



CLINICAL EFFICACY OF *SHIBB-E-YAMANI BIRYAN* (ALUMINIUM POTASSIUM SULFATE) (ROASTED ALUM) IN UTERINE PROLAPSE

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ABSTRACT

The protrusion of uterus into or out of the vaginal canal is called as Uterine Prolapse (*Nutu-e-Raham*). Uterine prolapse is falling or sliding of womb (uterus) from its normal position into the vaginal area. Pelvic organ prolapse is one of the common clinical conditions met in day to day gynaecological practice especially among the parous women. The entity includes the decent of the vaginal wall and or the uterus. The choice of treatment available in modern system of medicine is comparatively limited. However surgery is considered to be an effective treatment. On the other hand, *Tibb-e-Unani* claims to possess a number of effective and safe therapeutic agents and various regimens that are commonly used in the management of uterine prolapse. *Qabiz*, *Habis*, *Mujaffif* and *Muqawwi Rahem* drugs are commonly used to treat the disease successfully. Therefore, in the present study an attempt has been made to evaluate the efficacy of Unani drug *Shibb-e-Yamani Biryani* (roasted alum) in patients of 1st and 2nd degree of uterine prolapse.

Result & Discussion: The results of the study revealed that the test drug is effective in 43.33% of the patients as the clinical features of uterine prolapse were found to be relieved completely in these patients. Other patients who were not cured completely were found to have symptomatic relief as some of the symptoms improved significantly indicating that the test drug at least has partial relief for all the patients. Uterine prolapse is considered a difficult ailment to be treated completely with drug.

Conclusion: The findings suggested that the test drug is effective in the management of 1st and 2nd degree of uterine prolapse and well tolerated by the patients without any side effects.

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INTRODUCTION

Pelvic organs prolapse (POP) is one of the common clinical condition met in day to day gynaecological

practice especially among the parous women. The entity includes the decent of the vaginal wall and or the uterus. It is in fact a form of hernia³. Prolapse i.e.

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procidencia is derived from the Latin word 'procidere, to fall or downward descent'⁴. The condition is mainly due to insufficiency of the pelvic floor and weakening of supportive pelvic muscles, tissues and ligaments⁵.

Uterine prolapse happens mostly in postmenopausal and multiparous women. Nulliparous prolapse is seen in 2% and vault prolapse in 0.5% following hysterectomy⁶. The global prevalence of uterovaginal prolapse is estimated to be 2-20% in women under age of 45 year⁷. In India, a higher incidence and a more severe degree of Uterovaginal prolapse occurs in women who are delivered at home by dais (untrained mid-wives)⁶.

The most important etiological factor in prolapse is atonicity and asthenia that follow menopause. Activating factors such as increased intra-abdominal pressure caused by a chronic cough, chronic constipation, ascitis, tumour formation, lifting heavy weights, straining at stool, obesity these all tend to increase any degree of prolapse which may previously be present, raising the intra abdominal pressure^{1,4,6,8}.

The patient may complain of sensation of swelling or fullness in vagina, a dragging discomfort in lower abdomen and pelvis, back ache, vaginal discharge, difficulty in emptying of bowel, urinary symptoms like frequency of micturition, difficulty in micturition, stress incontinence and coital difficulties^{4,8}.

According to the Unani system of medicine, *Nutu-e-Rahem* (uterine prolapse) is falling or sliding of womb (uterus) from its normal position into the vaginal area². It is a condition in which the uterus descends down into the vaginal cavity or outside the introitus, which is due to the weakness of ligaments or due to the laxity which leads to it's descend⁹.

The causes of *Nutu-e-Rahem* are grouped into three headings. They are external, internal and obstetrical and gynaecological^{11,17}.

The external causes are falling from height on back, lifting and pulling of heavy weight, trauma on pelvic floor, shouting loudly, sneezing and fear that causes weakness in ligaments of uterus, leading to prolapse. The obstetric causes are prolonged labour, delivery of heavy weight baby, forceful pulling of foetus or placenta by untrained dais or spontaneous delivery of baby^{2,9,10,11}. The internal cause is *Ratubat-e-Balghami* that accumulates on the ligaments of the uterus and

causes their looseness or weakness which leads to the uterine prolapse. It is often seen in old age women and in patients having *Martoob Mizaj*. *Qrha-e-Rahem* also causes laxity and weakness in the ligaments of uterus causing downward displacement of the organ¹⁰.

The choice of treatment available in modern system of medicine is comparatively few, it includes preventive, physiotherapy, pessary and surgical treatment⁸ but the only effective method of treating prolapse is surgery. Pessaries are used only for temporary basis¹. It is a palliative treatment which does not cure Uterovaginal prolapse, it is used as a temporary measure in the early pregnancy, or in patients who hope to have another child, or to postpone operative treatment¹².

Unani system of medicine claims to possess a number of effective and safe drugs that can be used in the management of uterine prolapse.

A large number of single and compound drugs have been included in *Unani* materia medica that possess *Qabiz*, *Habis*, *Mujaffif* and *Muqawwi Rahem* properties are useful in uterine prolapse^{9,4}. *Shibb-e-Yamani Biryani* (roasted Alum) is one such drug which possesses *Qabiz*, *Habis*, *Mujaffif* and *Muqawwi Rahem* properties.

It has also described in classical Unani literature that *farzija* of *Shibb-e-Yamani Biryani* (roasted alum), is useful per vaginally in uterine prolapse^{14,15}.

In the present study an attempt has been made to evaluate the efficacy of Farzija (prepared by powder of *Shibb-e Yamani Biryani*) in quantity of 5 gms in patients suffering from 1st and 2nd degree of uterine prolapse.

MATERIALS AND METHODS

Farzija was prepared with the help of the powder of *Shibb-e-Yamani Biryani* (roasted alum), in a quantity of 5gms. The test drug was procured from local market of Malegaon, District Nashik, Maharashtra and it was roasted to become *Biryani* in the Saidla department. The permission of Institutional Ethics Committee (IEC) was taken prior to the initiation of the clinical trial.

The patients visited the OPD of Ilmul Qabalat wa Amraz-e-Niswan during 2016-2017, were screened for the 1st and 2nd degree uterine prolapse on the basis of clinical signs and symptoms compatible with the classical description of the disease. After taking the

informed consent, 30 diagnosed patients of reproductive age group were included in this study. They were informed about the disease, examination performed and type of treatment given. On the basis of computer randomized technique, the patients was selected for clinical trail. Since surgery is the only treatment in the modern system of medicine, so, there were no standard controls.

The patients were treated with (intravaginal pessary) *Farzija of shibbe-e-Yamani Biryani* of 5gms daily for 8hours three months except menses. The patients were advised to follow up once a week for 3 months during treatment and once in 15 days for 1 month after treatment.

The progress of each patient was recorded systematically in the Case Record Form (CRF). At every visit the patients were carefully interviewed and their statement about the sensation of something coming down per vagina, vaginal discharge, dyspareunia, frequency of micturition, stress incontinence and backache were recorded. After general and systemic examination each patient underwent per vaginal examination in lithotomy position so as to assess the degree of prolapsed and the improvement if any. USG (Ultrasonography) of abdomen and pelvis was done on first and last day of treatment to confirm the diagnosis and assess the improvement.

All the symptoms and signs were graded on pointer scale and the changes were noted in CRF on every

follow up. The findings or clinical observations were tabulated on a computerized format. Finally recorded information were analyzed using Dunn's multiple comparison tests to determine the significance and arriving at a conclusion.

Inclusion criteria:

- Married women.
- Reproductive age group.
- Patient with the first and second degree of utero vaginal prolapse.

Exclusion criteria:

- Patient with procidentia, congenital elongation of the cervix, cervical fibroid, polyp, and the chronic inversion of the uterus.
- Pregnant women.
- Patients with any systemic illness and malignancy.
- Patients other than uterine prolapse.

RESULTS AND DISCUSSION

On the basis of different parameters i.e. subjective and objectives, the data was analysed and assessed for the effect and efficacy of test drug *Shibbe-e-yamani* in the patient of uterine prolapse. The test drug was studied by observing clinical signs and symptoms, per vaginal examination and ultrasonographic studies. The findings of clinical features have been tabulated, analyzed and compared with the baseline findings. (Table.1)

Table 1: Effect of Farzija on uterine prolapse.

Clinical Features	Table 1: Effect of <i>Farzija</i> on uterine prolapse.					
	Baseline		Post Treatment		Improvement	
	No	%	No	%	No	%
Per vaginal (uterine prolapse)	30	100	17	56.66	13	43.33
Sensation of something coming down	30	100	17	56.66	13	43.33
Vaginal Discharge	29	96.66	14	48.27	15	51.72
Dyspareunia	27	90.00	16	59.25	11	40.74
Frequency of Micturition	23	76.66	12	52.17	11	47.83
Stress Incontinence	16	53.33	06	37.50	10	62.50
Low back pain	30	100	25	83.33	05	16.67

On the day of registration per vaginally all patients (100%) have diagnosed uterine prolapsed as 19 (63.3%) and 11(36.6%), with the degrees of I and II respectively. After the treatment the 13(43.3%) patients have been completely cured while as 15(50%) and 2(6.6%) were observed in I and II degree respectively.

Prior to treatment sensation of feeling of something coming down were found in 30 (100%) of cases. but after treatment it was remain in 17(56.66%) and improvement were observed in 13 (43.33%).

On the day first, the vaginal discharge was present in 29 (96.66%) of cases. while after treatment only 14 (48.27%) patients remain and 15 (51.72%) improvement were observed.

On the day of registration prior to treatment dyspareunia was found in cases out of 27(90.00%) patients. After treatment it was remain in 16 (59.25%) cases and improvement was observed in 11 (40.74%) of positive complain patients.

On the day zero, frequency of micturition was found 23 (76.66%) of the cases. Whereas after treatment it was significantly reduced and found in, 12 (52.17%) in positive complains patients and improvement was observed 11 (47.83%).

Before treatment stress incontinence was observed in 16 (53.33%) of the cases. Whereas after treatment it was reduced and remain in 6 (37.50%) and improvement was observed in 10 (62.50%) of the cases.

On the day of registration Low back pain was found in 30 (100%) of the cases before starting the treatment. Whereas after treatment it was found in 25 (83.33%) of the cases and improvement was observed in 5 (16.67%) of the cases.

The result of the study revealed that *Farzija* is effective to relieving the clinical features of uterine prolapse. All the parameters were found to be significantly improved suggesting that the local application of *Farzija* (pessary) per vaginally in the management of first and second degree of uterine prolapse is quite effective.

Relief in clinical features of uterine prolapse such as degree of prolapse, sensation of something coming down pervaginally, vaginal discharge, dyspareunia, frequency of micturition, stress incontinence and backache is due to qabiz, habis and mujaffif properties of the test drug. Complete cure was observed in 13(43.33%) of patients in farzija (Pessary). Other

patients though were not cured completely but got significant symptomatic relief as shown there symptomatic parameters.

Shibb-e-Yamani possesses Qabiz¹⁰, Habisuddam¹⁶, Mujaffif-e-ratubat properties¹⁸. It also possesses caustic, haemostatic, antispasmodic and antiseptic propertis¹⁵. It constricts uterine wall after delivery¹⁸. It is externally used in a number of diseases such as uterine and anal prolapse¹⁵.

The results of the study revealed that the test drug is effective in 13(43.3%) of the patients as the clinical features of uterine prolapse (*Nutu-e-Rahem*) were found to be relieved completely in these patients. All the parameters were found to be significantly improved in 13(43.3%) of the cases suggesting that the use of *Farzija* in uterine prolapse is effective in sizeable number of patients. Other patients who were not cured completely were found to have symptomatic relief as some of the symptoms improved significantly indicating that the test drug at least has partial relief for all the patients. Uterine prolapsed is considered a difficult ailment to be treated completely with drug and regimenal treatment. However, even a symptomatic relief is also considered important as it improves the quality of life significantly. Test drug by curing 13(43.3%) of the patient and inducing partial relief to other patients indicated that it can be used in the management of uterine prolapsed. The study also revealed that uterine prolapse is more prevalent in the patients having Balghami Mizaj (70%). Therefore a combined therapy of farzija along with the oral administration of other drugs that can correct the qualitative and quantitative anomalies of phlegm may be recommended for a better result.

Response to treatment.

Response	(Farzija)	
	No	%
Cured	13	43.33
Not cured	17	56.66

Conclusion

On the basis of above observations, it can be concluded that drug is very effective in relieving the clinical features of uterine prolapse. Test drug is well tolerated by the patients without having any side effects. Therefore, the present study scientifically substantiates the therapeutic use of *Farzija* (pessary) per vaginally in uterine prolapse. However, for the

exact mechanism of action of the test drugs, more elaborative and extensive studies should be done for further research.

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