Thawing the frozen shoulder

A RANDOMISED TRIAL COMPARING MANIPULATION UNDER ANAESTHESIA WITH HYDRODILATATION

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This study prospectively evaluated the outcome of manipulation under anaesthesia and hydrodilatation as treatments for adhesive capsulitis. A total of 36 patients (38 shoulders) were randomised to receive either method, with all patients being treated in stage II of the disease process.

The mean age of the patients was 55.2 years (44 to 70) and the mean duration of symptoms was 33.7 weeks (12 to 76). Eighteen shoulders (17 patients) underwent manipulation under anaesthesia and 20 (19 patients) had hydrodilatation. There were three insulin-dependent diabetics in each group. The mean visual analogue score in the manipulation under anaesthesia group was 5.7 (3 to 8.5; n = 18) before treatment, 4.7 (0 to 8.5; n = 16) at two months (paired *t*-test *p* = 0.02), and 2.7 (0 to 9; n = 16) at six months (paired *t*-test, *p* = 0.0006). The mean score in the hydrodilatation group was 6.1 (4 to 10; n = 20) before treatment, 2.4 (0 to 8; n = 18) at two months (paired *t*-test, *p* = 0.001), and 1.7 (0 to 7; n = 18) at six months (paired *t*-test, *p* = 0.0006). The visual analogue scores in the hydrodilatation group were significantly better than in the manipulation under anaesthesia group over the six-month follow-up period (*p* < 0.0001).

The mean Constant score in those manipulated was 36 (26 to 66) before treatment, 58.5 (24 to 90) at two months (paired *t*-test, *p* = 0.001) and 59.5 (23 to 85) at six months (paired *t*-test, *p* = 0.0006). In the hydrodilatation group it was 28.8 (18 to 55) before treatment, 57.4 (17 to 80) at two months (paired *t*-test, *p* = 0.0004) and 65.9 (28 to 92) at six months (paired *t*-test, *p* = 0.0005). The Constant scores in the hydrodilatation group were significantly better than in the manipulated group over the six-month period of follow-up (*p* = 0.02).

The range of movement improved in all patients over the six months, but was not significantly different between the groups. At the final follow-up, 94% of patients (17 of 18) were satisfied or very satisfied after hydrodilatation compared with 81% (13 of 16) of those receiving a manipulation.

Most of our patients were treated successfully, but those undergoing hydrodilatation did better than those who were manipulated.

Adhesive capsulitis is common but poorly understood. It was first described by Duplay¹ in 1872 as a 'peri-arthritis scapulo-humeral' and in 1934, Codman² first used the term 'frozen shoulder'. He stated that most cases resolved in about two years without treatment. In 1945, Neviaser³ coined the term 'adhesive capsulitis' to describe his operative and post-mortem findings. Itoi, Morrey and An⁴ defined it as a condition of uncertain aetiology, characterised by substantial restriction of active and passive shoulder movement and occurring in the absence of a known intrinsic shoulder disorder.

Adhesive capsulitis usually affects those in the sixth decade, and more often women. It can be bilateral, especially in patients with dia-

betes.⁵ Although it is generally considered self-limiting, there are studies demonstrating a considerable number of untreated patients, with long-term disability and pain.⁶ Accordingly, there remains a group of patients who require definitive treatment. In stage II, where pain and stiffness are present, options include manipulation under anaesthesia (MUA), injection of corticosteroids, arthroscopic and open release of contractures, and hydrodilatation. Unfortunately, many studies assessing these treatments are flawed because they lack proper objective and subjective outcome data.

Hydrodilatation was first described in 1965 by Andren and Lundberg.⁷ It involves the intra-articular injection of a large amount of normal saline to distend and rupture the capsular adhe-

Fig. 1a

Fig. 1b

Visual analogue scores in a) the manipulation under anaesthesia group and b) the hydrodilataion group (** $p < 0.005$).

sions. A number of studies on hydrodilataion report varied results.^{5,8,9} Manipulation under anaesthesia consists of controlled forced restoration of shoulder movement using a short lever arm to reduce the risk of producing a fracture. Usually abduction and flexion are restored before the anterior and inferior capsular structures are ruptured by external and internal rotation.

This blinded and randomised study prospectively evaluated the outcome of two treatments for adhesive capsulitis of MUA and hydrodilataion.

Patients and Methods

Following ethical approval between 2002 and 2004, 40 patients with adhesive capsulitis were eligible for inclusion in the study, according to the following criteria. All were aged over 18 years and all had stage II primary adhesive capsulitis, a global loss of active and passive shoulder movement, restriction of external rotation to less than 50% of normal and normal anteroposterior and axillary lateral radiographs of the glenohumeral joint. All patients were assessed by a consultant specialising in shoulder surgery (AJC) before inclusion in the study.

We excluded patients with post-traumatic or other extrinsic cause, those with suspected osteoporosis, and those unfit for general anaesthesia.

The initial evaluation by two of the authors (NAQ, PJ) included a detailed history, completion of a subjective visual analogue score (VAS)¹⁰ for pain and a Constant score.¹¹ At the end of treatment patients were asked to document their level of satisfaction as very satisfied, satisfied or dissatisfied.

Randomisation was achieved by a computer program, and the investigator (NAQ, PJ) was blinded to the treatment. The treatment was performed with the involvement of two of the authors (MC, AJC), and all testing was repeated at two and six months after treatment.

Of the 40 patients eligible for inclusion in the study, 36 agreed to participate. There were 15 men and 21 women, and two had bilateral involvement (38 shoulders). At the time of the initial assessment 16 patients were receiving physiotherapy and 22 had already had corticosteroid injections; 11 patients had received both treatments.

There were 17 patients (18 shoulders) with a mean age of 54.5 years (39 to 69) and a mean duration of symptoms of 39.8 weeks (16 to 102) who underwent MUA.

There were 19 patients (20 shoulders) who received hydrodilataion with a mean age of 55.2 years (44 to 70) and a mean duration of symptoms of 37.4 weeks (12 to 76). There were three insulin dependent diabetics in each group. **Treatment.** Manipulation under anaesthesia was performed by AJC, and consisted of restoration of shoulder movement following a specific protocol to ensure safe breakage of adhesions by using a short lever arm.¹² A total of 2 ml of 2% lignocaine and 30 mg (0.75 ml) of triamcinolone acetate (Kenalog; Bristol-Myers Squibb, New York, New York) were injected anteriorly into the glenohumeral joint without contrast medium. Hydrodilataion was carried out in the outpatient radiology department by a consultant radiologist (MC) through an anterior approach. A needle was inserted into the glenohumeral joint and the position checked by image intensifier before and after injection of a small quantity of radio-opaque contrast material followed by normal saline to progressively distend the capsule. This was continued until the capsule ruptured, which usually occurred through the subscapularis bursa, but occasionally down the biceps sheath.⁸ It required between 10 ml and 55 ml, usually 30 ml to 40 ml, to cause rupture.

After either procedure, all patients followed the same protocol. They were permitted to resume normal activities as soon as possible, and were asked to carry out a self-exercise programme of pendular exercises and wall-climbing movements.

Fig. 2a

Fig. 2b

Constant scores in a) the manipulation under anaesthesia group and b) the hydrodilataion group (* $p < 0.05$, ** $p < 0.005$).

Fig. 3a

Fig. 3b

Range of movement in a) the manipulation under anaesthesia group and b) the hydrodilataion group (Abd, abduction; FE, forward elevation; ER, external rotation; IR, internal rotation; 2m, 2 months; 6m, 6 months) (* $p < 0.005$, ** $p < 0.005$).

Statistical analysis. All data were stored on a SPSS 11.5 (SPSS Inc., Chicago, Illinois) and analysed with the help of a statistician. Wilcoxon's signed ranks paired t -test was used to evaluate significant changes within each treatment group at the different time intervals. The Mann-Whitney test was used to calculate differences between the groups ($p < 0.05$ and $p < 0.005$ were considered significant).

Results

Three patients (two from the MUA group and one from the hydrodilataion group) either refused to take further part in the study or were lost to follow up.

Visual analogue scores (Fig. 1). The mean VAS scores in the MUA group were 5.7 (3 to 8.5, $n = 18$) pre-opera-

tively, 4.7 (0 to 8.5; $n = 16$) at two months (paired t -test, $p = 0.02$), and 2.7 (0 to 9; $n = 16$) at six months (paired t -test, $p = 0.0006$). The mean scores in the hydrodilataion group were 6.1 (4 to 10; $n = 20$) pre-operatively, 2.4 (0 to 8; $n = 18$) at two months (paired t -test, $p = 0.001$) and 1.7 (0 to 7; $n = 18$) at six months (paired t -test, $p = 0.0006$). The VAS pain scores in the hydrodilataion group were significantly better than in the MUA group over the six-month follow-up period (Mann-Whitney test, $p < 0.0001$). The mean VAS for patients undergoing hydrodilataion at the time of the procedure was 5.5 (2 to 8).

Constant scores (Fig. 2). In the MUA group, the mean Constant score was 36 (26 to 66) before treatment, 58.5

(24 to 90) at two months (paired *t*-test, $p = 0.001$) and 59.5 (23 to 85) at six months (paired *t*-test, $p = 0.0006$). The mean Constant scores in the hydrodilatation group were 28.8 (18 to 55) before treatment, 57.4 (17 to 80) at two months (paired *t*-test, $p = 0.0004$), and 65.9 (28 to 92) at six months (paired *t*-test, $p = 0.0005$). The Constant scores in the hydrodilatation group were again significantly better than those in the MUA group over the six-month follow-up period (Mann-Whitney test, $p = 0.02$).

Range of movement (Fig. 3). In the MUA group there were significant improvements in abduction at two months (paired *t*-test, $p = 0.0006$), forward elevation at two months (paired *t*-test, $p = 0.0008$), and external rotation at six months (paired *t*-test, $p = 0.02$). In the hydrodilatation group there were significant improvements in all movements at two months (paired *t*-tests, abduction: $p = 0.0005$; forward elevation: $p = 0.0004$; external rotation: $p = 0.004$; internal rotation: $p = 0.02$). These differences were not statistically different between the two groups over the six months (Mann-Whitney test, abduction: $p = 0.62$; forward elevation: $p = 0.8$; external rotation: $p = 0.13$; internal rotation: $p = 0.48$).

Satisfaction levels. At the final follow-up, 94% (17 of 18) of patients were satisfied or very satisfied after hydrodilatation, compared with 81% (13 of 16) after MUA. All the diabetics were satisfied with their outcome, except for one who had an MUA and later went on to do well with hydrodilatation.

Discussion

The best treatment for adhesive capsulitis is unclear.^{13,14} Rizk et al⁹ reported the results of hydrodilatation in 16 patients. The fluid contained steroid, and distension of the joint was continued until rupture occurred. Relief of pain occurred in 75% after two weeks, and by six months only one patient had residual pain. Bell et al⁸ found an improvement in 79% of 109 patients after hydrodilatation.

Mulcahy et al¹⁵ used air to distend the capsule, followed by cortisone, in 22 patients, of whom 73% reported symptomatic improvement. The difference in these results might be due to the use of fluid containing cortisone rather than air for capsular distension. Hamdan and Al-Essa⁵ showed that patients who had an intra-articular injection of normal saline followed by MUA did better than those with MUA alone.

In our study most of the patients were treated successfully, but those who received hydrodilatation were significantly better than those who underwent MUA.

We recommend hydrodilatation for patients with adhesive capsulitis resistant to conservative treatment. MUA is a more costly inpatient procedure, whereas hydrodilatation can be carried out as an outpatient without general anaesthetic. There is also the risk of humeral neck fracture and rupture of the rotator cuff during MUA.¹⁶

Whereas some studies have shown that patients with diabetes do worse after treatment,⁵ we were unable to confirm or refute this owing to the small number of patients.

There is a lack of evidence on how to treat frozen shoulder. One of the main reasons is the difficulty of designing a randomised trial with appropriate controls. In our study, all patients were treated and so it is not known whether a control group would have done as well or better. Further studies with appropriate controls are needed to confirm the true efficacy of hydrodilatation.

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