



Research Article

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SINGLE-ARM CLINICAL TRIAL OF YONISHAITHILYAHAR YOGA YONIDHAVAN LOCALLY IN YONISHAITHILYA WITH SPECIAL REFERENCE TO VAGINAL WALL PROLAPSE

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ABSTRACT

Yonishaithilya is a common gynaecological problem in women after the reproductive age group. This must not be taken as easily as it can adversely affect a woman's life quality and may hamper her day-to-day activities. As per Bruhatrayi, yonishaithilya represents symptoms of mahayoni yonivyapada, Vataj yonivyapada and Phalini yonivyapada. Aetiology (samprapti), signs (lakshana), symptoms, and treatment (chikitsa) of yonishaithilya resembles perineal laxity. Perineal laxity is the condition where there is loosening of supporting structures of the female pelvis, thereby allowing the descent of one or more pelvic organs through the lax anterior and posterior vaginal walls and showing symptoms like something coming out through the vagina, increased frequency of micturition, difficulty in voiding urine, stress incontinence, toda (pricking pain), chosha (burning), kandu (itching). Ayurveda provides us with formulations like Yonishaithilyahar yoga yonidhavan in Gadanigraha. In this study, we took 100 patients diagnosed with yonishaithilya in a single group and gave them Yonishaithilyahar yoga yonidhavan for 3 cycles of 8 days. After the study, it was found that 31(31%) patients had complete remission, 66(66%) patients had marked improvement and 3(3%) patients had moderate improvement.

Keywords: Yonishaithilya, Yonivyapada, Phalini Yonivyapada

INTRODUCTION

Pelvic relaxation is a problem in women. It is much more likely to become symptomatic and to progress during the reproductive and post-reproductive years. Most commonly developing prolapse are of menopausal age when the pelvic floor muscles and ligaments that support the female genital tract become lax and atonic. It may be the predisposing factor for vaginal wall prolapse and uterine prolapse.¹

While discussing the treatment, contemporary science doesn't have a major conservative remedy for this condition except for pessary², Kegel's pelvic floor exercise³ and surgery, which has side effects with the chances of recurrence. Hence such a measure **Primary Objective:** To evaluate the role of Yonishaithilyahar yoga yonidhavan locally in Yonishaithilya with special reference to vaginal wall prolapse.

Secondary Objective: To study Yonishaithilya in detail with particular reference to vaginal wall prolapse according to Ayurveda and modern texts.

MATERIALS AND METHODS

Study Design: By single-arm clinical trial technique from OPD, IPD and Camp conducted by Yashwant Ayurvedic Medical College PGT and RC, Kodoli, Kolhapur, Maharashtra, India, in surrounding villages and 100 diagnosed patients of Yonishaithilya (Vaginal Wall Prolapse) having age of 30 to 60

is needed where the hospital stay is reduced; it is non-invasive and is beneficial for the women without hampering their family life and for many who don't want to undergo surgery.

Ayurveda provides us with the formulations like Yonidrudhikaran yoga in the texts like Bhaishajya Ratnavali and Bhavaprakasha. Shunthyadi Veshwar dharan explained in Sushruta Samhita that Charaka Samhita and Yogaratnakara are considered to strengthen the prolapsed organs.

Hence, in this study, an attempt has been made to find the therapeutic role of Yonishaithilyahar yoga in Yonishaithilya.

years were selected. Regular follow-up is taken after starting the research study.

Yonishaithilyahar yoga ⁴
Madayantika beej churna 170 gm
Ashwagandha moola churna 170 gm
Mocharasa 170 gm

Eight litres of water were added and subjected to agni for 1 litre of Yonishaithilyahar yoga.

For within the group assessment of all parameters, to test the hypothesis, Wilcoxon signed ranks test has been applied at a 5% level of significance. The hypothesis for each parameter was tested, and the result was interpreted accordingly.

Table 1: Medicine Protocol

Medicine	Dose	Kaal	Duration	Route	Follow Up
Yonishaithilyahara yoga-childbearing age	1 litre	Morning 6 th day of the menstrual cycle (after cessation of menstrual bleeding)	8 Days	Per vaginally (Locally)	After 1 month (after cessation of menstrual bleeding)
Yonishaithilyahara yoga-post-menopausal age	1 litre	Morning 1 st day	8 Days	Per vaginally (Locally)	After 1 month

Selection Criteria

Inclusion Criteria

- Patients between 30-60 years of age.
- The patient diagnosed as Yonishaithilya
- Patients, irrespective of caste, income group, and occupation.
- Controlled Diabetes Mellitus (80-160 mg/dl)
- Controlled Hypertension (130/80 mm of Hg)
- Cystocele without uterine descent
- Phalini Yonivyapada
- Rectocele
- Enterocele
- Urethrocele

Exclusion Criteria

- Patients having major illnesses, e.g., HIV, HBsAg, TB, VDRL
- Menorrhagia
- Uncontrolled Diabetes Mellitus
- Uncontrolled Hypertension

- Uterine descent
- H/O Malignancies of genital organs
- Prolapse with uterine fibroid/ Ovarian cysts
- H/O Pelvic Inflammatory Disease
- Local infections of the vagina
- H/O recurrent Urinary Tract Infection
- Hb % <8 gm/dl

Withdrawal Criteria

- The patient is unable to tolerate the therapy.
- Any adverse drug reaction
- Patients fail to report follow-up or irregular treatment.
- Patients are not willing to continue the trial.

Criteria for Assessment of Results

A case record form was designed, including various examinations. Therapy efficacy was measured from subjective and objective parameters based on Ayurvedic and Modern texts.

Table 2: Subjective Parameters

Subjective Parameters	Grade 0	Grade 1 (+)	Grade2 (++)	Grade3 (+++)
Frequency of micturition	No	Frequency of micturition every 2 hours	Frequency of micturition for less than 2 hours	Frequency of micturition for less than half an hour
Difficulty in voiding urine	No	Taking more than 2 mins	Taking more than 3 mins	Taking more than 5 mins
Stress incontinence	No	Only after raised intra-abdominal pressure like coughing, weightlifting with a full bladder	Only after raised intra-abdominal pressure like coughing, weightlifting without a full bladder	On mild pressure, also like on movement without a full bladder
Pelvic discomfort	No	A feeling of per vaginal mass only in the squatting position	A sense of perineal and pelvic discomfort for the whole day	Pelvic pain, back pain with protrusion of mass even on slight movement
Toda (Pricking Pain)	No	Cured by taking a rest	Not cured by taking rest but not continuous	Worst continuous toda
Chosha (Burning Micturition)	No	Burning sensation while passing urine or during micturition	Persisting burning micturition after micturition for 15 mins	Continuous burning micturition for a whole day
Kandu (Itching)	No	Occasionally	Kandu is not disturbing sleep	Kandu disturbing sleep

Measurement of the size of mass per vagina ⁶.

Measured using a measuring scale before and after treatment in centimetres according to the POP-Q system in grids ^{5,7}. (Tables 3 and 4)

Table 3: Objective Parameters

Aa Anterior wall (-3 cm to +3 cm)	Ba Anterior wall (-3 cm to +8 cm)	C Cervix or vaginal cuff (-8 cm to +8 cm)
Gh Genita hiatus (2 cm)	Pb Perineal body (3 cm)	tv1 Total vaginal length (10 cm)
Ap Posterior wall (-3 cm to +3 cm)	Bp Posterior wall (-3 cm to +8 cm)	D Posterior fornix (-10 cm)

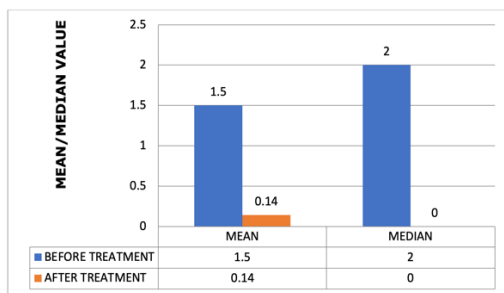
Table 4: Site with a description

Site	Description	Range
Aa	Anterior vaginal wall, midline 3 cm proximal to the external urinary meatus	-3 cm to +3 cm
Ba	Anterior vaginal wall, the most dependent portion between Aa and anterior fornix	-3 cm to + tvl
C	Cervix or vaginal cuff	1 tvl
D	Posterior fornix or vaginal apex	+tvl
Ap	Posterior vaginal wall, midline 3 cm proximal to the hymen	-3 cm to +3 cm
Bp	Posterior vaginal wall, the most dependent portion between Ap and posterior fornix	-3 cm to + tvl
Gh	External urinary meatus to posterior	2 cm
Tvl	Point D to the hymenal ring	10 cm
PB	Posterior hymen to the anal opening	3 cm

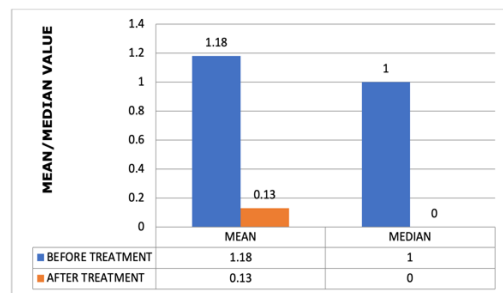
The study is carried out as per the International Harmonization-Good Clinical Practices Guidelines [ICH-GCP] or the Declaration of Helsinki guidelines. This study is approved by IEC with reference number YAC/PG/370/2020, Dated 22/06/2020.

OBSERVATIONS AND RESULTS

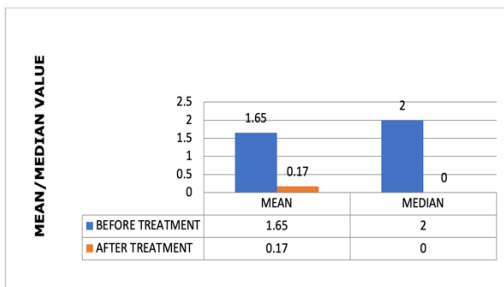
For within the group assessment of all parameters, to test the hypothesis, Wilcoxon signed ranks test has been applied at a 5% level of significance. The hypothesis for each parameter was tested, and the result was interpreted accordingly.



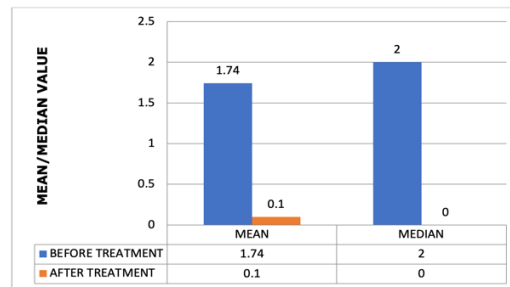
Graph 1: Changes in mean and median values of frequency distribution



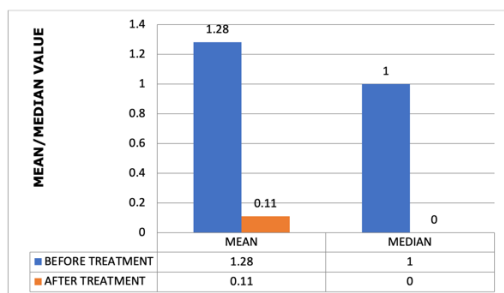
Graph 2: Changes in mean and median values of difficulty in voiding urine



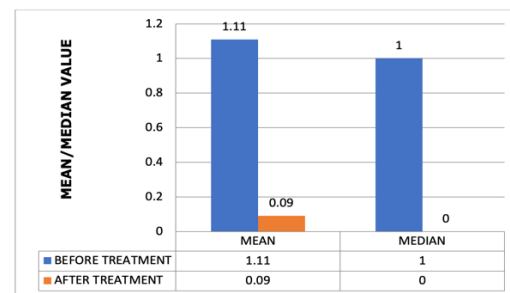
Graph 3: Changes in mean and median values of stress incontinence



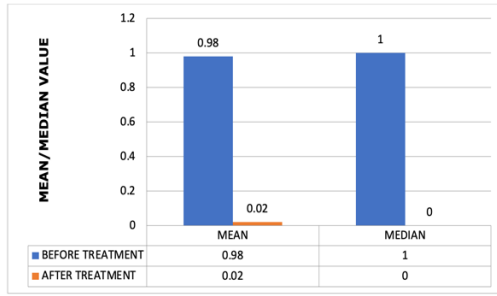
Graph 4: Changes in mean and median values of Pelvic discomfort



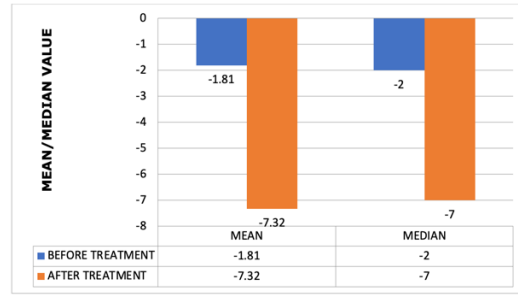
Graph 5: Changes in mean and median values of Toda



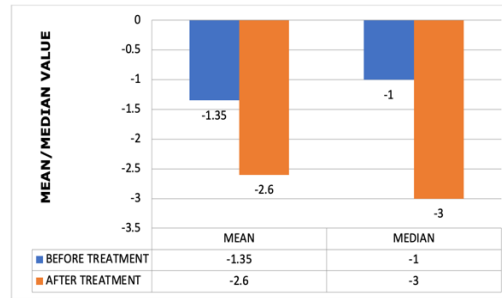
Graph 6: Changes in mean and median values of Burning micturition



Graph 7: Changes in mean and median values of Kandu



Graph 8: Changes in mean and median values of Cystocele



Graph 9: Changes in mean and median values of Rectocele

Table 5: Statistical data within the group analysis of various assessment criteria

Sign /Symptom	Inference
Frequency of micturition	<0.0001 (ES)
Difficulty in voiding urine	<0.0001(ES)
Stress Incontinence	<0.0001 (ES)
Pelvic Discomfort	<0.0001 (ES)
Toda (Pricking pain)	<0.0001 (ES)
Chosha (Burning micturition)	<0.0001 (ES)
Kandu (Itching)	<0.0001 (ES)
Cystocele	<0.0001 (ES)
Rectocele	<0.0001 (ES)

ES - Extremely Significant

DISCUSSION

One hundred patients were registered under a single group. According to the age group, the maximum number of patients aged 30-35 years is 34%. This was followed by 31% of patients aged 35-40 years. Then 28% in the 40-45 age group, 6% in the 45-50 age group and 1% from the 50 to 55 years age group. Out of 100 patients, 73 (73%) were housewives, 10(10%) patients were doing services, and 17(17%) belonged to the farmer category. In the present study, out of 100 patients, 92(92.00%) were from the middle class, while 8(8.00%) were from the wealthy class, respectively.

Yonishaithilyahar yoga yonidhavan in Yonishaithilya is found highly significant and clinically more effective on the subjective parameters of assessment, increased frequency of micturition, difficulty in voiding urine, stress incontinence, something coming out through the vagina, toda, chosha, kandu.

Mode of action

Yonishaithilyahar yoga contains Madayantika, Ashwagandha, and Mocharasa. Madayantika beeja has tikta-kashaya rasa and sheeta virya, which are Pittashamak, stambhak, shothahar and vedanasthapaka and dahaprashamak property. Ashwagandha moola has tikta-katu-madhur rasa, which is Pittashamak.

Mocharasa has grahi property, which gives strength to the vaginal walls.

CONCLUSION

From the observation and result of the present study, an attempt has been made to reach the following conclusions.

The study entitled "Single arm clinical trial of Yonishaithilyahar yoga locally in Yonishaithilya with special reference to vaginal wall prolapse" was carried out on 100 patients. The effect of therapy on chief complaints has shown significant results. It is concluded that in the present clinical study, Yonishaithilyahar yoga is effective in Yonishaithilya. Sheeta virya and dahaprashamak property of Madayantika beeja helps in reducing burning micturition. The vedanasthapak property of Ashwagandha moola helps in reducing toda (pricking pain). Madayantika beeja has an analgesic property which helps in lowering pricking pain. The balya property of Ashwagandha moola and grahi property of Mocharasa gives strength to the vaginal walls, which helps reduce mass felt per vagina, reducing the frequency of micturition and difficulty in voiding urine. Madayantika is Pittashamak, Ashwagandha is Vatakaphahar, and Mocharasa is Pittavathara, meaning all three drugs help normalise tridosha. No adverse effects were observed during clinical study. Thus, the present study concludes that Yonishaithilyahar yoga has a significant role in Yonishaithilya. Yonishaithilyahar yoga's role

has been clinically and statistically significant in treating Yonishaithilya.

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