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Feasibility of Using the Patient-Reported Outcomes Measurement Information System in Academic Health Centers: Case Series Design on Pain Reduction After Chiropractic Care

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Abstract

Objective: The purpose of this study was to test the utility of Patient-Reported Outcomes Measurement Information System (PROMIS) as a resource for collecting data on patient-reported outcomes (PRO) within academic health centers at a chiropractic college; and, to describe changes in PRO following pragmatic chiropractic care incorporating instrument-assisted soft tissue mobilization (IASTM) on pain symptoms.

Methods: This was a pre-post intervention design without a control group (case series) involving 25 patients (14 females and 11 males; 40.5 ± 16.39 years, range 20-70 years) who completed their chiropractic care and their baseline and post-treatment pain assessments. The pragmatic chiropractic care intervention included both spinal manipulation and IASTM to treat pain symptoms. PRO's were collected using PROMIS to measure pain behavior, pain interference and pain intensity.

Results: The average pre-post assessment interval was 33 ± 22.5 days (95% CI, 23-42 days). The durations of treatments ranged from one week to 10 weeks. The median number of IASTM treatments was six. Pre-post decreases in T-scores for pain behavior and pain interference were 55.5 to 48.4 and 57.7 to 48.4, respectively ($P < .05$). Only 12 patients had a baseline T-score for pain intensity greater than 50. The pre-post decrease in pain intensity T-scores for these 12 patients was from 53.4 to 40.9.

Conclusion: Within the limitations of a case series design, these data provide initial evidence on the utility of PROMIS instruments for clinical and research outcomes in chiropractic patients.

Introduction

Instrument-assisted soft tissue mobilization (IASTM) may enhance the ability of clinicians to

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effectively break down scar tissue and fascial restrictions. Preliminary data suggested that IASTM treatments may effectively alleviate the clinical symptoms of various cumulative trauma disorders.[1–5] For example, in the case of carpal tunnel syndrome (CTS), IASTM may be used to provide a precise method of manipulating the myofascia of the forearm, wrist and palm of the hand to alleviate compression directly over the pathway of the median nerve. A pilot study provided evidence that manual therapy, including IASTM, increased range of motion and grip strength in wrists affected by CTS.[1] Preliminary data also indicated that chiropractic manipulations—of the cervical spine, shoulder, elbow, and wrist joints—physiotherapy procedures, stretching exercises, and/or myofascial release techniques were effective in relieving clinical symptoms and functional loss in CTS patients who were candidates for surgical interventions.[6–9] These preliminary studies also showed improvements in sensory and motor conduction latencies of the median nerve and increases in anatomical dimensions of the carpal tunnel as revealed by electrodiagnosis studies and MRI, respectively.[8,9] These clinical improvements support the theory that IASTM may increase myofascial mobility; thereby, increasing blood flow within the vasa nervorum, which in turn, alleviates local ischemic effects that may contribute to pain generation and impairments of muscle and nerve function.

There are also case reports that describe clinical outcomes with IASTM treatments. An athlete presented with chronic ankle pain, reduced range of motion, fibrotic lesions surrounding the ankle joint, and a medical history including recurrent ankle sprains, two arthroscopic surgeries, and physiotherapy.[3] The athlete reported no pain, increased range of motion, and improved physical function following six to eight weeks of IASTM treatments.[3] Although magnetic resonance imaging (MRI) did not reveal any anatomical changes to the ankle, the athlete did stop taking non-steroidal anti-inflammatory medications.[3] After 8 weeks of IASTM treatments and stretching exercises for palmar adhesions due to Dupuytren's contracture, there were increases in active (11.5% and 57.1%) and passive (77.8% and 30.0%) ranges of motion of the 4th and 5th digits, respectively; photographic evidence of decreased contractures; and subjective improvements in hand function.[10] There are numerous case reports on the inclusion of IASTM in multimodal rehabilitative programs for treating post-surgical anterior cruciate ligament or patellar tendon repairs,[11,12] Achilles or high hamstring tendinopathy,[13–17] anterior chest pain and midthoracic stiffness associated with acute costochondrities,[18] lower back pain,[19,20] and various other musculoskeletal injuries of the upper and lower extremities.[21–31] These case reports suggested that IASTM may promote faster recovery times, alleviate pain, and facilitate improvements in joint and muscle function to "optimal" levels. However, comparative clinical studies were inconclusive on the independent or additive therapeutic benefits of IASTM.[1,32]

Despite the data presented above and a small number of mechanistic studies on IASTM using animal models,[33–36] clinical indications and treatment protocols for using IASTM remain theory-driven. ConnecTX Therapy is a recent development in the field of IASTM that uses a single, double-beveled, convex and concave, instrument with long and short radius surfaces to treat the various shapes and curves of soft tissue structures of the body.[37] ConnecTX Therapy protocols reflect meticulous contributions of time and energy by clinical academicians to provide evidence-informed recommendations underlying treatment protocols.[37] However, data are still needed to substantiate, modify, or refute these evidence-informed recommendations for treating patients with ConnecTX Therapy protocols.

Randomized trials with control groups and blinding are the gold standard of clinical research to address treatment effectiveness. Randomized trials are expensive to implement and their external validity depends upon adequately defining: (1) hypotheses; (2) recruitment strategies; (3) sampling of patient populations to include eligibility criteria, sample size and randomization procedures; (4) therapeutic and control interventions with procedures to monitor treatment adherence and adverse events; (5) blinding; (6) primary and secondary outcome measures; and (7) appropriate statistical procedures.[38] Thus, there is growing emphasis on the development of reliable and valid patient-reported outcomes (PRO) that may be used to facilitate the interpretation and comparison of clinical research.[39–42] PRO instruments that are reliable, precise, and valid within a "real world" clinical setting would provide another source of data for conducting rigorous clinical research.[43–45] Towards this end, the National Institutes of Health funded Patient Reported Outcomes Measurement Information System (PROMIS) is developing reliable and valid PRO instruments and a data management system that are readily available to compare how various treatments might affect what patients are able to do and the symptoms they experience across medical conditions and relative to the US population.[39,41–44,46,47]