

## Research Article

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# A CLINICAL STUDY TO EVALUATE THE EFFECT OF BALABRUHATIKADI TAILA YONIPICHU DHARANA IN PELVIC ORGAN PROLAPSE

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#### ABSTRACT

Pelvic organ prolapse is one of the common clinical conditions met in a day-to-day gynaecological practice. The entity includes the descent of the vaginal wall and/ or the uterus. Approximately 1/3<sup>rd</sup> of adult women affected with Pelvic organ prolapse have a significant impact on their quality of life. In Ayurveda, Yoni bhramsa, Prasramsini, Andini, Phalini and Mahayoni Yonivyapath closely resemble Pelvic organ prolapse. Vata is the prime dosa involved in the pathogenesis of Yoni bhramsa. Balabruhatikadi taila mentioned in Kuchimaratantrabhasyam in the context of Vatiki Yonivyapath chikitsa was selected for the study to evaluate the effect in the degree of descent in Pelvic organ prolapse by Pelvic Organ Prolapse Quantification (POPQ) scale and to assess the quality of life by using Pelvic Floor Distress Inventory-20 (PFDI-20). The study design was an interventional study with pre-and post-test evaluations, without a control group, and with a sample size of 28. Participants of the age group 30-60 years with 1<sup>st</sup> and 2<sup>nd</sup> degree Pelvic organ prolapse were administered with Balabruhatikadi taila Yonipichu dharana continuously for seven days other than the bleeding phase for two consecutive months. Assessments were done on the 1<sup>st</sup> and 7<sup>th</sup> day of treatment for two consecutive months, and follow-up was done on the 21<sup>st</sup> day after the completion of treatment. The study showed that Balabruhatikadi taila Yonipichu dharana effectively manages Pelvic organ prolapse.

Keywords: Pelvic organ prolapse, Yoni bhramsa, Balabruhatikadi taila, Yonipichu, Pelvic Organ Prolapse Quantification (POPQ) scale, Pelvic Floor Distress Inventory-20 (PFDI-20)

## INTRODUCTION

Pelvic organ prolapse is a highly prevalent condition in the female population, which impairs the quality of life of affected individuals. It refers to loss of support to the uterus, bladder, and bowel, which leads to their descent from the normal anatomical position towards or through the vaginal opening<sup>1</sup>. The true incidence of pelvic organ prolapse is unknown, as many women with clinically severe prolapse are largely asymptomatic, and many with mild degrees of prolapse may have severe pelvic floor symptoms<sup>2</sup>. The prevalence of this is increasing with the growing aged population. Based on pelvic examination, the prevalence varies between 30-40%. In the Women Health Initiative study, pelvic organ prolapse was detected in 41% of women aged 50-59 years; this includes cystocele 34%, rectocele 19% and uterine prolapse 14%<sup>3</sup>.

Pelvic organ prolapse is a disturbed healing condition caused by the damage of pelvic floor muscles and connective tissue or a combination of the two. Its development is multifactorial and includes multiparity, vaginal childbirth, advancing age, connective tissue disorders and activities which increase the intra-abdominal pressure. The accumulation of reactive oxidative species (ROS) by sustained mechanical stress, estrogen deprivation and genetic mutations, which disturbs the activities of extracellular matrix (ECM) constituents (collagen, elastin, fibroblast, MMPs, TIMPs, etc.). While increasing the level of collagen degrading enzyme- MMPs (matrix metalloproteinases)

causes impaired collagen metabolism and results in biomechanical weakness of supporting structures of the pelvic floor, which leads to the development of Pelvic organ prolapse<sup>4</sup>. Current research focuses on the changes in the supporting network, where the ECM constituents play a vital role in accelerating connective tissue remodelling in POP patients<sup>5</sup>. Hence, Ayurvedic drugs, which can promote the synthesis of ECM components, especially collagen fibre, along with antioxidant and phytoestrogenic properties, can effectively manage POP.

Our Acharyas mentioned Yoni Bhramsa, Prasramsini, Andini, Phalini and Mahayoni Yonivyapath, which have close similarities with the symptoms of Pelvic organ prolapse. Yoni Bhramsa is Yoni Bahirgamana<sup>6</sup> due to Vata vrudhi. Hence, Balabruhatikadi taila Yonipichu is mentioned under the 10<sup>th</sup> Dalam of Kuchimarathanthrabhasyam<sup>7</sup>, having Vatahara property.

# MATERIALS AND METHODS

**Study Design:** Interventional study with pre and post-test evaluation without a control group.

**Study Setting:** Outpatient department of PNNM Ayurveda College and Hospital, Cheruthuruthy, Kerala, India.

**Study Population:** Participants of the age group 30-60 years who came with Pelvic organ prolapse diagnosed by POP-Q scale and

those subjects satisfying the inclusion and exclusion criteria were selected for the study.

#### **Inclusion Criteria**

- Subject diagnosed with Pelvic organ prolapse by POP-Q scale
- The age group of 30-60 years.
- 1st and 2nd degree Pelvic organ prolapse.

#### **Exclusion Criteria**

- Known cases of rectal, bladder and genital organ malignancies
- Infectious disorders of the genital tract
- · Congenital anomalies leading to Pelvic organ prolapse
- Subjects with irregular menstrual cycle

**Ethical Clearance:** The Institutional Ethical Committee approved this study with reference number PNNM/A2/PG/IEC-05/2020 dated 10/06/2020.

Method of Preparation of Balabruhatikadi taila: Kashaya was prepared using Bala, Bruhati, Kantakari and Devadaru. Kalka was made with Sathahwa, Nata, Kushta, Abda and Kounthi. Then, taila was prepared with ¼ part kalka, 4 parts kashaya, 1 part Tila taila, 2 parts ikshurasa and 4 parts goksheera in taila kalpana vidhi.

**Duration of Drug Administration:** Balabhruhatikadi taila Yonipichu dharana continuously for seven days, other than the bleeding phase for two consecutive months.

**Assessment:** Objective parameters were assessed on the 1<sup>st</sup> and 7<sup>th</sup> day of treatment for two consecutive months, and follow-up was done on the 21<sup>st</sup> day after the completion of treatment. Subjective parameters were assessed before and after treatment and during the follow-up period.

**Objective Parameter:** Degree of descent in Pelvic organ prolapse assessed by POP-Q scale.

Table 1: Ingredients of Balabruhatikadi taila

Drugs	Botanical name
Bala	Sida cordifolia
Bruhati	Solanum indicum
Kantakari	Solanum xanthocarpum
Devadaru	Cedrus deodara
Satahwa	Anethum graveolens
Natha	Valeriana wallichii
Kushta	Saussurea lappa
Abda	Cyperus rotundus
Kounthi	Vitex agnus castus
Tila taila	Sesamum indicum
Ikshu rasa	Saccharum officinarum
Goksheera	

Table 2: POP-Q Scale (Scoring System) <sup>8</sup>

Stage 0	No prolapse, points Aa, Ba, Ap, and Bp are all at -3 cm, and C or D is between total vaginal length -2 cm
Stage 1	The most distal portion of the prolapse is $>1$ cm above the level of the hymen.
Stage 2	The most distal portion of the prolapse is <=1 cm proximal or distal to the plane of the hymen.
Stage 3	The most distal portion of the prolapse is >1 cm below the level of the hymen but protrudes no farther than 2 cm less than the total
	vaginal length in centimetres.
Stage 4	Complete eversion of the total length of the lower genital tract.

Table 3: 9 Sites of POP-Q Scoring System 9

Point /site	Description	Range
Aa	Anterior vaginal wall, midline 3cm proximal to external urinary meatus (point of ureterovesical crease)	-3 cm to +3 cm
Ba	Anterior vaginal wall, most distal position between Aa and anterior fornix	-3 cm to +TVL
С	Cervix or vaginal cuff	$\pm TVL$
D	Posterior fornix or vaginal apex	$\pm TVL$
Ap	Posterior vaginal wall, midline 3cm proximal to the hymen	-3 cm to +3 cm
Вр	Posterior vaginal wall, most distal position between Ap and posterior fornix	-3 cm to +TVL
Gh	Genital hiatus: External urinary meatus to posterior midline hymenal ring	2 cm
Pb	Perineal body: Posterior hymen to the anal opening	3 cm
TVL	Total vaginal length: Point C or D to the hymenal ring	10 cm

Table 4: POP-Q Scoring Grid 10

Aa	Ba	C
Gh	Pb	TVL
Ap	Вр	D

Subjective Parameter: Quality of life assessed by PFDI-20.

Table 5: Pelvic Floor Distress Inventory (PFDI-20) 11

#### Pelvic Organ prolapse Distress Inventory 6 (POPDI-6)

Do You	No	Yes
1. Usually experience pressure in the lower abdomen?	0	1 2 3 4
2. Usually experience heaviness in the pelvic area?	0	1 2 3 4
3. Usually have a bulge or something falling out that you can see or feel in your vaginal area?	0	1 2 3 4
4. Ever have to push on the vagina or around the rectum to have or complete a bowel movement?	0	1234
<ol><li>Usually experience a feeling of incomplete bladder emptying?</li></ol>	0	1 2 3 4
6. Ever have to push up on a bulge in the vaginal area with your fingers to start or complete urination?	0	1234

#### Colorectal-Anal Distress Inventory 8 (CRAD-8)

Do You	No	Yes
7. Feel you need to strain too hard to have a bowel movement?	0	1 2 3 4
8. Feel you have not completely emptied your bowels at the end of a bowel movement?	0	1 2 3 4
9. Usually lose stool beyond your control if your stool is well-formed?	0	1 2 3 4
10. Usually lose stool beyond your control if your stool is loose?	0	1 2 3 4
11. Usually lose gas from the rectum beyond your control?	0	1 2 3 4
12. Usually have pain when you pass your stool?		1 2 3 4
13. Experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?	0	1 2 3 4
14. Does part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?	0	1 2 3 4

#### **Urinary Distress Inventory 6 (UDI-6)**

Do You		Yes
15. Usually experience frequent urination?		1 2 3 4
16. Usually experience urine leakage associated with a feeling of urgency, that is, a strong sensation of needing	0	1 2 3 4
to go to the bathroom?		
17. Usually experience urine leakage related to coughing, sneezing or laughing?	0	1 2 3 4
18. Usually experience small amounts of urine leakage (that is, drops)?	0	1 2 3 4
19. Usually experience difficulty emptying your bladder?	0	1 2 3 4
20. Usually experience pain or discomfort in the lower abdomen or genital region?	0	1 2 3 4

Total= 20 questions, Symptom scale: 0 = not present, 1= not at all, 2 = somewhat, 3 = moderately, 4 = quite a bit

## Scoring of PFDI-20

**Scale Scores:** Obtain the mean value of all the answered items within the corresponding scale (possible value 0 to 4) and then multiply by 25 to obtain the scale score (range 0 to 100). Missing items are dealt with by using the mean from answered items only.

**PFDI-20 Summary Score:** Add the scores from the 3 scales together to obtain the summary score (range 0 to 300).

**Statistical Analysis:** The Friedman test was used to compare the effect of intervention on objective parameters at different time

periods, and pair-wise comparison was done using the Wilcoxon signed rank test. Repeated measures of ANOVA were used to compare the quality of life before and after treatment, and a follow-up period and pair-wise comparison was done using the Least significance difference test (LSD).

## RESULTS AND DISCUSSION

**Effect of Intervention on Objective Parameter-** Degree of descent in Pelvic organ prolapse.

**Table 6: Degree of Descent in Different Compartments** 

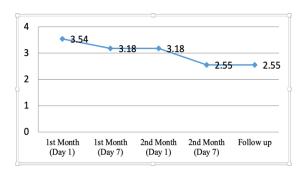
Period	Degree of descent	Number of subjects in Anterior compartment descent	Posterior compartment descent	Central compartment descent
Before treatment	2 <sup>nd</sup>	10	2	6
	1 <sup>st</sup>	7	7	11
After treatment	2 <sup>nd</sup>	5	2	3
	1 <sup>st</sup>	12	3	14
	0 <sup>th</sup>	0	4	0

The effect found after treatment was maintained during follow-up.

Table 7: Result of Freidman Test

Period	Mean rank	SD
1st Month (Day 1)	3.54	0.686
1st Month (Day 7)	3.18	0.663
2 <sup>nd</sup> Month (Day 1)	3.18	0.663
2 <sup>nd</sup> Month (Day 7)	2.55	0.612
Follow up	2.55	0.612

Chi-square	32.414
P-value	0.001



Graph 1: Mean rank of Overall Pelvic organ prolapse

After analysing the objective parameter by the Friedman test, it was found that the mean rank before treatment was 3.54, which gradually declined to the mean rank of 2.55 after treatment and which was maintained during follow-up. The Chi-Square value for comparing the effect of the intervention on the degree of

descent in pelvic organ prolapse at different time periods [32.414] was found to be significant, and the P-value was 0.001.

A pair-wise comparison was done using the Wilcoxon Signed Rank test.

Table 8: Result of Wilcoxon Signed Rank Test

Pairs	Calculated value	P-value	Significance difference
1 <sup>st</sup> Month (Day 1) and 1 <sup>st</sup> Month (Day 7)	-2.000	0.046	Present
1 <sup>st</sup> Month (Day 1) and 2 <sup>nd</sup> Month (Day 1)	-2.000	0.046	Present
1 <sup>st</sup> Month (Day 7) and 2 <sup>nd</sup> Month (Day 1)	0	1	Absent
1 <sup>st</sup> Month (Day 7) and 2 <sup>nd</sup> Month (Day 7)	-2.646	0.008	Present
1 <sup>st</sup> Month (Day 1) and 2 <sup>nd</sup> Month (Day 7) (Before and after treatment)	-3.317	0.001	Present
1st Month (Day 1) and Follow up	-3.317	0.001	Present
1st Month (Day 7) and Follow up	-2.646	0.008	Present
2 <sup>nd</sup> Month (Day 1) and 2 <sup>nd</sup> Month (Day 7)	-2.646	0.008	Present
2 <sup>nd</sup> Month (Day 1) and Follow up	-2.646	0.008	Present
2 <sup>nd</sup> Month (Day 7) and Follow up	0	1	Absent

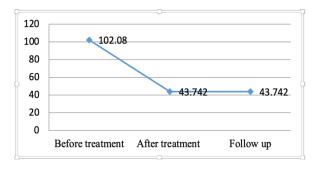
There was a significant difference between before and after treatment and also between before and follow-up periods with a P-value of 0.001

Effect of Intervention on Subjective Parameter- Quality of life.

Table 9: Results of Repeated Measures of ANOVA

Period	Mean	SD
Before treatment	102.08	36.327
After treatment	43.742	12.413
Follow up	43.742	12.413

F-value	120.341
P-value	< 0.001



Graph 2: Mean Quality of life

On the analysis of subjective parameters by Repeated Measures ANOVA, the mean before treatment was 102.08, which was reduced to the mean of 43.742 after treatment and maintained on

follow-up. The F-value for comparing the quality of life [120.341] was significant, and the P-value was <0.001. Pair-wise comparison was done using the Least Significant Difference test [LSD].

Table 10: P-values of LSD test

Period	Before treatment	After treatment	Follow up
Before treatment	1		
After treatment	<0.001*	1	
Follow up	<0.001*	1	1
*Significant difference present at 0.05 level			

There was a significant difference between before and after treatment and also between before and follow-up periods with a P-value <0.001

#### Discussion on Probable Mode of Action of Medicine

Balabruhatikadi taila contains 12 drugs such as Bala, Bruhathi, Kantakari, Devadaru, Satahwa, Natha, Kushta, Abda, Kounthi, Tila taila, goksheera and ikshu rasa.

Bala is Vatahara and indicated in Vatavyadhi. Balya, brimhana and dhatu ojo bala vardhana<sup>12</sup> help strengthen the supporting structures of pelvic organs. Ethanolic extract of *Sida cordifolia* has a wound-healing property, which promotes cellular proliferation and collagen synthesis in damaged tissues by increasing hydroxyproline content (the main component of collagen)<sup>13</sup>. So, it can manage the damaged pelvic connective tissue by correcting collagen metabolism. Its ethanolic extracts also possess antioxidant property<sup>14</sup>, so it helps to reduce the reactive oxidative species (ROS) accumulated by sustained mechanical stress on the pelvic floor.

Bruhati is Vatahara<sup>15</sup> which helps to reduce aggravated Vata in this condition. *Solanum indicum* has antioxidant property<sup>16</sup>, thus helping to reduce ROS.

Kantakari is Vatahara and bala pushtikari<sup>17</sup>; thereby, it can strengthen the supporting network. Studies showed that the alcoholic extract of *Solanum xanthocarpum* has wound-healing potential by significantly increasing collagen levels in rats<sup>18</sup>. This property may help to stimulate collagen production in damaged pelvic connective tissue in POP patients. Crude extract of *Solanum xanthocarpum* has antioxidant property<sup>19</sup>, so this can reduce ROS.

Devadaru is Kaphavatahara and dushtavruna visodhana karma<sup>20</sup>. Chloroform extract of *Cedrus deodara* showed antioxidant properties and significant wound healing potential by increased hydroxyproline expression<sup>21</sup>, so this can repair the damaged pelvic cellular tissue.

Satahwa is Vatakaphahara<sup>22</sup>. Thus, it can correct the Vatavaigunya in Yoni bhramsa. It has Vrunahara property also. Studies mentioned that *Anethum sowa* showed accelerated reepithelialisation of collagen deposition on wounds by increasing the expression of fibroblast growth factors and alpha receptors of estrogen<sup>23</sup>. So this can repair the damaged pelvic floor by increasing the collagen level. Chemical constituents of *Anethum sowa*, such as kaempferol, trans-anethole and limonene, have phytoestrogenic property<sup>24</sup>. Its estrogenic effect also stimulates the synthesis of collagen fibres, which helps strengthen the pelvic supporting network.

Natha is Kaphavatahara<sup>25</sup>, which can reduce the aggravated Vata dosa. Its ethanolic extract showed antioxidant property<sup>26</sup>, which helps to reduce the accumulated ROS.

Kushta is Vatakaphahara<sup>27</sup>. Alcoholic extract of *Saussurea lappa* possesses significant wound healing activity by increasing hydroxyproline content, thereby promoting collagen synthesis<sup>28</sup>. This property can strengthen the supporting network of the pelvic floor. Its antioxidant property<sup>29</sup> helps to reduce the ROS level.

Abda is balya and vrunagni<sup>30</sup>. Cyperus rotundus has significant wound-healing activity due to increased collagen concentration. Abda contains tannins, which help to increase the number of fibroblast cells and stimulate transforming growth factor <sup>31</sup>; in this way, it helps improve the collagen content in damaged pelvic connective tissue. Its antioxidant property<sup>32</sup> help to reduce the POS

Kounthi has tridoshagna, balya, kshayagna, ojovardhaka and dourblya unmoolana karma<sup>33</sup>. This helps to strengthen the supporting networks of pelvic organs. Studies showed that *Vitex agnus castus* contains flavonoids such as apigenin, penduletin and vitexin, which exerted estrogenic effects, and flavonoid casticin showed the antioxidant property.<sup>34</sup>

Tila taila has Kaphavatahara, balakruth, sthirakara, yoni visodhana and vrunashodhana karma, which is indicated in Vataroga<sup>35</sup>. These properties help correct the Vatavaigunya and strengthen the pelvic floor musculature. Sesame oil revealed better wound healing activity by increasing collagen content. Tila taila contains zinc, one of the co-factors for collagen synthesis, which stimulates re-epithelialization<sup>36</sup>. This may help remodel the ECM components on the pelvic floor. Sesame seeds also contain lignans that act as phytoestrogen<sup>37</sup>, so its estrogenic effect can regulate collagen metabolism. Its antioxidant property<sup>38</sup> help to reduce the ROS.

Goksheera has madhura rasa, guru and snigdha guna, madhura vipaka and Vatapittahara karma to alleviate aggravated Vata dosa. Its jeevaneeya, rasayana, balya and dhatuvardhana karma<sup>39</sup> help strengthen the pelvic floor's supporting structures. Cow's milk is one of the methylsulfonylmethane sources, an essential sulphur for collagen synthesis and inhibits collagen breakdown<sup>40</sup>. This facilitates the remodelling process of damaged pelvic cellular tissue. Cow's milk contains coumestans and lignans, which have phytoestrogenic property<sup>41</sup>. This helps in the synthesis of collagen fibres and results in the strengthening of the supporting network. Its antioxidant property<sup>42</sup> helps to minimise the level of ROS.

Ikshurasa has madhura rasa, guru and snigdha guna, madhura vipaka and Vatapittahara karma, so it helps to correct Vatavaigunya. It possesses balya, brimhana, and santharpana karma<sup>43</sup>, which can strengthen the pelvic floor. Phenolic extract of sugar cane juice showed antioxidant property<sup>44</sup> to reduce ROS.

Balabruhatikadi taila having Vatahara karma and most of the drugs possess balya karma. Bala, Devadaru, Abda, Kushta, Satahwa, Tila taila and goksheera facilitate collagen synthesis, and Satahwa, Kounti, Tila taila and goksheera showed phytoestrogenic properties. All of the drugs in this formulation also have antioxidant properties.

#### Mode of Action of Yoni Pichu

Yoni pichu is among the stanika chikitsa, and it is a simple, costeffective, acceptable and effective therapy. So by keeping the Pichu ball for a particular period of time (till the urge of micturition), it can support the weakened pelvic floor and which favours easy absorption of medicines through the vaginal epithelium and also accelerates pelvic connective tissue remodelling by changing the ECM components.

#### CONCLUSION

Balabruhatikadi taila is having Vatahara karma by its madhura rasa, guru and snigdha guna, and madhura vipaka or by its usna veerya. So, it helped to correct Vatavaigunya's involvement in this condition. Most drugs possess balya and dhatuvardhana karma, which have antioxidant and phytoestrogenic properties and can facilitate collagen synthesis. These properties helped to strengthen the supporting network of the pelvic organ. Keeping the Pichu ball for a while could help to support the weakened pelvic floor and favours easy absorption of medicines through the vaginal epithelium. It was found that Balabruhatikadi taila yoni Pichu dharana was statistically significant in reducing the degree of descent in Pelvic organ prolapse with P- value <0.001 and considerably improved their quality of life. So this study concluded that Balabruhatikadi taila yoni Pichu dharana effectively manages Pelvic organ prolapse.

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