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ORIGINAL ARTICLE

Randomized controlled trial of supervised physiotherapy versus a home exercise program after hydrodilatation for the management of primary frozen shoulder

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Hypothesis and background: Hydrodilatation and physiotherapy are commonly used treatments for primary frozen shoulder. Little is known about the optimal form of physiotherapy. This study reports a randomized controlled trial comparing 2 forms of physiotherapy after hydrodilatation. The null hypothesis was that there would be no difference between the 2 groups at 1 year as measured by the Oxford Shoulder Score (OSS).

Methods: We randomized 41 patients undergoing hydrodilatation for primary frozen shoulder into 2 treatment groups: group 1 (n = 20) underwent supervised physiotherapy in addition to a home exercise program, and group 2 (n = 21) followed a self-directed home exercise program in isolation. Assessment was carried out by a blinded research nurse at baseline, 4 weeks, 3 months, 6 months, and 1 year. The primary outcome measure was the OSS. Other measures were range of movement, visual analog scale pain score, and EQ-5D index.

Results: There was no significant difference between the treatment groups at any time point as measured by the OSS or EQ-5D index. In group 1, the OSS improved significantly from 25.00 (95% confidence interval [CI], 21.92-28.08) at baseline to 38.29 (95% CI, 34.01-42.58; $P < .0001$) at 4 weeks and 43.71 (95% CI, 41.61-45.80; $P < .0001$) at 1 year. In group 2, the OSS improved significantly from 26.60 at baseline (95% CI, 22.50-30.70) to 40.07 (95% CI, 36.77-43.36; $P < .0001$) at 4 weeks and 43.00 (95% CI, 39.69-46.31; $P < .0001$) at 1 year. All outcome measures improved significantly from baseline to 4 weeks.

Conclusion: In this group of patients, after a hydrodilatation procedure for the treatment of primary frozen shoulder, there was no significant difference in clinical outcomes between supervised physiotherapy in addition to a home exercise program and a self-directed home exercise program in isolation.

Level of evidence: Level II; Randomized Controlled Trial; Treatment Study

Keywords: Shoulder; adhesive capsulitis; frozen shoulder; hydrodilatation; hydrodistension; physiotherapy

This study was performed at The Ipswich Hospital NHS Trust, Ipswich, UK. Regional ethics committee (REC) approval was obtained (National Research Ethics Service (NRES) Committee East of England—Cambridge East, REC reference 12/EE/0403, Integrated Research Application System (IRAS) project number 103304).

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Frozen shoulder is a common and debilitating disorder, accounting for around 5% of all shoulder disease, with an estimated incidence of between 0.75% and 5.0% in the general population.[5,13] It presents with a characteristic gradual onset of shoulder pain and stiffness.[18] The patient typically has severe shoulder pain with night pain in the initial stages, causing them to seek treatment from medical professionals. Frozen shoulder is not a benign condition, and long-term clinical outcome studies have documented ongoing pain and disability several years after the diagnosis.[22] There is no gold-standard initial treatment for frozen shoulder, and many different management strategies are used, with hydrodilatation and physiotherapy being two of the most common.[17] In the senior author's unit, the first-line treatment for primary frozen shoulder usually consists of a combination of fluoroscopically guided hydrodilatation with a mixture of local anesthetic and steroid, followed by supervised one-to-one physiotherapy. Hydrodilatation (arthrographic distension with steroid and saline solution) has been reported to provide short-term benefits regarding pain, range of movement (ROM), and function for frozen shoulder.[2] The use of physiotherapy (manual therapy and exercise) is routine for many shoulder conditions, including frozen shoulder. However, high-quality evidence for the efficacy of physiotherapy in patients with frozen shoulder is currently lacking.[17] Furthermore, the efficacy of supervised physiotherapy compared with that of a home exercise program has not been previously established after hydrodilatation. Unsupervised, home-based exercise programs have provided equivalent results to traditional supervised physiotherapy after other musculoskeletal interventions, such as rotator cuff repair[12] and total knee replacement.[11] In the shoulder, they have also been used after breast and axillary surgery.[15] We hypothesized that a self-directed home exercise program would produce equivalent clinical outcomes to a supervised face-to-face physiotherapy program after hydrodilatation for primary frozen shoulder.

The aim of this research was to establish if there is a difference in the clinical outcome as measured by the Oxford Shoulder Score (OSS) between supervised physiotherapy accompanied by a home exercise program and a self-directed home exercise program in isolation after patients underwent hydrodilatation for primary frozen shoulder. The null hypothesis of the study was that there would be no difference between the mean OSS of the 2 groups of patients at 12 months after treatment.

Materials and methods

The study was a randomized controlled trial comparing supervised physiotherapy in addition to a home exercise program (group 1) with a self-directed home exercise program in isolation (group 2). The study conformed to the CONSORT (CONsolidated Standards Of Reporting Trials) 2010 statement.[6] All participants underwent an informed consent process before taking part in the study.

Table I Criteria for diagnosis of frozen shoulder[4] used in study

Shoulder pain for at least 1 month
Sleep disturbance: night pain or inability to lie on affected side
Restriction of all active and passive movements
Restriction of passive glenohumeral external rotation by at least 50% compared with normal side

Table II Study inclusion and exclusion criteria

Inclusion criteria
Primary frozen shoulder treated by hydrodilatation
Ability to understand and participate in study
Exclusion criteria
Glenohumeral osteoarthritis on radiographs
Previous shoulder procedures
Steroid medication
Other shoulder pathology
Inflammatory joint disease
Significant shoulder injury within 6 months
Neurologic or referred pain

Diagnosis

Cases of frozen shoulder were diagnosed in the orthopedic clinic and by the musculoskeletal triage service at our hospital. We used the diagnostic criteria described by Bulgen et al[4] (Table I) for diagnosing frozen shoulder. The diagnosis was made by 2 experienced musculoskeletal physiotherapists and a consultant shoulder surgeon (C.P.R.). The inclusion and exclusion criteria are listed in Table II.

Screening and recruitment

Potential participants were screened by a research nurse for their suitability for the study by reviewing referrals made for hydrodilatation for primary frozen shoulder. Potential participants were also approached by the extended scope physiotherapist (J.N.) and consultant shoulder surgeon (C.P.R.) in their respective clinics. If a patient was thought to be suitable for the study, a letter of invitation and a participant information sheet were issued and follow-up contact was made by telephone. Participants underwent the consent process and were recruited into the trial at a further hospital visit.

Randomization

Participants were randomized to 1 of 2 treatment groups by drawing sealed opaque envelopes. For randomization purposes, 40 envelopes were created: 20 contained an allocation card to group 1 and 20 contained an allocation card to group 2. The cards were shuffled by a blinded research nurse, placed into opaque sealed envelopes, and shuffled again. The envelopes were then numbered 1 to 40. Once a participant was recruited, the next envelope in numerical order was drawn and the participant was allocated to the appropriate study group.

One participant who was randomized to group 2 was not contactable for any of the assessments after the hydrodilatation