

Effect of Mula Bandha Yoga in Mild Grade Pelvic Organ Prolapse: A Randomized Controlled Trial

Abstract

Background: Pelvic organ prolapse is the growing health issue related to women of the reproductive and postmenopausal age group in India and across the globe. Treatment option for pelvic organ prolapse includes both surgical and non-surgical intervention. The development of pelvic organ prolapse is an indication for major surgery among 20% of all women. Nevertheless, the recurrence of pelvic organ prolapse is detected among 58% of the patient after surgery. This highlights the need for preventive measures for reducing the impact of pelvic organ prolapse. **Aims and Objective:** To study the effect of 3 months yoga therapy in female patients suffering from mild pelvic organ prolapse. **Material and Methods:** 50 Participants were allocated into two groups (25 in each group) by generating Random allocation sequence. Women aged 20-60 with symptomatic mild pelvic organ prolapse in the yoga group were offered Mulabandha yoga therapy along with other conventional treatment modalities, while the control group was only on conventional treatment. All participants gave written informed consent. An assessment was done by improvement in chief complaints and Pelvic Floor Distress Inventory-20 (PFDI-20) & Pelvic floor impact Questionnaire-7 (PFIQ-7) at baseline and at the end of 4, 8 & 12 weeks. Results At the end of 12 weeks, Post-study comparison between the two groups showed a significant improvement in chief complaints like perennial pain, P/V discharge, Perineal muscle laxity and Feeling of something coming out P/V ($P < 0.001$). Participants in the yoga group improved by (on average) 5.7 (95% confidence interval 3.1 to 14.7) points more on the PFDI-20 than did participants in the control group ($P = 0.1$) and a mean score of PFIQ-7 was also improved significantly. **Conclusions:** Although Mulabandha (Root Lock) yoga therapy led to a significantly greater improvement in PFDI-20 & PFIQ-7 scores the difference between the groups was below the presumed level of clinical relevance (15 points). More studies are needed to identify factors related to the success of Mulabandha (Root Lock) yoga therapy and to investigate long-term effects.

Keywords: Mula bandha pelvic floor distress, pelvic organ prolapse, yoga

Introduction

Pelvic organ prolapse (POP) is the most frequently reported cause of poor health among women of reproductive age and postmenopausal women.^[1] The global prevalence of uterine prolapse is 2%–20%. According to the international data, Oxford Family Planning Association UK, the hospital admission for uterine prolapse is 20.4%.^[2] Concerning about India, it is found that among women visiting private clinics in Bengal, Delhi, Punjab, and Uttar Pradesh with gynecological problems, one in five are suffering from uterine prolapse.^[3] Most women in developing countries have to undertake manual work on a regular basis, frequently involving heavy lifting, even while pregnant or shortly after

delivery. This probably contributes to high rates of prolapse, and yet, paradoxically, prolapse makes it more difficult for women to undertake heavy work, over which they often have little or no choice. Undernutrition as a cause of poor tissue tensile strength may be a cofactor in the development of pelvic organ prolapse. Moderate and severe anemia also appear to be a risk factor associated with Pelvic organ prolapse.^[4,5]

Mula bandha is a most important part of the Hatha Yoga tradition often shadowed of its real grace and benefits due to lacunae of proper knowledge. The Sanskrit word Mula means “root, source, basis, lowest part or bottom, foundation.” Bandha means “lock, restrain, shut or close.” In the treatment of infertility, Mula bandha may be used as both a therapeutic and preventive practice.

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At the curative level, it allows us to regain a state of health on the physical, emotional, and mental planes, while at the preventive level, it allows us to maintain health and expand our normal, stable function to the cosmic level where we can do, and enjoy, so much more.

At the physical level, the practice of Mula bandha tones and strengthens the muscles of the pelvic region, especially the perineum, also playing a major role in increasing the circulation of concerned areas. The actions associated with it are also beneficial for supporting, toning, and strengthening the lower back. It also helps in supporting greater mobility of the pelvis. Due to the action of toning of the muscles in the pelvic region, it lifts and supports the lumbar spine, helping the upward extension of the spine, while toning and lengthening the psoas muscle and reducing tension in the lower back muscles and quadratus, thus effective to treat pelvic organ prolapse.^[6]

Material and Methods

Study design

The study was a prospective, randomized, intervention-controlled trial with 1:1 allocation of the participants into the two study groups. Participants were screened based on inclusion and exclusion criteria and then were randomly allocated into two groups (yoga and control) by generating random allocation sequence. In yoga group, patients were advised Mula bandha whereas in the other group, patients were given dietary supplements (multivitamins) along with Mula bandha.

Assuming 20% change in the mean value and taking the alpha as 5% and power as 80%, the sample size calculated were 25 and 23, respectively. Therefore, the higher of the two, i.e., 25 was considered as the required sample size for each group, i.e., yoga and control group. Hence, a total of 50 cases were required for the study. It was further assumed that 10% cases might lose during follow-up score. Therefore, on whole, 56 participants were enrolled for the study among which 6 declined to participate.

Hence, in the present study, a total of fifty cases were registered from Department of Gynaecology and Obstetrics, Sir Sunder Lal Hospital, Institute of Medical Sciences, Banaras Hindu University, Varanasi and were randomly divided into two equal groups of 25 cases each. To ensure effectiveness of the Mula bandha yoga therapy, the present study advocates a minimum of 12 weeks (90 days) therapy. Participants were followed up with observation once in 4 weeks up to 12 weeks for assessment of the result and to check for symptomatic improvements.

Mechanism of Mula bandha

The probable mechanism of Mula bandha has been shown in Figure 1.

Technique of Mula bandha^[7]

1. First of all, it is needed to take a suitable pose or Asana. It can be the lotus pose (Padmasana), the perfection pose (Siddhasana or Siddha yoni asana), or Mulabandhasana (which is considered to be more difficult) or in Sukhasana pose
2. Place the hands over the knees, close the eyes, and relax. Focus on breathing then move the attention to the pelvic floor region and genital-anal openings
3. Inhale deeply and retain the breath
4. Now slowly contract the genitourinary and anal openings (pelvic floor muscles [PFMs]) and pull them up slightly. Hold the lock, but do not overstrain. This is the final position
5. During the performance of Mula bandha, breathing is retained. Hold the Bandha as long as person can retain their breath, but again, without much strain
6. To end the root lock practice, relax the genitourinary and anal openings (PFMs) and exhale
7. This is considered as one cycle/round of Mula bandha
8. Repeat this cycle for 8–10 times/5–7 min twice a day.

Blinding and masking

As this was an interventional study, double blinding was not possible. The answer sheets of the questionnaires were coded and analyzed only after the study was completed. The statistician who did the randomization and data analysis was blinded to the treatment status of the individuals.

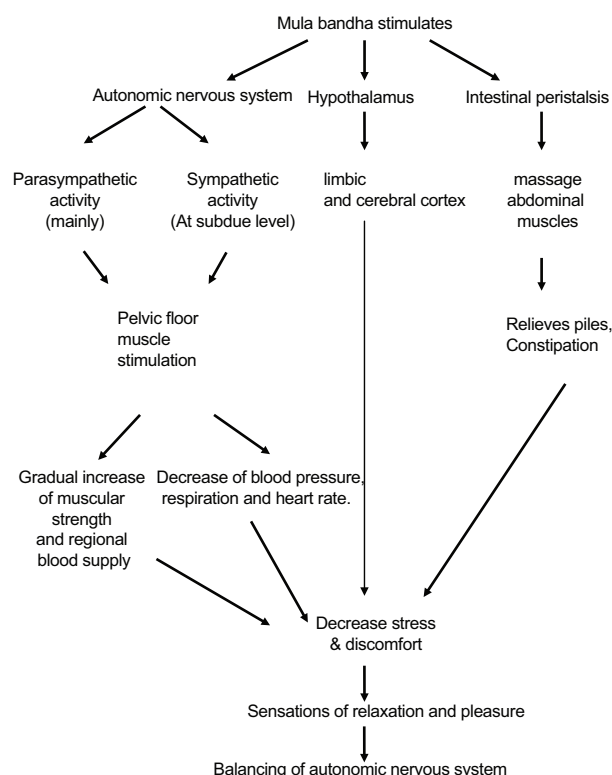


Figure 1: The probable mechanism of action of Mula bandha

Study participants

Eligibility criteria

The participants were screened for their eligibility to participate in the study during the screening visit (Visit 1).

a. Inclusion criteria

1. Women of age between 20 and 60 years
2. Willing to participate
3. Participants who discontinued all current modern medications before the start of study
4. Participants meeting the criteria for disease mild-grade uterine prolapse by clinical diagnosis.

b. Exclusion criteria

1. Participants who have severe grade of prolapse
2. Pregnant or nursing women
3. Participants who had undergone surgeries and had malignancy of pelvic organs.

The participant flow chart is shown in Figure 2.

Ethical clearance and informed consent

The protocol number ECR/526/Inst/UP/2014 was approved by Institutional Human Research Ethics Committee of Banaras Hindu University, IMS, Varanasi, on March 20, 2015. Patients were enrolled from a Department of Gynaecology and Obstetrics, Sir Sunder Lal Hospital, IMS-BHU, Varanasi, India. Each participant received detailed information about the study and provided written informed consent before the trial commenced.

Assessment

Criteria for assessment

The assessment was performed on the basis of changes in pelvic floor dysfunction inventory score-20 and pelvic floor impact questionnaire-7^[8] before, during, and after treatment.

The improvement in the patients was assessed on the basis of relief in the symptoms and signs of the disease. All the symptoms and signs were given grade scores and assessed before, during, and after treatment. Pelvic floor muscle function was examined by vaginal palpation of the PFMs in the lithotomy position.^[9] The obtained results were analyzed statistically.

Data analysis

Data analysis was done using SPSS software 20.0 (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp). For statistical analysis, results of all clinical parameters were tabulated. Total number of cases in percentage of each of these parameters was calculated for each group at baseline and at 3 months. All the data were expressed till two decimal places. Significance of difference within each group was calculated by Wilcoxon signed-rank test. We compared the difference in the mean change of questionnaire scores (Pelvic Floor Disability Index [PFDI]-20, Pelvic Floor Impact Questionnaire [PFIQ]-7)

Table 1: Demographic profile

	Number of cases (%)
Age (years)	
20-30	4 (8)
31-40	22 (44)
41-50	13 (26)
51-60	11 (22)
Occupation	
Homemaker	37 (74)
Private job	9 (18)
Government job	4 (8)
Business	0
Locality	
Rural	29 (58)
Urban	21 (42)

from baseline to follow-up between groups. We used a $P < 0.05$ significance level for all statistical tests.

Results

The results are given. Overall, intragroup comparison of pre-post data showed statistically significant ($P < 0.001$) differences for all the parameters. No significant change was observed in the controls.

Demographic profile

A total of 50 participants satisfying inclusion and exclusion criteria participated in the study. Baseline characteristics of the patients are detailed in Table 1. Uterine prolapse was more prevalent in 31–40 and 41–50 age groups. About 74% patients were homemakers, 18% were doing private jobs, and 8% had government jobs. Regarding locality, 58% belonged to rural area while 42% were from urban area.

Effect of therapy on chief complaints

Significant improvement in the percentage of cases was found between the pre- and posttreatment in various symptomatic domains in yoga group individuals.

In yoga group, 100% cases had moderate-to-severe grade of perineal pain before treatment, which decreases at successive follow-ups, and at 3rd follow-up, 72% were belonged to absence of pain up to mild grade pain. This change in severity grade of pain is statistically significant ($P < 0.001$) while it was found insignificant in control group [Table 2].

In yoga group, initial number of cases with absence of Per vaginum discharge were 0% which became 32% after 3rd follow-up, which is statistically significant ($P < 0.001$). In control group, number of cases with absence of symptom was 8% initially which becomes 20% after 3rd follow-up, which is statistically insignificant ($P > 0.05$) [Table 3].

Observation in yoga group shows that number of cases with absence of Perineal muscle laxity were 0% initially which becomes 20% after 3rd follow-up, which is statistically significant ($P < 0.001$); in control group, number of

Table 2: Effect of therapy on perineal pain

Grade	Perineal pain			
	Yoga group		Control group	
	Baseline (%)	Poststudy (%)	Baseline (%)	Poststudy (%)
Absent	0	6 (24)	1 (45)	1 (4)
Mild	0	12 (48)	3 (12)	9 (36)
Moderate	10 (40)	0	13 (52)	8 (32)
Severe	15 (60)	7 (28)	8 (32)	7 (28)
Within the group comparison (Wilcoxon signed-rank test)				
Z		3.64		1.34
P		<0.001		0.006

Table 3: Effect of therapy on P/V discharge

Grade	P/V discharge			
	Yoga group		Control group	
	Baseline (%)	Poststudy (%)	Baseline (%)	Poststudy (%)
Absent	0	8 (32)	2 (8)	5 (20)
Mild	1 (4)	8 (32)	8 (32)	7 (28)
Moderate	14 (56)	4 (16)	7 (28)	6 (24)
Severe	10 (40)	5 (20)	8 (32)	7 (28)
Within the group comparison (Wilcoxon signed-rank test)				
Z		3.49		1.41
P		<0.001		0.34

P/V=Per vaginum

Table 4: Effect of therapy on perineal muscle laxity

Grade	Perineal muscle laxity (ICS scale Slikeker - ten Hove <i>et al.</i> 2009)			
	Yoga group		Control group	
	Baseline (%)	Poststudy (%)	Baseline (%)	Poststudy (%)
Absent	0	5 (20)	1 (4)	1 (4)
Mild	1 (4)	14 (56)	5 (20)	9 (36)
Moderate	14 (56)	2 (8)	15 (60)	11 (44)
Severe	10 (40)	4 (16)	4 (16)	4 (16)
Within the group comparison (Wilcoxon signed-rank test)				
Z		3.72		0.81
P		<0.001		0.03

ICS=International Continence Society

cases with absence of symptom in 3rd follow-up remain same with some improvement which is also statistically significant ($P < 0.05$) [Table 4].

In yoga group, severity of feeling of something coming out P/V decreases with each follow-up. Initially, the number of cases with absence of symptom was found only 8% which becomes 20% after 3rd follow-up, which is statistically significant ($P < 0.001$) while it was found insignificant in control group [Table 5].

Effect of therapy on changes in mean scores of Pelvic Floor Disability Index-20 and Pelvic Floor Impact Questionnaire-7

The pre- and post-intervention assessments were carried out by using the PFDI-20 and PFIQ-7 score questionnaire designed for this study. In the intention to treat analysis,

participants in the Mula bandha yoga therapy group showed (on average) a 5.7 point greater improvement on the Pelvic Floor Distress Inventory-20 scale than participants in the watchful waiting group ($P = 0.199$). For the subscales, the difference between pelvic floor muscle training and watchful waiting was significant on the Urinary Distress Inventory-6 but not on the Pelvic Organ Prolapse Distress Inventory-6 or Colorectal-Anal Distress Inventory-8. Condition- specific quality of life (Pelvic Floor Impact Questionnaire-7) improved in both groups (and was found significant in the intervention group) [Table 6].

Discussion

Discussion on symptomatological observations

In the present study, 12 weeks of yogic intervention resulted in statistically significant improvement in chief complaints

Table 5: Effect of therapy on feeling of something coming out P/V

Grade	Feeling of something coming out P/V			
	Yoga group		Control group	
	Baseline (%)	Poststudy (%)	Baseline (%)	Poststudy (%)
Absent	2 (8)	5 (20)	10 (40)	0
Mild	1 (4)	12 (48)	1 (4)	1 (4)
Moderate	10 (40)	8 (32)	8 (32)	13 (52)
Severe	12 (48)	0	6 (24)	11 (44)
Within the group comparison (Wilcoxon signed-rank test)				
Z		4.20		1.35
P		<0.001		0.004

P/V=Per vaginum

Table 6: Change in mean (standard deviation) questionnaire scores from baseline to follow-up

Parameters	Yoga group		Control group		Difference (95% CI) in mean change from baseline*, P	
	Baseline score	Follow-up score	Baseline score	Follow-up score	Yoga group	Control group
PFDI-20	96.7 (11.3)	70.51 (14.07)	85.54 (16.2)	79.76 (15.2)	26.19 (33.44-18.93), <0.001	5.78 (14.71-3.15), 0.19
POPDI-6	49.3 (11.71)	36.48 (10.78)	45.41 (11.50)	42.15 (10.71)	12.82 (19.22-6.41), 0.002	3.26 (9.57-3.05), 0.30
CRADI-8	15.41 (6.80)	10.37 (6.03)	11.50 (5.75)	13.12 (6.68)	5.04 (8.69-1.38), 0.007	1.62 (1.92-5.16), 0.36
UDI-6	32.0 (10.98)	23.66 (11.07)	28.62 (12.60)	24.49 (10.50)	8.34 (14.60-2.07), 0.01	4.13 (10.72-2.46), 0.21
UIQ-7	12.94 (9.96)	7.80 (6.57)	10.09 (6.91)	7.04 (4.97)	5.140 (9.93-0.34), 0.036	3.05 (6.47-0.37), 0.07
CRAIQ-7	4.37 (3.04)	3.04 (2.70)	3.80 (2.38)	5.52 (4.04)	1.33 (2.96-0.30), 0.1	1.72 (0.16-3.6), 0.07
POPIQ-7	23.95 (11.19)	8.94 (7.69)	21.32 (9.22)	14.81 (8.66)	15.01 (20.46-9.55), <0.0001	6.510 (11.59-1.42), 0.01
PFIQ-7	41.28 (17.33)	23.8 (6.29)	35.22 (11.49)	27.37 (10.37)	17.48 (24.89-10.06), <0.0001	7.85 (14.07-1.62), 0.014

*Adjusted for baseline score. PFDI=Pelvic Floor Distress Inventory-20 (range 0-300), POPDI=Pelvic Organ Prolapse Distress Inventory-6 (range 0-100), CRADI=Colorectal-Anal Distress Inventory-8 (range 0-100), UDI=Urinary Distress Inventory-6 (range 0-100), PFIQ=Pelvic Floor Impact Questionnaire-7 (range 0-300), UIQ=Urinary Impact Questionnaire (range 0-100), CRAIQ=Colorectal-Anal Impact questionnaire (range 0-100), POPIQ=Pelvic Organ Prolapse Impact Questionnaire (range 0-100), CI=Confidence interval

of yoga group patients. However, no significant changes in chief complaints were seen in control group patients receiving only conventional therapy. Significant relief is suggestive of decrease in severity of symptoms after 12 weeks of yoga therapy. These findings are suggestive of the impact of intervention in the yoga therapy group and showed remarkable improvement in the above-said symptom. Mild grade prolapse could get reversed by consistent practice of Mula bandha yoga. This yoga also helps to maintain the pelvic floor muscle strength.

Pain associated with uterine prolapse can be located centrally or suprapubic and can be described as “dragging” in the groin. This pain is due to stretching of the ligamentous supports and secondarily to abrasion of the prolapsed tissues.^[10] Observed improvements in the perception of pain ($P < 0.001$) in yoga group may result from increased blood supply, which is due to the regular practice of contraction and relaxation of the perineal muscles, i.e., Mula bandha causes increase in blood supply to the pelvic regions; hence, it results in normal stretching and healing of the wear and tear of PFMs. It may be helpful in pain reduction by having a direct effect on sympathetic nervous system fibers, which helps to control blood flow through pelvis. Various studies have shown that influencing the sympathetic nervous system by yoga can block pain. Hence, regular practice of Mula

bandha could be helpful for attainment of normalcy of the symptoms.

Prolapsed vaginal tissue protrusion may lead to chronic vaginal discharge and bleeding due to ulceration. Observed improvements in prolapsed vaginal tissue and P/V discharge ($P < 0.001$) can be explained as a regular indulgence in the intervention techniques, i.e. yoga may have positive effect on metabolism and other physiological processes.

Regarding perineal muscle laxity, the result demonstrates better improvement in yoga group ($P < 0.001$). In yoga group doing Mula bandha, the vaginal muscles and perineum tone reach normal tone more smoothly and fastly in comparison to control group. In yoga, Mula bandha is one of the fundamentals of core body strength. The Mula bandha had significant role in strengthening the pelvic floor muscle, vaginal muscles, and perineum tone. There is evidence that a vaginal delivery significantly weakens and stretches the pelvic floor (Allen *et al.* 1990; Jones 1995; Bo *et al.* 2007) and that building up the PFMs improves the strength of the muscles (Harvey 2003; Bo *et al.* 2007a; Wagg and Bunn 2007).

Discussion on Pelvic Floor Disability Index-20 and Pelvic Floor Impact Questionnaire-7 Score

Females with mild prolapse who received Mula bandha yoga therapy showed greater improvement in PFDI-20

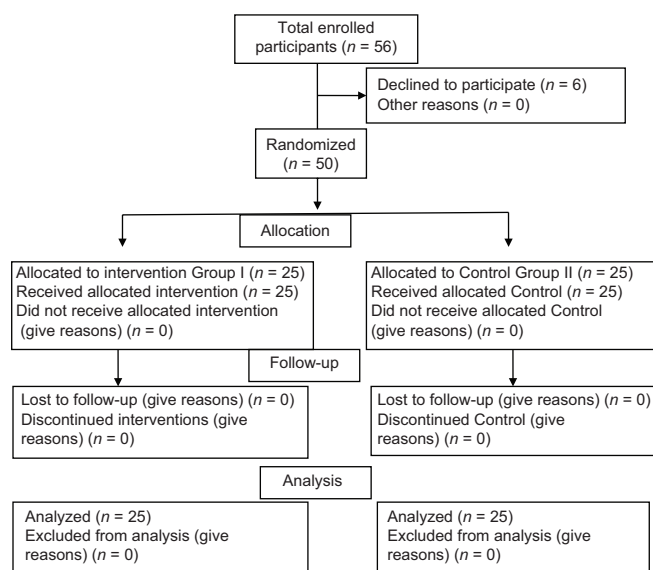


Figure 2: Participant flow chart

mean scores than did women randomized to a control group. Although the difference between the groups (5.7 points) was significant, it was below the presumed level of clinical relevance (15 points). Typical symptoms of prolapse (such as seeing or feeling a vaginal bulge) are thought to emerge when the leading edge of the prolapse is at or below the hymen.^[11,12] Therefore, in women with mild prolapse, other common prolapse related symptoms, such as urinary and bowel symptoms, should be assessed. In this study, in women with mild prolapse, Mula bandha yoga mainly affected the urinary symptoms. The largest difference in mean change from baseline was achieved in the PFDI-20 subscale measuring urinary symptoms (Urogenital Distress Inventory-6). The other PFDI-20 subscales (measuring prolapse and bowel symptoms) showed no significant differences in change between the groups. The relation between prolapse and urinary symptoms is not yet completely understood. Although stress urinary incontinence and prolapse are thought to be two coexisting problems that share causative factors rather than having a cause and effect relation,^[13] prolapse might cause bladder outlet obstruction, leading to irritable bladder symptoms (urgency, urge incontinence, frequency, nocturia).^[14] Similar findings were found for PFIQ-7 score.

Women receiving Mula bandha yoga therapy seemed to gain more insight into their symptoms and underlying conditions, leading to a higher subjective appreciation of improvement in the symptoms than was reflected in the change in PFDI-20 and PFIQ-7 scores.

Conclusion

This is the first study to investigate the effects of Mula bandha yoga technique in a female population with symptomatic mild degree of prolapse, which were identified by screening. Three-month yoga therapy is safe and effective

measure as adjuvant therapy to conventional treatment modalities in reducing severity of symptoms and improving quality of life in patients with mild degree of prolapse. Better conservative management with Mula bandha yoga therapy can help reduce dependence on pessaries, surgical interventions, and its associated side effects.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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