

Watchful Waiting Achieves Higher Value than Physical Therapy for the Treatment of Idiopathic Frozen Shoulder: A Prospective Randomized Controlled Trial

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INTRODUCTION: Adhesive capsulitis, also known as frozen shoulder, is a painful condition characterized by capsular contracture and restricted active and passive glenohumeral range of motion. Although adhesive capsulitis afflicts approximately 2 to 5% of the general population, the optimal treatment regimen for relieving pain and restoring function remains controversial. Physical therapy remains a ubiquitous treatment modality for the management of adhesive capsulitis (frozen shoulder) despite a paucity of high-level evidence supporting its use. This study leveraged patient-reported outcome measures (PROMs) and healthcare costs to compare the value achieved through watchful waiting (WW) versus physical therapy (PT) for the conservative management of frozen shoulder.

METHODS:

This study was a single-provider, randomized controlled trial (RCT) comparing PROMs and costs between patients receiving PT versus WW for the treatment of idiopathic adhesive capsulitis. Following institutional review board approval and registration on ClinicalTrials.gov, consecutive patients presenting to a single academic medical center sports medicine clinic between November 2014 and November 2022 were offered enrollment into the study. Subjects were randomized to PT or WW in a 1:1 ratio. The primary outcome was the American Shoulder and Elbow Surgeons Score (ASES). Secondary outcomes included patient value (defined here as the 12-month ASES score divided by healthcare costs), the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire, and Visual Analog Scale (VAS) pain scores. To protect confidentiality, value and direct patient costs were normalized to set the study means equal to 100 and 1,000, respectively. Outcomes were assessed at baseline and at 6 weeks, 3 months, 6 months, and 12 months. Primary analyses were conducted following intention-to-treat principles using linear mixed-effects models. Sensitivity analyses incorporated nonlinear mixed-effects models and as-treated analyses.

RESULTS: [Between November 2014 and November 2022](#), 175 patients were screened, 61 of whom (34.9%) were assigned WW (31 patients, 51.8%) or PT (30 patients, 49.2%) (**Table 1**). [Relative to baseline scores, patients from both cohorts improved significantly at each timepoint and for all PROMs \(p<0.05 for all\)](#) (**Figure 1**). However, there were no significant differences in PROMs between treatment modalities at any timepoint (p>0.05 for all) (**Table 2**). Compared to those assigned WW, patients randomized to PT incurred 10.0x higher costs (normalized mean difference: 1,635.67; 95% CI: 967.19, 2,304.15; p<0.001) and achieved only 16.9% of the patient value (normalized mean difference: -146.97; 95% CI: -207.47, -86.47; p<0.001) (**Table 3**). These results held across all sensitivity analyses.

DISCUSSION AND CONCLUSION:

To our knowledge, this is the first RCT to compare PT versus WW for the treatment of adhesive capsulitis through a value-based healthcare framework. Consistent with our hypothesis, patient-reported pain and function improved significantly in both cohorts, but the improvement trajectory did not differ between modalities. Furthermore, patients randomized to PT both incurred significantly higher direct costs and imposed a greater economic burden upon the healthcare system. As such, the present study equips physicians, advanced practice providers, and other stakeholders with Level 1 evidence demonstrating WW as a high-value treatment modality for the conservative management of primary adhesive capsulitis.