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RANDOMIZED MULTICENTER PILOT TRIAL SHOWS BENEFIT OF MANUAL PHYSICAL THERAPIES IN TREATMENT OF UROLOGIC CHRONIC PELVIC PAIN

Hypothesis / aims of study

Urologic Chronic Pelvic Pain (UCPP) includes Painful Bladder Syndrome (PBS) in men and women, and Chronic Prostatitis/Pelvic Pain Syndrome (CPPS) in men. Although manual physical therapy is gaining popularity as a treatment approach, there is no strong evidence to support its use. Our objective was to determine the feasibility of a randomized study of manual physical therapy and estimate efficacy.

Study design, materials and methods

All study procedures were in accordance with rules of the Declaration of Helsinki. All study participants gave informed consent. Forty-seven participants with symptom duration of less than 3 years were recruited at six clinical centers. We recruited men and women with a clinical diagnosis of PBS, with both bladder pain and frequency rated 3/10 or greater. We also recruited males with CPPS who had NIH-CPSI scores >15, with $\geq$1 in the pain domain. All subjects had pelvic floor muscle tenderness on examination. Physical therapists at each center were certified in performance of two standardized manual therapies and patients were randomized to undergo 10 weekly, 1-hour treatments. Patients were randomized to manual physical therapy (MPT) or traditional global therapeutic massage (GTM). The MPT group underwent connective tissue manipulation to body wall tissues of abdominal wall, back, buttocks, thighs and internal pelvic floor that clinically were found to contain connective tissue abnormalities or painful trigger points. Patients randomized to the massage group underwent total body massage therapy without internal treatment. After completing the course of treatment the primary efficacy endpoint, a Global Response Assessment, was blindly assessed. Patients were considered to be 'responders' if they indicated that compared to before treatment, their symptoms were either 'moderately' or 'markedly' improved. Responder rates were compared using Mantel-Haenszel testing.

Results

126 patients with UCPP were approached for study participation, 68 (54%) agreed to participate and 47 were randomized including 23 (49%) men and 24 (51%) women). All patients identified as eligible by their study physician were also considered eligible by the study physical therapist. Participants were randomized to MPT (n=23) or GTM (n=24). Study groups were comparable; overall 93% had moderate/severe pain and 91% had moderate/severe urgency at baseline. Forty-four (94%) patients completed the study, with 2 patients withdrawing from GTM and 1 withdrawal from MPT.

As detailed in the Table, in the MPT group 13/23(57%) were responders, compared to 5/24(21%) in the massage group (p=0.03). There were no serious adverse events and 44/47 (94%) completed therapy. The success of treatments in UCPPS patients was variable across the study centers and might be attributed to the differential responses in CP/CPPS compared with IC/PBS, differential responses by gender, or due to differences in delivery of manual therapy techniques.

Interpretation of results

This novel randomized trial suggests that it is feasible to study MPT for treatment of UCPP and also that MPT is an efficacious treatment for UCPP. The low rate of withdrawal from study participation also suggests that manual therapies are acceptable to patients.

Table: **Global Response Assessment (GRA) by Treatment Group**

GRA Response	GTM (24)	MTM (23)	Total (47)
Moderately or markedly improved*	5 (21%)	13 (57%) †	18 (38%)
Slightly improved	10 (42%)	8 (26%)	24 (34%)
No change	5 (21%)	2 (9%)	7 (15%)
Slightly worse	1 (4%)	0	1 (21%)
Moderately or markedly worse	1 (4%)	1 (4%)	2 (4%)
Withdrawn or lost to follow-up	2 (8%)	1 (4%)	3 (6%)

* Patients with GRA responses of markedly and moderately improved are considered responders to treatment.

Concluding message

A randomized multicenter trial of manual therapy for treatment of UCPP proved to be feasible and also suggests that manual therapy offers benefit to UCPP patients.

Specify source of funding or grant	**Funded by the National Institutes of Health/National Institute of Diabetes, Digestive and Kidney Diseases, USA.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Clinicaltrials.gov number NCT00434343**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Loyola Stritch School of Medicine**
Was the Declaration of Helsinki followed?	**Yes**

Was informed consent obtained from the patients?	**Yes**