Randomized Multicenter Clinical Trial of Myofascial Physical Therapy in Women With Interstitial Cystitis/Painful Bladder Syndrome and Pelvic Floor Tenderness

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Purpose: We determined the efficacy and safety of pelvic floor myofascial physical therapy compared to global therapeutic massage in women with newly symptomatic interstitial cystitis/painful bladder syndrome.

Materials and Methods: A randomized controlled trial of 10 scheduled treatments of myofascial physical therapy vs global therapeutic massage was performed at 11 clinical centers in North America. We recruited women with interstitial cystitis/painful bladder syndrome 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 global response assessment scale. Secondary outcomes included ratings for pain, urgency and frequency, the O'Leary-Sant IC Symptom and Problem Index, 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: A total of 81 women randomized to the 2 treatment groups had similar symptoms at baseline. The global response assessment response rate was 26% in the global therapeutic massage group and 59% in the myofascial physical therapy group ($p = 0.0012$). Pain, urgency and frequency ratings, and O'Leary-Sant IC Symptom and Problem Index decreased in both groups during followup, and were not significantly different between the groups. Pain was the most common adverse event, occurring at similar rates in both groups. No serious adverse events were reported.

Abbreviations and Acronyms

GRA = global response assessment

GTM = global therapeutic massage

IC = interstitial cystitis

ICPI = O'Leary-Sant IC Problem Index

ICSI = O'Leary-Sant IC Symptom Index

MPT = myofascial physical therapy

PBS = painful bladder syndrome

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Conclusions: A significantly higher proportion of women with interstitial cystitis/painful bladder syndrome responded to treatment with myofascial physical therapy than to global therapeutic massage. Myofascial physical therapy may be a beneficial therapy in women with this syndrome.

Key Words: pelvic pain; cystitis, interstitial; physical therapy modalities

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THE treatment of IC/PBS remains suboptimal and its clinical course can be highly variable. However, most patients display tension and tenderness of the pelvic floor musculature and other somatic tissues.[1–8] Frequently found abnormalities include muscular tenderness and connective tissue restrictions of muscle, fascia and subcutaneous tissues of the pelvic floor, hip girdle and abdominal wall. These somatic abnormalities may contribute to the pain of IC/PBS. There is suggestive evidence that treatment of these tissue abnormalities using myofascial physical therapy techniques can significantly relieve the symptoms of IC/PBS.[4,5,9]

We previously reported the findings of a multicenter, randomized feasibility study comparing specialized pelvic floor myofascial physical therapy to treatment with nonspecific global therapeutic massage for the relief of symptoms in patients with IC/PBS or chronic prostatitis/chronic pelvic pain syndrome.[9] In that study the benefit of MPT compared to GTM was most marked in patients with IC/PBS, almost all of whom were women. We were able to standardize both treatments across multiple study sites and found that patients readily accepted the study treatments. Among patients with IC/PBS the response rate was 50% in the MPT group and 7% in the GTM group, suggesting that MPT may be a useful treatment for this syndrome. Based on the findings from our pilot study we conducted a second study to further compare the efficacy, safety and durability of MPT to GTM in women with interstitial cystitis/painful bladder syndrome.

METHODS

We conducted a single-blind, randomized clinical trial comparing pelvic floor MPT to GTM. The design and methods of this randomized trial are identical to those described previously for our feasibility study,[9] with the exception that in this study the recruitment was limited to women.

Female patients were eligible for study inclusion if they had a clinical diagnosis of IC/PBS, and recorded ratings for bladder pain, frequency and urgency each at a usual level of at least 3 on a 0 to 10 scale, present for at least 3 months but not for longer than 3 years. Baseline symptom ratings were recorded twice, 2 weeks apart, and the average rating of symptom severity was used to determine study eligibility. An additional eligibility requirement was the finding of pelvic floor tenderness during vaginal examination by the study physician and confirmed by the study physical therapist.

Women were excluded from study if they had not previously undergone at least 1 course of a standard therapy for IC/PBS or if they had previously received treatment with pelvic floor MPT. Those who met the eligibility criteria at baseline screening were randomized equally to MPT or to GTM. The goal of randomizing 88 subjects (44 per treatment arm) at 11 clinical centers, with 4 to 5 participants at each center, was chosen to provide 80% power to detect a difference of 30% in the response rates, assuming a rate for GTM of 10% as shown in our pilot study. Those randomized to MPT received targeted internal and external tissue manipulation, focusing on the muscles and connective tissues of the pelvic floor, hip girdle and abdomen. The MPT methodology has been described in detail previously.[9] The GTM treatment followed a traditional full body Western massage program.[10] Physical therapists from each site were centrally trained and certified in the performance of both interventions to standardize treatment. Subjects received up to 10, 60-minute treatment sessions during a 12-week period. Subjects were not informed whether the treatment they were receiving was MPT or GTM. No other changes in urological care occurred during the course of the study.

Physician examiners and research nurses collecting outcome data were masked to treatment assignment. Outcomes related to symptom improvement were assessed at 12 weeks (at the completion of the treatment phase) and were planned again 3 months later during a followup