance with the finding of Tamrakar A. [28] Mean BMI was 28.32 ± 5.85 kg/m^2 and 27.93 ± 5.65 kg/m^2 in Group A and Group B, respectively ($P=0.831$), similar BMI was also reported by Levin et al. [29] 40% patients, possessed *balghami mizaj*, which is in accordance with the theories proposed by eminent Unani physicians, who have quoted that this disease is more common in individuals with dominance of *khilte balgham*, as the abnormal accumulation of *balghame lazij* in uterine ligaments causes its weakness and leads to uterine prolapse. [2, 3, 4] Mean parity was 3.75 ± 2.09 and 2.85 ± 0.98 in Group A and Group B respectively with $P=0.124$ which is in conformance with the finding of Kim et al. [1] Maximum patients (95%), had vaginal deliveries which are considered as a major risk factor for the development of uterovaginal prolapse [30] as Larsson et al [31] have linked vaginal birth to pelvic organ prolapse. Mean

weight of babies at birth was 2.99 ± 0.52 kg in Group A and 3.25 ± 3.37 kg in Group B with $P=0.076$. (Table 1).

Stress test

Before treatment, it was positive in 95% patients in Group A and 100% in Group B; after treatment, it was negative in 65% patients in group A with an improvement of 60% strongly significant ($P<0.001$) and in Group B, stress test was negative in 72.2% patients with an improvement of 72.2% strongly significant ($P<0.001$). (Table 2) This effect may be attributed to *qabiz* and *muqawwi* properties of test drugs which strengthen the pelvic floor muscles and prevents leakage of urine. [32, 33]

Objective parameter

Pelvic Floor Distress Inventory Questionnaire (PFDIQ)

At baseline, total score of PFDIQ was 74.05 ± 30.08 in Group A and 67.39 ± 20.02 in Group B ($P=0.415$). Reduction in total score of PFDIQ was strongly significant in both groups with $P<0.001$ as score reduced to 31.14 ± 20.27 in Group A and 29.97 ± 15.45 in Group B after treatment and the change was not significant on inter group comparison ($P=0.844$). (Table 3)

Pelvic Floor Impact Questionnaire (PFIQ)

At baseline, total score of PFIQ was 107.32 ± 45.42 in Group A and 105.38 ± 34.39 in Group B ($P=0.879$) which reduced to 41.55 ± 34.69 in Group A and 39.07 ± 13.43 in Group B after treatment with $P<0.001$, considered strongly significant within the group and the change was not significant on inter group comparison with $P=0.783$. (Table 4) The study conducted by Tamang et al [34] in women suffering from 3rd and 4th degree uterine prolapse demonstrated significant improvement in total scores of PFDIQ and PFIQ ($P<0.001$) on pre and post-surgery of pelvic floor, which is compatible with present study as it also exhibit strongly significant improvement in total scores of PFDIQ and PFIQ with intervention ($P<0.001$).

Pelvic Organ prolapse Quantification System

Stages of prolapse at baseline according to POPQ system; in Group A, 15 and 5 patients were in 2nd and 1st stage respectively; in Group B, 18 and 2 patients were in 2nd and 1st stage respectively. After treatment in group A, 14 patients remain persist in 2nd stage, 1 patient improved from each 2nd stage to 1st stage and from 1st stage to 0 stage; in group B, 13 and 2 patients remain persist in 2nd and 1st stage respectively, while 3 patients improved from 2nd stage to 1st stage, 2 patients were dropout after 2nd fortnight. No significant improvement in POPQ system was observed in both groups ($P=1.000$). (Table 5)

Main Outcome Measures

Improvement in PFDIQ was achieved in 14 patients in Group A and 11 in Group B ($P=0.734$). Improvement in PFIQ was achieved in 19 patients in Group A and 18 in Group B ($P=1.000$). No significant improvement in POPQ system was observed ($P=0.653$), only 2 patients in Group A and 3 in Group B showed improvement in POPQ system. (Table 6) No adverse effects were observed and safety parameters were normal during the study. One of the primary strength of this study is that, the effect of Unani medicine on health related quality of life of women suffering from uterovaginal prolapse

was focused with validated tools like PFDIQ, PFIQ and POPQ. The limitations of this study were small sample size, short duration of intervention, loss of long term follow up. Future trials are recommended with increment of dosage of drug used locally to get significant results and Phase III trial can be carried out to assess the efficacy and safety of test drugs.

5. Conclusion

It can be inferred that *Habbulaas* and *Mocharas* are equally effective in improving quality of life of women assessed by PFDIQ and PFIQ as it possess *mujaffif*, *qabiz* and *muqawwi* properties due to the presence of chemical constituents such as tannin, catechin and flavonoids which absorb the excessive fluid, constrict the ligaments and provide strength to pelvic floor muscles. However, test drugs fail to improve the degrees of uterovaginal prolapse assessed by POPQ system.

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