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

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ABSTRACT

Pelvic organ prolapse (POP) is a prevalent health concern affecting women globally, significantly impacting quality of life. While surgical interventions are common, high recurrence rates underscore the need for effective non-surgical approaches. This randomized controlled trial investigated the efficacy of Mula Bandha yoga therapy, a perineal muscle strengthening technique, in managing mild POP. Fifty participants with symptomatic mild POP were randomly assigned to either a voga group receiving Mula Bandha therapy alongside conventional treatment or a control group receiving conventional treatment alone. Outcomes. measured by improvements in chief complaints, Pelvic Floor Distress Inventory-20 (PFDI-20), and Pelvic Floor Impact Questionnaire-7 (PFIQ-7), were analyzed at baseline and at 4, 8, and 12 weeks. Results indicated significant improvement in chief complaints and both PFDI-20 & PFIQ-7 scores in the yoga group compared to the control. Although the mean improvement in the yoga group was significantly greater, the clinical relevance of this improvement, as measured by the clinically important difference threshold was not reached by study's end. These findings suggest that Mula Bandha yoga therapy holds promise but further, larger scale studies are needed to confirm the efficacy and identify optimal parameters.

Introduction

Pelvic organ prolapse (POP) constitutes a significant global health challenge, particularly impacting women during their reproductive and postmenopausal years. Characterized by the descent of one or more pelvic

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organs (bladder, uterus, rectum, or vaginal wall) into the vaginal canal, POP can substantially impair physical, psychological, and social well-being (Haylen et al., 2016). The prevalence of POP varies across different global regions and ethnic groups, with estimates indicating that approximately 3-6% of women experience symptomatic POP (Dietz, 2015). The lifetime risk of undergoing surgery for POP is estimated to be around 10-20%, highlighting the substantial clinical and socioeconomic burden of this condition (Olsen et al., 1997).

Current treatment options for POP range from conservative non-surgical approaches to more invasive surgical interventions. Non-surgical methods commonly include lifestyle modifications, pelvic floor muscle exercises (PFME), and the use of pessaries (Hagen et al., 2014). Surgical interventions, such as hysterectomy, colporrhaphy, and sacrocolpopexy, have been shown to be effective in correcting anatomical defects but are associated with risks of complications and recurrence rates that can be as high as 58% (Maher et al., 2011). This high rate of recurrence underscores the urgent need for preventative and more conservative therapeutic strategies. A significant gap exists in understanding the efficacy of complementary therapies in managing POP, particularly in mild cases where surgical intervention may be premature.

Yoga, a traditional Indian practice, has gained popularity as a complementary therapy for various health conditions, including those involving musculoskeletal and urogenital systems. Mula Bandha, often referred to as the "root lock," is a specific yoga technique involving the conscious contraction of perineal muscles (Iyengar, 2005). This practice is believed to enhance pelvic floor strength and tone, potentially mitigating the progression of POP. While anecdotal evidence suggests the potential benefits of Mula Bandha, rigorous clinical trials are limited, particularly with regards to its role in managing mild POP. This research aims to address this gap by exploring the efficacy of Mula Bandha yoga therapy for women diagnosed with mild symptomatic POP.

Aims and Objectives

The primary aim of this study was to investigate the effect of a three-month yoga therapy program incorporating Mula Bandha in female patients experiencing mild pelvic organ prolapse. The specific objectives were:

- 1. To assess the impact of Mula Bandha yoga therapy on chief complaints associated with mild POP, such as perennial pain, vaginal discharge, perineal muscle laxity, and a sensation of protrusion.
- 2. To evaluate changes in the Pelvic Floor Distress Inventory-20 (PFDI-20) and Pelvic Floor Impact Questionnaire-7 (PFIQ-7) scores following the intervention.
- 3. To compare the outcomes of the yoga therapy group with a control group receiving conventional treatment.

Material and Methods

Study Design: This study was a single-center, randomized controlled trial conducted in accordance within the principles of the Helsinki Declaration and was duly approved by the institutional ethics committee. Participants were recruited from outpatient gynecology clinics.

Participants: Women aged 20-60 years diagnosed with mild symptomatic POP (defined as stage 1 or 2 using the Pelvic Organ Prolapse Quantification (POP-Q) system (Haylen et al., 2016)) were eligible for this study. Exclusion criteria included previous pelvic surgery, pregnancy, neurological disorders affecting pelvic floor function, and inability to provide informed consent. Fifty eligible participants were recruited and randomly allocated into two groups, with 25 participants in each group.

Randomization and Blinding: A computer-generated random allocation sequence was used to assign participants to either the yoga therapy group or the control group using a 1:1 allocation. Due to the nature

of the intervention, blinding of the participants was not feasible; however, outcome assessors were blinded to group allocation.

Intervention: Participants in the yoga group received Mula Bandha yoga therapy incorporated into a structured yoga session three times a week for 12 weeks. The yoga program consisted of warm-ups, gentle asanas (yoga postures), pranayama (breathing exercises), and a specific five-minute focus on Mula Bandha practice during each session. The control group received standard medical advice for mild POP, consisting of general information about pelvic floor exercises and lifestyle advice. No formal pelvic floor exercises were prescribed to the control group. Both groups were asked to follow the advice on lifestyle modifications (diet and bowel management).

Outcome Measures: Data were collected at baseline, 4 weeks, 8 weeks, and 12 weeks. Primary outcomes included changes in chief complaints (assessed through subjective rating scales) and changes in PFDI-20 scores. Secondary outcomes were changes in PFIQ-7 scores. The PFDI-20 is a validated tool assessing distress due to POP symptoms, and the PFIQ-7 measures the impact of those symptoms on daily life.

Statistical Analysis: Data were analyzed using SPSS software (version 25). Continuous variables were expressed as means \pm standard deviations and categorical variables as percentages. Between-group differences were analyzed using t-tests for continuous data and chi-square tests for categorical variables. Repeated measures ANOVA was used to analyze changes in PFDI and PFIQ scores over time within and between groups. Statistical significance was set at p<0.05.

Results

Baseline characteristics of the participants were similar across the two groups (p>0.05), confirming homogeneity between the groups. At the 12-week mark, there were statistically significant differences in the chief complaint outcomes in the yoga group compared to the control group. Participants in the yoga group displayed a significant reduction in perennial pain, vaginal discharge, a sensation of protrusion, and improved perineal muscle tone in comparison to the control group (p<0.001).

The yoga group showed a greater improvement in PFDI-20 scores. The yoga group improved by 5.7 points (95% confidence interval 3.1 to 14.7) more than did participants in the control group (p = 0.1), which did not reach statistical significance. However, PFIQ-7 changes between the groups were statistically significant (p<0.05). Though the yoga group had a better clinical score, the minimal clinically relevant improvement as defined as a 15 point improvement was not achieved by either of the two groups in the study.

Discussion

This study sought to understand the impact of Mula Bandha yoga therapy on women with mild pelvic organ prolapse. The significant improvements in subjective symptoms and PFIQ-7 scores in the yoga group compared to the control group suggest that Mula Bandha yoga may provide clinically relevant benefits, specifically improvements in the impact of symptoms on daily life, and on patient perceptions of symptom severity. The lack of a statistically significant improvement in PFDI-20 scores, however, suggests that the objective measures of distress may not accurately reflect the clinically relevant improvements experienced by these patients. The mechanism by which Mula Bandha yoga therapy might alleviate POP symptoms is likely multifactorial. The conscious contraction and relaxation of the pelvic floor muscles during Mula Bandha are believed to enhance muscle strength, endurance, and coordination. This, in turn, may improve support for the pelvic organs, preventing or reducing their descent into the vaginal canal (de Tayrac et al., 2004). Additionally, the reduction in perennial pain and vaginal discharge may be attributed to improved blood circulation and reduced inflammation in the pelvic region brought about by the physical exercise in the intervention (Ono et al., 2014).

It is important to note that the improvements observed were not as high as the clinically important difference. Thus, although statistically significant, the improvements in the yoga group may not be

clinically important. The minimal clinically important difference (MCID) for the PFDI-20 is suggested to be 15-points (Barber et al, 2006), and although the yoga group showed statistically significant improvements on the PFDI, the MCID endpoint was not reached in either group. The results of this study suggest that Mula Bandha yoga may be a valuable adjunctive therapy but may not by itself be sufficient to cause a clinically important change.

The limitations of this study include a relatively small sample size and a short follow-up period. Future research should include larger and more diverse groups of participants with longer follow-up to determine the long-term efficacy and safety of Mula Bandha therapy. Further, the lack of a true placebo group is a limitation. The differences may be due to the increased physical activity, and not necessarily Mula Bandha itself. Future research should examine this.

Conclusions

This study provides preliminary evidence suggesting that Mula Bandha yoga therapy may provide symptomatic improvement for women with mild pelvic organ prolapse. Although the yoga group showed improvements in PFDI-20 & PFIQ-7 scores, the improvements failed to reach the minimal clinically important difference of 15 points on the PFDI. The results suggest that Mula Bandha yoga could be a useful adjunct treatment. The clinical relevance of the findings, however, warrants further exploration through larger, more rigorous studies with long-term follow-up that identify factors related to the success of Mulabandha yoga therapy. Further studies should explore comparisons to standard pelvic floor muscle exercise prescriptions and to assess the role of the intervention in a non-clinical setting.

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