



Research Article

**AN OPEN LABEL PRE AND POST TEST CLINICAL EVALUATION OF EFFICACY OF *TILA TAILA ABHYANGA* AND MASSAGE OF YONI IN CYSTOCELE WITH SPECIAL REFERENCE TO *CHYUTA AVASTHA* OF *VASTI***

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**ABSTRACT**

Prolapse or downward displacement of pelvic organs especially vagina, uterus and rectum is a common and disabling condition among women of menopausal age group. It affects their quality of life also. Displacement of vaginal anterior compartment results in cystocele. Quoting Acharya Susruta reference, the aim of this study is to find the efficacy of *Tila taila yoni Abhyanga* in *Cyuta avastha* of *Vasti* with respect to first degree cystocele. 30 subjects were selected satisfying inclusion and exclusion criteria with the approval of Institutional ethical committee. Clinical evaluation is done with the help of relevant subjective and objective parameters. The subjective parameters were assessed before and after the treatment for a period of one month with UDI questionnaire and objective parameter with Baden-Walker system of grading Pelvic Organ Prolapse. Three months follow-up evaluation was also done with same parameters. The Wilcoxon Signed Rank Test is used to statically decompose the clinical data. Subjective parameters showed improvement of the condition viz., frequency and urgency of urination, urine leakage with and without any activity, cough, sneeze, small amount of urine leakage, difficult and incomplete bladder emptying, bulging in vagina. However, leakage not related to urgency, lower abdominal pressure, painful urination and lower abdomen or genital area, pelvic area heaviness or dullness, pelvic discomfort and burning micturition showed only a little reduction with the treatment. Objective parameter is also highly statistically significant at  $p$  value  $< 0.001$ .

**INTRODUCTION**

Pelvic organ prolapse [1] is a relatively common condition in women that can have a significant impact on quality of life. Prolapse encompasses a range of disorders, from asymptomatic altered pelvic anatomy to complete prolapse of the pelvic organs associated with severe urinary, defecatory, and sexual symptoms. The pathophysiology of prolapse is multifactorial, yet not properly understood.

*Aggravated Vayu* brings about *Agni dushti*, the *Rasa dhatu kshaya* and *Kapha kshaya*. Due to this *Kapha* loses its *Shlish alingana* property and hampers the *Dharana shakti* of *Mamsa dhatu*. Further there is the loss of compactness and integrity in structures leading to *Dhatu shithilata* and "*sramsam*" [2]. 7.1% were detected with genital prolapse [3] in a study conducted with villagers of Nashik district Maharashtra among 1167 women. In the study conducted for Medicare claims, patients undergoing surgery for stress urinary incontinence (SUI) may be at fairly high risk for requiring subsequent prolapse surgery within the first year after their SUI procedure [4]. In another study, systemic hormone therapy worsened the urinary incontinence [5].

Among the various treatment modalities of *Yoni vyapat*, the emphasis has been given to *Sthanika cikitsa* which is noteworthy. *Acarya Sushruta* explained *Tila taila* for its *Sukshma*, *vyavayi*, *Brmhana*, *Mardava*,

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*Mamsasthairya*, *Balakara* properties. He also explained it can be used in *Cyuta avastha*<sup>[6]</sup>. *Acarya Charaka* explained for all *Vata* related *Yoni rogas*, *Abhyanga*<sup>[7]</sup> can be performed. Above all *Taila* can be considered as best for women.

**OBJECTIVE**

To study the effect of *Tila taila Yoni Abhyanga*<sup>[8]</sup> in *Cyuta avastha* of *Vasti* w.r.t 1<sup>st</sup> degree cystocele.

**MATERIALS AND METHODS**

For the clinical study, patients were selected from the O.P.D. of the Department of *Prasutitantra* and

*Striroga*, Amrita School of Ayurveda, Kollam. Patients fulfilling the criteria for selection were integrated into the study irrespective of caste, religion. *Tila taila Yoni Abhyanga* was done for all the selected cases. A representative image of *Tila* is shown in Fig. 1.

A detailed history was filled up in specially prepared proforma on Ayurveda and Biomedical science guidelines. General physical examination, per vaginal and per speculum examination was also carried out. The study was done for a period of 18 months.



Figure 1. *Kṛshna tila*

**Drug Review**

*Tila taila* is the fresh oil expressed from clean and healthy seeds of *Sesamum indicum* L (Fam. Pedaliaceae) widely cultivated in India. It has light golden colour with pleasant aroma.

**Inclusion Criteria**

Patients with

- Age group 45-65 years.
- Stress incontinence.
- First degree cystocele.
- Incomplete bladder evacuation.
- Feeling of mass coming down on straining.
- Recurrent UTI.

**Exclusion criteria**

- 2<sup>nd</sup> and 3<sup>rd</sup> degree prolapses.
- Vaginal infections.
- Uterine pathologies such as fibroids, bulky uterus.
- History of any surgical procedures in pelvic area.
- Polyuria associated with uncontrolled diabetics.
- Carcinoma of bladder and genital organs.

**Criteria for Diagnosis**

Diagnosis was based on per vaginal examination. The prolapse was graded based on Baden-Walker system<sup>[9]</sup> of grading Pelvic Organ Prolapse.

Table 1: Baden Walker System

|   |                                    |
|---|------------------------------------|
| 0 | Normal                             |
| 1 | Descent to half way to hymen       |
| 2 | Progression to hymen               |
| 3 | Progression half way through hymen |
| 4 | Maximal progression through hymen  |

**Treatment Protocol**

Patient with menstruation were called during post-menstrual period. This is not applicable to women who have attained menopause.

- The patients were asked to empty the bladder before treatment.
- Luke warm *Tila taila* was taken in a disposable needleless syringe and inserted into vaginal canal with aseptic precautions. *Abhyanga* was done for a period of 20mts with repeated syringing of *Taila*. A total of 20 ml *Tila taila* was used to complete the procedure. The same process was done once, consecutively for the period of 10 days.
- Patient was asked to come for the follow-up period of 3 months.

**Advice**

- Patients were instructed to avoid heavy weight lifting.
- Avoid constipating food habits.
- They were asked to report if any discharge per vagina was noticed.
- To maintain hygiene.

## Follow-up

After the course of treatment lasting for 10 days, patients were asked for follow-up once in a month for a period of consecutive three months.

## Outcome Measures

### Subjective Parameters

The parameters are assessed on the basis of UDI Questionnaire. The questionnaire is given below.

1. Frequent urination?
2. A strong feeling of urgency to empty your bladder'?
3. Urine leakage related to the feeling of urgency?
4. Urine leakage related to physical activity, coughing, or sneezing?
5. General urine leakage not related to urgency or activity'!
6. Small amount of urine leakage (drops)?
7. Large amounts of urine leakage?
8. Nighttime urination
9. Bedwetting?
10. Difficulty emptying your bladder?
11. A feeling of incomplete bladder emptying?
12. Lower abdominal pressure?
13. Pain when urinating?
14. Pain or discomfort in the lower abdominal or genital area?
15. Heaviness or dullness in the pelvic area?
16. A feeling of bulging or protrusion in the vaginal area?
17. Pelvic discomfort when standing or physically exerting yourself?

For the questions grading was given as follows: 0-not at all, 1-mild, 2-moderate, 3-severe.

### Objective Parameter

A scale with grading was used for this after sterilization. Total vaginal length was first measured and then the level of prolapse from external os was noted in centimeters. This length was subtracted from Total vaginal length. This was done before and on third follow-up, improvement was assessed based on this.

## RESULTS AND OBSERVATIONS

Out of the 30 patients investigated, 27 subjects have completed the study. Of these 3 cases were noted as drop out, 2 subjects were due to family problems and the other one subject was unable to complete the follow-up period. All the statistical analyses were done with the help of IBM SPSS (V20) statistical tool. Pre and post clinical evaluation was performed using Wilcoxon Signed Rank Test.

It was observed that 51.85% showed symptoms of chronic constipation. It was also observed that 55.56% of the subjects had attained menopause and 70.37% had full term normal vaginal delivery with a prolonged second stage.

### Data related to Clinical Features

A brief summary of the subjective and objective assessment parameters are given in Table 2 and Table 3, respectively.

## DISCUSSION

### Subjective Criteria

In this study, cystocele was more commonly found in women under peri-menopausal age group. It was more evident in the age group of 45 to 55 years. It may be due to increased awareness about menopause and its associated discomforts in the society. Health issues were least cared among the female population. Only a few among old age population were bothered about prolapse symptoms, whose quality of life got affected. In the peri-menopausal period there occurs reduction in estrogen causing loss of integrity to vaginal collagen tissues.

Majority of the study population were under middle socio-economic group. This could be due to their early approach in seeking medical attention. Low socio-economy group were not in the position to approach a Gynaecologist because they lack education and knowledge, about the condition. Upper category was not willing to reveal such a distress in the beginning stage because of their higher status. When the condition started affecting quality of life they seek medical attention for a surgical cure.

**Table 2: Subjective Assessments**

| Clinical feature                                   | Mean |      | Z     | P     | Mean FU3 | Z     | P      |
|--|------|------|-------|-------|----------|-------|--------|
|  | BT   | AT   |       |       |          |       |        |
| Frequency of urination                             | 1.37 | 0.81 | 3.873 | 0.000 | 0.11     | 4.786 | 0.000  |
| Urgency of urination                               | 1.04 | 0.81 | 2.449 | 0.014 | 0.11     | 4.811 | 0.000  |
| Urine leakage related with urgency                 | 0.59 | 0.44 | 2.000 | 0.046 | 0.000    | 4.000 | 0.000  |
| Urine leakage related with physical activity       | 1.26 | 0.85 | 3.317 | 0.001 | 0.26     | 4.208 | 0.0000 |
| Urine leakage not related with urgency or activity | 0.04 | 0.04 | 0.000 | 1     | 0.000    | 1.000 | 0.317  |



|   |      |      |       |       |       |       |       |
|---|------|------|-------|-------|-------|-------|-------|
| Small amount of urine drops                             | 0.26 | 0.11 | 2.000 | 0.046 | 0.000 | 2.646 | 0.008 |
| Difficulty in bladder emptying                          | 0.96 | 0.70 | 2.646 | 0.008 | 0.000 | 4.914 | 0.000 |
| Incomplete bladder emptying                             | 1.04 | 0.67 | 3.162 | 0.002 | 0.000 | 5.112 | 0.000 |
| Lower abdominal pressure                                | 0.04 | 0.04 | 0.000 | 1.000 | 0.00  | 1.000 | 0.317 |
| Pain while urination                                    | 0.04 | 0.00 | 1.000 | 0.317 | 0.00  | 1.000 | 0.317 |
| Pain/discomfort in lower abdomen or genital area        | 0.04 | 0.00 | 1.000 | 0.317 | 0.00  | 1.000 | 0.317 |
| Heaviness/dullness in pelvic area                       | 0.04 | 0.04 | 0.000 | 1.000 | 0.00  | 1.000 | 0.317 |
| Bulging/protrusion in the vaginal area                  | 0.78 | 0.52 | 2.646 | 0.008 | 0.067 | 4.146 | 0.000 |
| Pelvic discomfort while standing or physically exerting | 0.04 | 0.00 | 1.000 | 0.317 | 0.00  | 1.000 | 0.317 |
| Burning micturition                                     | 0.48 | 0.11 | 3.162 | 0.002 | 0.11  | 2.887 | 0.004 |

Table 3: Objective Assessments

| Mean  |       | Z     | P     |
|-------|-------|-------|-------|
| BT    | FU3   |       |       |
| 3.967 | 3.581 | 4.563 | 0.000 |

Those who were having long standing cases of chronic constipation and cough, met with an increase in intra-abdominal pressure, which in turn resulted in prolapse symptoms. During peri-menopausal period estrogen started to decline from the female genital tract. There occurs laxity of pelvic supporting structures. Menopause along with this long-standing illness highly contribute for anterior vaginal wall prolapse.

Multiple childbirth, prolonged second stage of labor and instrumental delivery causes injury to perineum. This may also cause injury to pudental nerve supply. These triggered symptoms of cystocele.

Urinary symptoms like frequency, urgency and leak with physical activity got marked improvement through *Tila taila Abhyanga*. By the collagen protein resynthesizing effect of phytoestrogen present in *Tila taila*, bladder supporting structures got strengthened where by symptoms of cystocele got marked improvement. Patients were able to hold urine for more time compared to the state before treatment, by this frequency of urination also got decreased. This provides an improved quality of life for the patients.

Other symptoms like leakage of urine with urgency, Urine leakage with physical activity, coughing, sneezing, small amount of urine drop, difficulty and incomplete bladder emptying, bulging or protrusion in the vaginal area showed marked improvement with *Tila taila abhyanga* through increased bladder support. Pelvic discomfort, lower abdominal pressure, pain while urination, heaviness or dullness in pelvic area and burning micturition didn't get any statistical significance.

### Objective Criteria

Before and after treatment prolapse reduction showed a change from  $3.967 \pm 0.9290$  to  $3.581 \pm 0.9904$  which is significant at a p value  $< 0.001$ . Tone of musculature got increased, estrogen receptors play a vital role in preventing further laxity of supporting structures. Phytoestrogens present in *Tila taila* paves the way for support. Hence, during third follow-up so that reduction of prolapse has got significant improvement.

### Probable Mode of Drug Action

*Tila taila* by its *Ushna*, *Tikshna*, *Sukshma*, *Vyavayi*, *Vikashi guna* enter into the *Srotas*, thereby helping in controlling the *Vata*. With *Tila taila abhyanga dhrdhata* of *Mamsa dhatu* could be improved. As per the explanation of *Acarya Dalhana*, *Sneha* enter into the body through *Sira mukha*<sup>[10]</sup>. The phytoestrogens which are in the *Taila* acts on collagen fibers and prevent break down of collagen structures<sup>[11]</sup>. Estrogen receptors which are depleting with menopausal changes got enhanced by the use of *Tila taila*. This provides support to the pelvic structures. So that symptoms of cystocele can be brought under control.

By *Abhyanga* growth hormones are stimulated by which denatured proteins are thrown out of the circulation. Anabolism of collagen proteins are supported<sup>[12]</sup>. This gives an increased support to pelvic structures. Anatomical correction of the condition was not able to achieve to a higher extend but symptoms of cystocele can be brought under control with the help of *tila taila abhyanga*.

## CONCLUSION

It was found that many women in the menopausal age group (about 78%) were affected by cystocele. Among various causative factors, chronic constipation (52%), multiparity (55%), vaginal delivery (70%) contribute to the cystocele condition. There is no direct mention of anterior vaginal wall prolapse (cystocele) in the *Samhita*, but, cystocele is a form of *Cyuta avastha* of *Vasti* for which *Tila taila* is effective. In the study conducted here it is found that with the help of *Tila taila Abhyanga*, frequency of urination, urgency of urination, urine leakage (without any activity), leakage with physical activity, cough, sneeze, small amount of urine leakage, difficult and incomplete bladder emptying, bulging in vagina, and the objective criteria are effectively brought under control. However, conditions like leakage not related to urgency, lower abdominal pressure, pain while urination, pain in lower abdomen or genital area, pelvic area heaviness or dullness, pelvic discomfort and burning micturition showed only a little reduction with the treatment. Thus, we conclude from this study that *Tila taila abhyanga* is effective in treating first degree cystocele. The quality of female life who are approaching menopausal stage can be improved with the help of cost-effective *Tila taila* treatment.

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