**Article Full Title**

Randomized Multicenter Clinical Trial of Myofascial Physical Therapy in Women with Interstitial Cystitis/Painful Bladder Syndrome (IC/PBS) and Pelvic Floor Tenderness

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**Paper Abstract**

Objectives: To determine the efficacy and safety of pelvic floor Myofascial Physical Therapy (MPT) in women with newly-symptomatic IC/PBS, as compared to Global Therapeutic Massage (GTM). Materials and Methods: A randomized controlled trial of 10 scheduled treatments of MPT vs. GTM was performed at 11 clinical centers located in North America. We recruited women with IC/PBS with demonstrable pelvic floor tenderness on physical examination and a limitation of no more than 3 years symptom duration. The primary outcome was the proportion of responders defined as ‘moderately improved’ or ‘markedly improved’ in overall symptoms compared to baseline on a 7-point scale Global Response Assessment (GRA). Secondary outcomes included ratings for pain, urgency, frequency; the O'Leary-Sant IC Symptom and Problem Index (ICSI/ICPI) and reports of adverse events. We compared response rates between treatment arms using the exact conditional version of the Mantel-Haenszel test to control for clustering by clinical center. For secondary efficacy outcomes, cross-sectional descriptive statistics and changes from baseline were calculated. Results: Eighty-one women randomized to the two treatment groups had similar symptoms at baseline. The GRA response rate was 26% in the GTM group and 59% in the MPT group (p=0.0012). Pain, urgency, and frequency ratings and in ICSI/ICPI decreased in both groups during follow-up and were not significantly different between the groups. Pain was the most common adverse event, occurring at similar rates in both groups. There were no serious adverse events reported. Conclusions: A significantly higher proportion of women with IC/PBS responded to treatment with MPT than with GTM. MPT may be a beneficial therapy in women with this syndrome.

**NIH Risk of Bias Tool**

Quality Assessment of Controlled Intervention Studies

**Was the study described as randomized, a randomized trial, a randomized clinical trial, or an RCT**

Yes

**Was the method of randomization adequate (i.e., use of randomly generated assignment)?**

Yes

**Was the treatment allocation concealed (so that assignments could not be predicted)?**

Yes

**Were study participants and providers blinded to treatment group assignment?**

Yes

**Were the people assessing the outcomes blinded to the participants' group assignments?**

Yes

**Were the groups similar at baseline on important characteristics that could affect outcomes (e.g., demographics, risk factors, co-morbid conditions)?**

Yes

**Was the overall drop-out rate from the study at endpoint 20% or lower of the number allocated to treatment?**

Yes

**Was the differential drop-out rate (between treatment groups) at endpoint 15 percentage points or lower?**

Yes

**Was there high adherence to the intervention protocols for each treatment group?**

Yes

**Were other interventions avoided or similar in the groups (e.g., similar background treatments)?**

Yes

**Were outcomes assessed using valid and reliable measures, implemented consistently across all study participants?**

Yes

**Did the authors report that the sample size was sufficiently large to be able to detect a difference in the main outcome between groups with at least 80% power?**

Yes

**Were outcomes reported or subgroups analyzed prespecified (i.e., identified before analyses were conducted)?**

Yes

**Were all randomized participants analyzed in the group to which they were originally assigned, i.e., did they use an intention-to-treat analysis?**

Cannot Determine, Not Reported, or Not Applicable

**Key Finding #1**

Myofascial Physical Therapy treatment for Interstitial Cystitis/Painful Bladder Syndrome caused 59% participants to rate their symptoms as “moderately improved” or “markedly improved”

**Key Finding #2**

Although the link between bladder syndromes and pain and tightness in the abdomen, hip, and pelvic floor is not entirely understood, myofascial physical therapy appears to be a successful treatment

**Key Finding #3**

**Key Finding #4**

**Please provide your summary of the paper**

Women with Interstitial Cystitis/Painful Bladder Syndrome (IC/PBS) with symptoms that had been occurring for 3-36 months and who rated their bladder pain, frequency, and urgency a 3/10 with pelvic floor tenderness were enrolled in this study to determine the effect of Myofascial Physical Therapy (MPT) versus Global Therapeutic Massage (GTM). Since IC/PBS is associated with tight connective tissue of the abdomen, pelvis, and pelvic floor, the MPT group received internal and external trigger point release and connective tissue manipulation. After up to 10, 60-minute treatment session, it was found that there were significantly more responders to MPT than GTM (p=0.0012). A responder was classified as someone who rated their symptoms as “moderately improved” or “markedly improved” compared to baseline. There was no significant difference between groups for the secondary outcomes of pain, urgency, or frequency of voiding after the 12-week treatment.

**Please provide your clinical interpretation of this paper. Include how this study may impact clinical practice and how the results can be implemented.**

This data suggests MPT can be used to help treat IC/PBS by focusing on the connective tissue of the abdominal wall, pelvic floor, and pelvis. One limitation is that this study only included women with IC/PBS who had pelvic floor tenderness upon examination. Therefore, it is unknown how these results would apply to someone without pelvic floor tenderness. Additionally, there was loss to follow up after the 12-week trial, so there was no data that showed the longer-term effects of the treatment. Overall, MPT appears successful for treatment of symptoms of IC/PBS, but more research is needed to determine if these results can be applied to those patients outside of the narrow inclusion criteria and the effect of the treatment long-term.