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Adhesive capsulitis: establishing consensus on clinical identifiers for stage one using the Delphi technique


Abstract

Background: Adhesive capsulitis is often both difficult to diagnose in its early stage and to differentiate from other commonly presenting shoulder disorders with the potential to cause pain and limited range of movement.

Objective: To establish consensus among a group of experts regarding the clinical identifiers for the first or early stage of primary/idiopathic adhesive capsulitis.

Design: The Delphi technique was employed which was correspondence based.

Methods: Three sequential questionnaires, each building on the results of the previous round, were used to establish consensus.

Results: A total of 70 experts from Australia and New Zealand involved in the diagnosis and treatment of adhesive capsulitis completed the three rounds of questionnaires. Following round three descriptive statistics were used to screen the data into a meaningful subset. Cronbach’s alpha and factor analysis were then used to determine agreement between experts. Consensus was achieved on eight clinical identifiers. These identifiers clustered into two discrete domains of pain and movement. For pain these included; a strong component of night pain, pain with rapid
or unguarded movement, discomfort lying on the affected shoulder, and pain easily aggravated by movement. For movement, clinical identifiers included a global loss of active and passive range of movement, with pain at the end of range in all directions. Onset was at greater than 35 years of age.

Conclusion: This is the first study to use the Delphi technique to establish clinical identifiers indicative of the early stage of primary idiopathic adhesive capsulitis. Whilst limited in differential diagnostic ability these identifiers may assist the clinician in recognizing early stage adhesive capsulitis and may inform management, as well as facilitate future research.

Introduction

Adhesive capsulitis of the shoulder is a disorder frequently encountered by primary health care professionals. It is often difficult to identify and correctly diagnose in its early stage. Labelled frozen shoulder by Codman in 1934 (Codman 1934) but subsequently termed adhesive capsulitis by Neviaser (Neviaser 1945) to better describe the pathology, this condition is generally characterized by pain and a gradual progressive loss of active and passive range of shoulder motion (Pearsall and Speer 1998). It has been reported that its prevalence is 2-3% in the general population (Pearsall and Speer 1998, Siegel, Cohen et al. 1999, Hannafin and Chiaia 2000). This figure is higher in the diabetic population (Scarlat, Goldberg et al. 2000) with a prevalence of 30% reported in patients with type 2 diabetes mellitus (Aydogan, Karan et al. 2003/2004). It is also reported to be more common in women, especially between
the ages of 40-60 years (Neviaser and Neviaser 1987, Pearsall and Speer 1998, Siegel, Cohen et al. 1999, Dias, Cutts et al. 2005). The condition usually very slowly progresses towards spontaneous resolution, however several long term studies have suggested ongoing impairment may persist in some patients (Reeves 1975, Binder, Bulgen et al. 1984, Shaffer, Tibone et al. 1992, Vecchio, Kavanagh et al. 1995, Hand, Clipsham et al. 2008).

Adhesive capsulitis is described as being either primary or secondary (Reeves 1975, Chambler and Carr 2003, Harrast and Rao 2004). Primary adhesive capsulitis is due to an unknown cause (i.e. it is idiopathic), whereas secondary adhesive capsulitis results from a known cause or surgical event (Hannafin and Chiaia 2000). Published descriptions of the condition commonly further sub-divide it into three or four stages. Following arthroscopic evaluation, Neviaser and Neviaser (Neviaser and Neviaser 1987) identified four stages of involvement. These four stages have been correlated with clinical examination findings and histological appearance of the tissues (Hannafin and Chiaia 2000). The more recent literature however, generally describes adhesive capsulitis as consisting of three stages (Pearsall and Speer 1998, Siegel, Cohen et al. 1999, Chambler and Carr 2003). These have been identified as the painful stage (first), adhesive stage (second) and resolution stage (third). The painful stage in this nomenclature includes both stage one (the pre-adhesive stage) and stage two as described by Neviaser and Neviaser (Neviaser and Neviaser 1987). The current study was concerned with identifying primary adhesive capsulitis and the painful or first stage of the condition.
Whilst ‘textbook’ descriptions of diagnostic criteria for adhesive capsulitis including variable pain and movement characteristics are present in the literature, validation of these descriptions is lacking. Currently the diagnosis of primary adhesive capsulitis is based on the findings of the patient history and physical examination. No specific clinical test or definitive investigation has been reported in the literature and there remains no gold standard to diagnose this disorder. A varying range of ‘typical’ signs and symptoms such as pain aggravated by shoulder movement (Siegel, Cohen et al. 1999, Hannafin and Chiaia 2000), pain at night(Neviaser and Neviaser 1987) and multidirectional limitation of active and passive joint movement accompanied by pain at the extremes of range(Pearsall and Speer 1998) have instead been proposed by authors. To date however, there are no agreed or validated diagnostic criteria for the disorder.

The lack of validity and reliability of the diagnostic classification of shoulder pain has been a topic of controversy for some time (Buchbinder, Goel et al. 1996, Winters, Groenier et al. 1997, de Winter, Jans et al. 1999, Groeiner, Winters et al. 2003, Walker-Bone, Palmer et al. 2003, Schellingerhout, Verhagen et al. 2008). In a study of interobserver agreement between general practitioners and physical therapists this deficit has been particularly highlighted (Liesdek, van der Windt et al. 1997). However, the need for diagnostic labels for shoulder disorders has been questioned as there is some evidence that the outcomes of treatment may be similar for heterogeneous groups of patients with shoulder pain lacking a specific diagnosis (Ginn, Herbert et al. 1997, Hay, Thomas et al. 2003, Ginn and Cohen 2004, Thomas, van der Windt et al. 2005). Conversely other authors suggest that a uniform method of defining shoulder
disorders is necessary (Green, Buchbinder et al. 1998, Buchbinder, Green et al. 2006). In a systematic review of randomized controlled trials of interventions for the painful shoulder it is commented that in the studies sampled no standard diagnostic definitions were used and indeed conflicting criteria were employed to define the same condition in various trials (Green, Buchbinder et al. 1998). This makes drawing conclusions across studies difficult. Whilst a set of diagnostic criteria may not exclusively represent a single pathological entity it may represent a subgroup of patients to which randomized controlled trials may be directed.

Similarly, early and accurate identification of diagnostic criteria is recommended in determining prognosis as well as for optimizing treatment outcomes in the clinic (van der Heijden 1999). Early presentation of shoulder disorders has been associated with favourable outcome (Bulgen, Binder et al. 1984). Some authors recommend that treatment and prognosis for adhesive capsulitis should be tailored to the stage of the disorder (Neviaser and Neviaser 1987, Hannafin and Chiaia 2000). Consequently, it is arguably appropriate to establish diagnostic criteria for each stage rather than the disease process as a whole.

The difficulty faced by clinicians in the diagnosis of shoulder disorders has recently been addressed by Mitchell and colleagues (Mitchell, Adebajo et al. 2005). These authors propose a simple model to assist in the diagnosis of rotator cuff, glenohumeral and acromioclavicular joint disorders, as well as referred cervical spine pain. Whilst potentially facilitating aspects of the clinical reasoning process, this model fails to
recognize the various stages of adhesive capsulitis. Agreed diagnostic criteria for early stage adhesive capsulitis therefore remain to be established.

The aim of this study was to reveal such consensus that may currently exist among a group of experts regarding the clinical signs and symptoms indicative of the first stage of primary adhesive capsulitis. The establishment of such consensus is the first step in the process of identification and validation of agreed diagnostic criteria for this disorder.

**Methods**

This study was approved by The University of Newcastle Human Research Ethics Committee.

The Delphi technique was chosen to explore this issue as it is an established and recognized method of deriving the opinion of experts to determine the degree of consensus where there is a lack of empirical evidence (Powell 2003, Brown, O'Connor et al. 2005). This technique has the advantages of maintaining anonymity amongst respondents, allowing time for participants to consider their response, not being influenced by dominant individuals and enabling recruitment from diverse geographical locations and clinical backgrounds (McKenna 1994, Sumson 1998). Using a panel of experts, the Delphi technique is a multi-stage process using a series of sequential questionnaires or rounds linked by feedback. Each round of the process builds on the results of the previous one and results in consensus by the final round. Previously his technique has been widely used in establishing consensus on various

**Participants**

The participants comprised a group of experts involved in the diagnosis and treatment of adhesive capsulitis and were recruited from several disciplines. These disciplines included rehabilitation medicine, physical medicine, orthopaedic surgery, physiotherapy, chiropractic and osteopathy. Medical practitioners invited to participate in the study were required to hold postgraduate qualifications in a relevant specialty or be members of a special interest group in a discipline relevant to the study. Rehabilitation medicine physicians were recruited from the Musculoskeletal Medicine and Pain Special Interest Group, a sub-group of the Australasian Faculty of Rehabilitation Medicine. Members of the Australasian Faculty of Musculoskeletal Medicine were also included, as were Members of the College of Physical Medicine. As a special interest group of the Australian Orthopaedic Association, members of the Shoulder and Elbow Society of Australia were approached. Physiotherapy participants were members of Shoulder and Elbow Physiotherapists Australia (a physiotherapy sub-group of the Shoulder and Elbow Society of Australia), as well as coordinators of postgraduate musculoskeletal physiotherapy programs at Australian and New Zealand universities. In addition, specialist musculoskeletal physiotherapists recognized by the Australian Physiotherapy Association and the Australian College of Physiotherapists were included. Australian and New Zealand authors who had
published on the topic of adhesive capsulitis in the past ten years in peer reviewed journals or texts were also invited to participate. These potential participants were identified through searching Medline and CINAHL databases using the search terms adhesive capsulitis and frozen shoulder. Only articles published in the English language between February 1996 and February 2006 were identified. The reference lists of identified articles were also scrutinized in an attempt to identify any texts or other references that may have been published during this period. Where the contact details of authors were in Australia or New Zealand inclusion in the study was determined. Finally, chiropractors and osteopaths who were coordinators of postgraduate musculoskeletal programs offered at Australian and New Zealand universities were also approached. A total of 185 potential participants were contacted in the first round.

**Pilot Study**

A pilot study, using a sample of convenience comprising six participants representative of the overall sample was performed prior to the commencement of the main study to determine if the instructions to participants were clear and to identify any improvements to the method. Following the pilot study, it was determined that two reminders should be issued to non-responding participants to maximize the response rate. It was also determined that documents should be highlighted to more clearly indicate that it was stage one of adhesive capsulitis being investigated, not the later more easily recognizable stages.
**Procedure**

The study was correspondence based and the questionnaires were distributed by the researchers to the participants’ work addresses. Addresses were obtained from the appropriate organizations and all contact details were available in the public domain with the exception of the rehabilitation medicine physicians whose members were approached through the chairman of the Musculoskeletal Medicine and Pain Special Interest Group. In this case, the letter of invitation was sent to the chairman of the group requesting it be forwarded to members, with those members potentially interested in participating asked to contact the researchers directly. Members of the Faculty of Musculoskeletal Medicine were also approached through the chairman of the Faculty who provided names and contact details of members. All of the participants who were clinicians were approached at their private clinics.

Experts were asked to participate in three rounds of questionnaires. For the first round, potential participants were posted a letter of invitation together with the first questionnaire, and were given two weeks to reply. Participants were given the opportunity to receive the subsequent questionnaires electronically and to supply a contact telephone number. A reminder was sent if a response was not received in the specified time and if necessary a second reminder was issued after a further two weeks. The same approach and timeframe for reminders was used for the two subsequent rounds. Telephone contact was used in the second and third rounds for the second reminder if a telephone number was made available by the participant.
**Round 1**

The first questionnaire requested participants to list as many or as few diagnostic criteria they considered necessary and sufficient to diagnose stage one primary adhesive capsulitis. Respondents were given the opportunity to provide a rationale for their criteria if they felt this appropriate. The responses were independently reviewed and collated by each of the three researchers using a series of operational rules. These rules involved listing all the criteria (individual responses) proposed, grouping the criteria into relevant clinical categories, eliminating single responses, merging repeated responses and discarding unclear responses. Responses clearly inconsistent with the literature or responses obviously relating to secondary adhesive capsulitis or the later stages of the target disorder were also discarded. Following initial independent review the researchers met and reached a consensus on the criteria to constitute the second round.

**Round 2**

The second round used the criteria identified in round one by all participants. In this round, participants were asked to score the importance of each criterion in the diagnosis of stage one adhesive capsulitis using the following five point Likert scale adapted from Cook et al.(Cook, Brismee et al. 2006).

1. *Strongly Agree:* the selected criterion is extremely important in the diagnosis of stage one of primary adhesive capsulitis

2. *Agree:* the selected criterion is important in the diagnosis of stage one of primary adhesive capsulitis
3. *Undecided:* uncertainty of the importance of the selected criterion in the diagnosis of stage one of primary adhesive capsulitis

4. *Disagree:* the selected criterion is not important in the diagnosis of stage one of primary adhesive capsulitis

5. *Strongly Disagree:* there is absolutely no importance whatsoever of the selected criterion in the diagnosis of stage one of primary adhesive capsulitis.

**Round 3**

The third round provided feedback to the participants in the form of the percentages for each of the five response options as to how all participants rated each criterion in round two. In the light of this information participants were requested to rescore each criterion on the same Likert scale used in round two.

**Data analysis**

The data was analyzed initially using simple descriptive statistics. Cronbach’s coefficient alpha was then used as a measure of the level of consistency of opinion among the respondents of the agreed criteria. Finally, to determine the underlying structure of the criteria a factor analysis was performed.

**Results**

From the 185 potential participants approached in the first round 89 (48.1%) responses were received. From the 89 respondents from round one, 75 (84.3%) responses were received following round two. Of these respondents 70 (93.3%) completed the final round. Overall, 37.8% of the original sample completed all three rounds. The response
rate of participants in each discipline is indicated in Table 1 and the flow of participants through the study is depicted in Figure 1.

<table>
<thead>
<tr>
<th>Group</th>
<th>Participants approached N (%)</th>
<th>Respondents Round 1 N (%)</th>
<th>Respondents Round 2 N (%)</th>
<th>Respondents Round 3 N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Member of the Musculoskeletal and Pain Special Interest Group of The Australasian Faculty of Rehabilitation Medicine</td>
<td>3 (1.6)</td>
<td>2 (2.2)</td>
<td>1 (1.3)</td>
<td>1 (1.4)</td>
</tr>
<tr>
<td>Member of the Australasian Faculty of Musculoskeletal Medicine</td>
<td>28 (15.1)</td>
<td>11 (12.4)</td>
<td>9 (12)</td>
<td>7 (10)</td>
</tr>
<tr>
<td>Member of the Australian College of Physical Medicine</td>
<td>28 (15.1)</td>
<td>10 (11.2)</td>
<td>7 (9.3)</td>
<td>6 (8.6)</td>
</tr>
<tr>
<td>Member of the Shoulder and Elbow Society of Australia</td>
<td>81 (43.8)</td>
<td>36 (40.4)</td>
<td>28 (37.3)</td>
<td>27 (38.6)</td>
</tr>
<tr>
<td>Member of Shoulder and Elbow Physiotherapists Australia</td>
<td>12 (6.5)</td>
<td>10 (11.2)</td>
<td>10 (13.3)</td>
<td>9 (12.9)</td>
</tr>
<tr>
<td>Coordinator of a post-graduate musculoskeletal physiotherapy program</td>
<td>11 (5.9)</td>
<td>11 (12.4)</td>
<td>11 (14.7)</td>
<td>11 (15.7)</td>
</tr>
<tr>
<td>Specialist musculoskeletal physiotherapist</td>
<td>4 (2.2)</td>
<td>3 (3.4)</td>
<td>3 (4)</td>
<td>3 (4.3)</td>
</tr>
<tr>
<td>Author of publication on adhesive capsulitis in the past 10 years</td>
<td>11 (5.9)</td>
<td>3 (3.4)</td>
<td>3 (4)</td>
<td>3 (4.3)</td>
</tr>
<tr>
<td>Coordinator of a post-graduate chiropractic program</td>
<td>5 (2.7)</td>
<td>3 (3.4)</td>
<td>3 (4)</td>
<td>3 (4.3)</td>
</tr>
<tr>
<td>Coordinator of a post-graduate osteopathic program</td>
<td>2 (1.1)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Total</td>
<td>185</td>
<td>89</td>
<td>75</td>
<td>70</td>
</tr>
</tbody>
</table>
Figure 1  Flow of participants through the study

Experts identified to participate in Delphi study

Round 1
Distribution of Questionnaire 1 to experts

Responses returned and collated

Generation of 367 items

Collation of items by author panel using operational rules resulting in 60 criteria to form Questionnaire 2

Round 2
Distribution of Questionnaire 2 requesting rating of criteria on 5pt Likert scale

Responses returned and collated

Percentages for each 5 response options calculated to form Questionnaire 3

Round 3
Distribution of Questionnaire 3 requesting re-rating of responses on 5 pt Likert scale

Responses returned N = 70

Data analysis

8 clinical identifiers established
Following round one, 367 criteria were generated. Collation of the data resulted in 60 diagnostic criteria structured into six sections being established to form round two.

These criteria are outlined in Table 2.

<table>
<thead>
<tr>
<th>Category</th>
<th>1. Pain is generally located over the upper arm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Pain is predominantly over the lateral shoulder/deltoid region</td>
</tr>
<tr>
<td></td>
<td>3. Pain is predominately over the anterior shoulder</td>
</tr>
<tr>
<td></td>
<td>4. Pain may be referred distally into the forearm</td>
</tr>
<tr>
<td></td>
<td>5. Pain is diffuse or poorly localized</td>
</tr>
<tr>
<td></td>
<td>6. The pain is described as deep</td>
</tr>
<tr>
<td></td>
<td>7. The intensity of the pain is described as severe</td>
</tr>
<tr>
<td></td>
<td>8. The pain is constant or unrelenting in nature</td>
</tr>
<tr>
<td></td>
<td>9. The pain is described as an ache</td>
</tr>
<tr>
<td></td>
<td>10. The level of pain is progressively increasing</td>
</tr>
<tr>
<td></td>
<td>11. There is an intermittent catching or pinching pain</td>
</tr>
<tr>
<td></td>
<td>12. There is a strong component of night pain</td>
</tr>
<tr>
<td></td>
<td>13. There is a marked increase in pain with rapid or unguarded movements</td>
</tr>
<tr>
<td></td>
<td>14. It is uncomfortable to lie on the affected shoulder</td>
</tr>
<tr>
<td></td>
<td>15. The patient reports the pain is easily aggravated by movement</td>
</tr>
<tr>
<td></td>
<td>16. Once aggravated the patient reports the pain is slow to settle</td>
</tr>
<tr>
<td></td>
<td>17. Function is limited by increasing stiffness in this stage</td>
</tr>
<tr>
<td></td>
<td>18. The history of onset of pain is spontaneous</td>
</tr>
<tr>
<td></td>
<td>19. Symptoms have been present for greater than 4 weeks</td>
</tr>
<tr>
<td></td>
<td>20. There is often a history of a minor trauma/precipitating event</td>
</tr>
<tr>
<td></td>
<td>21. The onset of the condition is sudden</td>
</tr>
<tr>
<td>Demographic factors</td>
<td>22. The onset is generally in people greater than 35 years of age</td>
</tr>
<tr>
<td></td>
<td>23. The onset is generally in people less than 60 years of age</td>
</tr>
<tr>
<td></td>
<td>24. The condition more commonly presents in females</td>
</tr>
<tr>
<td>Physical examination findings</td>
<td>25. On examination there is a global loss of active and passive range of movement</td>
</tr>
<tr>
<td></td>
<td>26. On examination there is pain at the end of range in all directions</td>
</tr>
<tr>
<td></td>
<td>27. On examination there is no painful arc with shoulder elevation</td>
</tr>
<tr>
<td></td>
<td>28. There is protective muscle guarding with movement</td>
</tr>
<tr>
<td></td>
<td>29. The loss of movement in any direction is minor</td>
</tr>
<tr>
<td></td>
<td>30. The greatest loss of movement is in external rotation</td>
</tr>
<tr>
<td></td>
<td>31. There is painful limitation of active external rotation range performed in supine at 90° shoulder abduction</td>
</tr>
<tr>
<td></td>
<td>32. There is marked pain during isometric external rotation strength testing performed in supine at 90° shoulder abduction</td>
</tr>
<tr>
<td></td>
<td>33. The patient’s range of movement is progressively decreasing due to pain</td>
</tr>
<tr>
<td></td>
<td>34. There is a global loss of passive glenohumeral joint movement</td>
</tr>
<tr>
<td></td>
<td>35. The loss of movement is in a glenohumeral joint capsular pattern i.e.: external rotation &gt;abduction&gt; internal rotation</td>
</tr>
<tr>
<td></td>
<td>36. Resisted isometric muscle testing is painfree</td>
</tr>
<tr>
<td></td>
<td>37. If pain is not inhibiting, muscle strength testing will be normal</td>
</tr>
<tr>
<td></td>
<td>38. There is diffuse tenderness to palpation around the shoulder</td>
</tr>
<tr>
<td></td>
<td>39. There is tenderness to palpation specifically over the anterior joint</td>
</tr>
<tr>
<td></td>
<td>40. The scapula position is elevated at rest or with movement</td>
</tr>
</tbody>
</table>
41. Provocative tests for tendonitis do not inform the diagnosis

Associated factors
42. There can be an association with diabetes
43. There may be a co-existing history of a thyroid condition
44. The onset of the condition is more common in spring and autumn
45. A minor viral illness may precede the onset
46. There is often a past history of adhesive capsulitis of the opposite shoulder
47. There is frequently a history of impingement syndrome in the same shoulder
48. The thoracic spine is kyphotic or hypomobile

Response to treatment
49. There is a non-response or an exacerbation of pain with treatment involving physical therapies
50. There is minimal or no response to usual analgesic medication
51. There is minimal or no response to non steroidal anti-inflammatory drugs (NSAIDs)
52. There is no response to subacromial steroid injection
53. There is a favorable response to a steroid injection into the glenohumeral joint

Investigations
54. A thickened joint capsule will be evident on magnetic resonance imaging (MRI)
55. A decreased joint volume will be evident on MRI
56. Ultrasound investigation does not inform the diagnosis
57. X-Ray examination only excludes osteoarthritis and calcific tendonitis
58. There is a mild elevation of erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP)
59. Blood factors exclude an infective or systemic inflammatory state
60. Arthroscopy reveals synovitis and inflammation of the joint capsule

Following round three, the data were analyzed initially using descriptive statistics. As the purpose of the study was to seek strongly held views by experts, and the initial request had been for necessary and sufficient criteria it was determined that only the ‘strongly agree’ response would be analyzed. Therefore the number of respondents scoring ‘strongly agree’ was calculated and is graphically represented in Figure 2
In order to determine the criteria to be used in further analysis several principles were applied. Firstly, the Pareto principle (Rao, Carr et al. 1996) that suggests that 20 per cent of the items would determine 80 per cent of the value or benefit in deciding what is important in diagnosis was employed to commence analysis. By applying this principle 12 criteria were identified. Secondly, the pattern of drop off of frequency for these items resulted in a delineation at ten criteria. As this was in reasonable agreement with the Pareto principle it was considered that this was an appropriate cut-off to select. As a result, ten criteria (in descending order, criteria 13, 14, 25, 42, 12, 15, 34, 22, 60, 26) were selected for further analysis.

In order to measure the internal consistency of the criteria Cronbach’s alpha was used. Using SPSS version 15 (SPSS Inc., Chicago, IL), an analysis of the ten selected criteria resulted in a Cronbach’s alpha value of 0.63. Step-wise removal of items whose inclusion reduced the alpha value was performed (criteria 42 and 60). Removal of these two criteria maximized Cronbach’s alpha to 0.71. Eight criteria were established as a result of this analysis and are presented in Table 3.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>There is a strong component of night pain</td>
</tr>
<tr>
<td>13</td>
<td>There is a marked increase in pain with rapid or unguarded movements</td>
</tr>
<tr>
<td>14</td>
<td>It is uncomfortable to lie on the affected shoulder</td>
</tr>
<tr>
<td>15</td>
<td>The patient reports the pain is easily aggravated by movement</td>
</tr>
<tr>
<td>22</td>
<td>The onset is generally people greater than 35 years of age</td>
</tr>
<tr>
<td>25</td>
<td>On examination there is global loss of active and passive range of movement</td>
</tr>
<tr>
<td>26</td>
<td>On examination there is pain at the end of range in all directions</td>
</tr>
<tr>
<td>34</td>
<td>There is global loss of passive glenohumeral joint movement</td>
</tr>
</tbody>
</table>
As the underlying structure of these criteria was of interest and factor analysis was proposed, a Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMO) was performed to determine whether this would be of benefit. The value of this test was 0.661. A value above 0.60 indicates that it is worthwhile proceeding with factor analysis (Tabachnick and Fiddell 1996). A factor analysis using varimax rotation was therefore performed on the remaining eight criteria to examine the underlying structure of these criteria.

![Scree plot of final components selected](image)

**Figure 3 Scree plot of final components selected**

Figure 3 demonstrates the scree plot for this calculation. The result of this factor analysis determined two discrete dimensions of pain and movement into which the criteria clustered. This is represented in Figure 4.
These factors together accounted for 56.3% of the total variance of the expert responses, with the pain factor accounting for 36% and the movement factor 20.3%. The relative weights of the eight criteria are shown in Table 4 which provides factor loadings for each criteria in the two factor solution.

Table 4 Factor loadings following principal components factor analysis of clinical criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Pain Factor</th>
<th>Movement Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>0.719</td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>0.717</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>0.695</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>0.604</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>0.595</td>
<td></td>
</tr>
<tr>
<td>34</td>
<td></td>
<td>0.928</td>
</tr>
<tr>
<td>25</td>
<td></td>
<td>0.888</td>
</tr>
<tr>
<td>26</td>
<td></td>
<td>0.447</td>
</tr>
</tbody>
</table>
Discussion

This study has successfully used the Delphi technique to establish consensus among a group of musculoskeletal professionals on eight clinical identifiers for the first stage of primary/idiopathic adhesive capsulitis. Though the initial aim of the study had been to establish diagnostic criteria and instructions to participants had been to respond as such, following data analysis it was considered more appropriate to alter the nomenclature of the set of resultant criteria to clinical identifiers. In a recent Delphi study of lumbar zygapophyseal joint pain (Wilde, Ford et al. 2007) a similar dilemma was encountered with experts in medical disciplines applying different definitions to the term ‘diagnostic criteria’. Following the first round of that study it was decided to replace the phrase “diagnostic criteria” with “criteria indicative” of lumbar zygapophyseal joint pain to more appropriately reflect the responses received. At the conclusion of the current study the term ‘clinical identifiers’ was similarly determined to be more appropriate for the set of criteria established as they could not be regarded as a gold standard for diagnosis or provide a differential diagnosis but rather a set of clinical identifiers that may assist the clinician in diagnosis, as well help form the basis for further research.

Unlike many earlier published studies employing the Delphi technique, the application of rigorous statistical analysis, rather than only simple descriptive statistics has been used to determine consensus. Notably, factor analysis in this study has resulted in identifiers clustering into two discrete domains of pain and movement.
Clinically, diagnosis of adhesive capsulitis is made through the history and physical examination. Textbook descriptions of the clinical characteristics of adhesive capsulitis identify a number of features present in each of the various stages of the disorder (Murnaghan 1990). These features encompass onset and description of pain, as well as effect on movement. Similarly, in published studies such as a recent systematic review of physical therapy for adhesive capsulitis, many of the clinical identifiers proposed by respondents in the present study are described (Cleland and Durall 2002) despite a lack of validation. Whilst these identifiers (including descriptions of pain and movement) are commonly proposed they have not previously been subjected to formal evaluation. Using the Delphi technique, the present study is the first to subject these descriptors to scrutiny and begin the process of validation.

To date, there has been no agreement on the necessary criteria or clinical identifiers required for diagnosing adhesive capsulitis in its early stage (Murnaghan 1990, Groeiner, Winters et al. 2003, Smidt and Green 2003, Dudkiewicz, Oran et al. 2004). However, it has been suggested that whilst the exact identifiers are poorly defined, pain is a significant feature in this stage (Hannafin and Chiaia 2000). Our study supports this premise with several dimensions of pain being qualified and achieving consensus. A strong component of night pain; a marked increase of pain with rapid or unguarded movements; discomfort lying on the affected shoulder; and pain easily aggravated by movement, were the four descriptors of pain on which consensus was achieved. Though not validated, night pain or sleep disturbance has previously been commonly described as a feature of this disorder in the early stage (Reeves 1975,
There are also descriptions of pain easily aggravated by movement in the literature (Siegel, Cohen et al. 1999, Hannafin and Chiaia 2000). Whilst probably not exclusive to adhesive capsulitis, these descriptors of pain may reflect the pathology of inflammatory synovitis that has been demonstrated at this stage (Neviaser and Neviaser 1987, Hannafin, DiCarlo et al. 1994). The panel of experts in this study concur that these identifiers are necessary to diagnose early stage primary adhesive capsulitis. Although the identifiers describing location and intensity of pain did not reach consensus, the pain identifiers described and for which consensus was reached, may assist the clinician in the diagnosis of early stage adhesive capsulitis.

The exact characteristics of movement dysfunction in the early stage of adhesive capsulitis are not clearly described in the literature. Whilst the effect on movement in the later stages of the disorder is usually described and even quantified, description of any movement deficit in the early stage is generally minimal. Nonetheless, general restriction of movement in all directions at this early stage has been previously described (Reeves 1975, Pearsall and Speer 1998, Siegel, Cohen et al. 1999). This study achieves consensus on the clinical identifiers of global loss of both active and passive ranges of movement, accompanied by pain at the end of range in all directions. Although no specific quantification of the loss at this stage has been determined, the nature of global loss rather than related to a specific direction is the key feature in this clinical descriptor. Unlike many other shoulder pathologies, adhesive capsulitis is a disorder mainly affecting the glenohumeral joint capsule (Neviaser and Neviaser 1987).
Global loss of active and passive range of movement is consistent with pathology of this structure. In addition, pain at the end of range in all directions is a feature that may also raise the level of clinical suspicion of adhesive capsulitis and is also consistent with capsular pathology (Pearsall and Speer 1998).

Demographic factors of adhesive capsulitis, including the age of onset, are considered a relevant clinical feature important in diagnosis. Generally, it is suggested in the literature that patients affected by this disorder are over 40 years of age (Neviaser and Neviaser 1987, Pearsall and Speer 1998, Hannafin and Chiaia 2000, Dias, Cutts et al. 2005). Following round one, a variety of responses quantifying age were received from the expert panel, such as “not seen less than 30 years of age”; “middle aged 45 – 60”; “age 50’s”. The most frequent response was captured in criterion 22 “the onset is generally in people greater than 35 years of age”. Interestingly, criterion 23 which was descriptive of the upper age limit for this disorder (“The onset is generally in people less than 60 years of age”) did not achieve consensus. Therefore in this study, consensus has been achieved on the age of onset of the disorder being generally in people greater than 35 years of age. This is consistent with previous published literature though no explanation is offered (Neviaser and Neviaser 1987, Pearsall and Speer 1998, Hannafin and Chiaia 2000, Dias, Cutts et al. 2005). The higher incidence of women in the 40-60 year age group, which failed to reach consensus, has been hypothesized to coincide with menopause and perimenopause (Vad and Hannafin 2000) but as yet this remains unproven. The factor analysis determined that those respondents who regarded clinical identifiers in the pain dimension as diagnostically
important, consistently reported age (criterion 22) alongside the pain identifiers. As pain behaviour and age are generally considered patient reported data and not physical examination findings, it is appropriate that the clinical identifier describing age clustered with identifiers describing pain rather than with movement findings.

Interestingly the eight clinical identifiers established in this study did not include any negative findings. Instructions to participants were not to limit responses to positive findings and indeed negative findings were solicited, however they failed to reach consensus. This is relevant as the presence of pathology in structures other than the glenohumeral joint capsule may elicit differing clinical characteristics that would question a diagnosis of adhesive capsulitis. Acute cervical radiculopathy or rotator cuff tendonitis for example, may be recognized by other clinical features that would contribute to a differential diagnosis. As such features did not reach consensus in the current study the limitation of the results in assisting differential diagnosis is acknowledged. A further consideration of the identifiers established is whether the resultant group should be regarded as a set or as individual items. Instructions to participants had been to give a ‘set of necessary and sufficient diagnostic criteria’, however it remains to be determined whether all or only some are necessary in diagnosis. This is particularly relevant as some of the identifiers may also be present in other acutely presenting shoulder disorders of differing pathology.

The recent suggestion that attempting to place diagnostic labels on groups of patients in clinical research trials is of little value(Schellingerhout, Verhagen et al. 2008) may overstate the case. Arguably one of the aims of establishing diagnostic criteria is to
identify a homogenous subgroup of patients with which to evaluate treatment outcomes and make comparisons across trials more meaningful. Although there is some evidence that the outcomes of treatment may be similar in heterogeneous groups (Ginn, Herbert et al. 1997, Hay, Thomas et al. 2003, Ginn and Cohen 2004, Thomas, van der Windt et al. 2005), it remains to be seen if subgroups of patients with common clinical features experience greater benefits with particular interventions.

The Delphi technique, and its application in this study, has a number of limitations. However it was chosen as it enabled the engagement of a large number of - musculoskeletal experts from a range of relevant professions and across a wide geographical area. One limitation often described is that there may be a poor response rate to the questionnaires (McKenna 1994, Sumsion 1998). In this study, the initial round had a moderate response rate of 48.1% whilst the second and third rounds had high response rates of 84.3% and 93.3% respectively. It has been suggested that a poor response rate may characterize the final rounds,(McKenna 1994) however this did not occur in the current study. The overall response rate for this study was 37.8% which compares favorably with recent studies that also utilized a large sample but achieved a response rate of only 8.4% (Cook, Brismee et al. 2005, Cook, Brismee et al. 2006).

Researcher bias has also been proposed as a weakness of the Delphi technique. The use of an open initial response in round one achieved a richness of collected data, however this required care in reducing data to a more manageable volume for the subsequent rounds. Strict operational definitions were employed by the three researchers to minimize bias. Furthermore, following round three, rather than just using simple
descriptive statistics as in many earlier studies, a more rigorous analysis was employed to provide more objective insight into the data.

Composition and size of the expert panel in Delphi studies vary across the literature. In a paper discussing the methodology of the Delphi technique, Williams and Webb (Williams and Webb 1994) note that there is no agreement regarding the optimal size of an expert panel. They comment that the panel size of studies reported in the earlier literature varied from 10 to 1685 participants. In the current study, the inclusion criteria for potential participants determined the size of the expert panel. These inclusion criteria were established to recruit musculoskeletal practitioners and leaders in several fields with expertise in clinical, research and educational facets of shoulder pain. Whilst medical practitioners were represented, omission of rheumatologists who may assess and treat musculoskeletal disorders could be regarded as a limitation of this study. This occurred as it was not possible to identify a defined special interest group in musculoskeletal medicine or orthopedics within the Australian Rheumatology Association. Regional differences in prevalence or characteristics of adhesive capsulitis are not described in the literature. However as the participants in this study were recruited from Australian and New Zealand experts the results may only reflect views held in this regional locality.

The present study has not only addressed the difficulty faced by clinicians in the diagnosis of shoulder disorders as described by Mitchell and colleagues (Mitchell, Adebajo et al. 2005), but is the first of its kind to establish a set of clinical identifiers for the early stage of primary adhesive capsulitis. Although a specific diagnostic test or
negative findings that may contribute to differential diagnosis have not achieved consensus in this study, several parameters of patient presentation have been established. These agreed clinical identifiers should assist in the clinical decision-making process and aid in the early recognition of this disorder. They also represent the first step in the longer process of identification and validation of the agreed diagnostic criteria for this disorder.

**Conclusions**

The results of this study provide a framework for the validation of clinical identifiers for early primary adhesive capsulitis in further studies as well as potentially facilitating comparisons across future clinical trials. Whilst the identifiers established in this study do not constitute an exclusive or discriminatory set of diagnostic criteria they may be of assistance to the clinician confronted with the diagnostic dilemma of recognizing the early stage of primary adhesive capsulitis.

**References**


