ORIGINAL REPORT

SHOULDER PAIN PATIENTS IN PRIMARY CARE – PART 1: CLINICAL OUTCOMES OVER 12 MONTHS FOLLOWING STANDARDIZED DIAGNOSTIC WORKUP, CORTICOSTEROID INJECTIONS, AND COMMUNITY-BASED CARE

Mark Laslett, PhD[1], Michael Steele, PhD[2], Wayne Hing, PhD[1,3], Peter McNair, PhD[1] and Angela Cadogan, PhD[1]

From the [1]Health & Rehabilitation Research Institute, Auckland University of Technology, Auckland, New Zealand [2]Department of Mathematical and Computing Sciences, Universiti Brunei Darussalam, Brunei, Griffith Graduate Research School, Griffith University, Gold Coast, and [3]Faculty of Health Science & Medicine, Bond University, Queensland, Australia

Objective: Measure changes in pain and disability of primary care shoulder pain patients over a 12-month period.

Design: A non-randomized audit with repeated measures of pain and disability at 3 weeks, 3, 6 and 12 months.

Patients: Of 208 patients, 161 agreed to participate with 96.9%, 98.1%, 86.3%, 83.9% follow-up at 3 weeks, at 3, 6 and 12 months, respectively. Mean age was 44 years, mean symptom duration 3.6 months.

Methods: Patients were treated with protocol driven corticosteroid injection and community based care. Primary outcome measure was the Shoulder Pain and Disability index (SPADI) questionnaire. Based on the SPADI and minimal clinically important difference (MCID), outcomes were categorized into: total recovery, 90% or more improved, better, unchanged and worse.

Results: There was significant reduction of pain and disability at 3 weeks ($p<0.001$), no change at the 3- and 6-month follow-up and a significant reduction at the 12-month follow-up ($p<0.001$). Excellent outcomes were achieved by 32.9% and 45.3%, and a poor clinical outcome resulted for 32.8% and 14.9% at the 3- and 12-month follow-up, respectively.

Conclusion: Though there was significant improvement at the 3-week and 12-month follow-up, 45% achieved an excellent outcome and a 16.7% of patients were the same or worse than baseline at 12 months.

Key words: shoulder pain; diagnosis; follow-up studies; primary health care; corticosteroid injection.

INTRODUCTION

Shoulder pain is a common and disabling complaint. The reported annual incidence of shoulder pain in primary care is 14.7 per 1,000 patients per year (1) with a lifetime prevalence of up to 70% (2). Recovery from shoulder pain can be slow and recurrence rates are high with 25% of those affected by shoulder pain reporting previous episodes, and 40 to 50% reporting persisting pain or recurrence at 12 months follow-up (3–5).

Guidelines for physiotherapy interventions exist (6) and there are broader recommendations and protocols available (7–19), but most general reviews are over 10 years old or refer to specific conditions or methods of treatment. With the exception of two guidelines (7, 18), recommendations are based on practice models in Europe and North America and are focused on management by general medical practitioners and surgical specialists. In New Zealand and Australia, initial contact with the health system for patients with musculoskeletal pain is usually a general medical practitioner (GP) or a physiotherapist in the private practice or acting as a triage clinician in a public hospital environment. There is limited evidence regarding the optimal diagnostic and therapeutic management protocol and no available data on the efficacy of the approach or outcomes associated with application of guideline informed principles (18, 17). The nature of care in the first 3 months after contact is likely quite heterogeneous and information about outcomes is lacking.

While outcomes of management of shoulder pain have been studied (5, 19–27), the heterogeneity of management protocols in these studies and in New Zealand primary care confound an understanding of reasonable expectations for recovery, need for imaging, the value of injection therapies, and surgery in the New Zealand environments. There is a need for basic data on outcomes associated with guideline informed community based care of shoulder pain presenting to primary care generally and in Australasia. The aim of this study was to document outcomes in shoulder pain patients over a 12-month period following a comprehensive and standardized diagnostic work up, management with community based care and a standardized protocol for steroid injection. Part 2 of this report presents predictive modelling for outcomes at 3- and 12-month follow-up.

METHODS

Consecutive patients presenting to their GP or physiotherapist for the first time with a new episode of shoulder pain were invited to participate

in a diagnostic study during which they received a series of baseline diagnostic tests that included a standardised clinical examination, shoulder x-ray series, diagnostic ultrasound scan and diagnostic injections of local anaesthetic into the subacromial bursa (SAB) and acromioclavicular joint (ACJ). Those not reporting a positive anaesthetic response (PAR) ($\geq 80\%$ reduction of pain about 15 min post procedure) to the SAB and ACJ diagnostic injections, also received an intra-articular glenohumeral joint (GHJ) injection as part of a MR arthrogram procedure. These procedures are described in detail elsewhere (28–31). Following completion of the diagnostic tests, all participants were invited to participate in a 12-month follow-up study. Study approval was acquired from The New Zealand Ministry of Health Regional Ethics Committee and informed consent was acquired at an initial appointment prior to commencement of the follow-up study. Those patients reporting a PAR in post-injection pain intensity following one of the diagnostic injections were offered a therapeutic corticosteroid injection (CSI) to be delivered to the structure(s) identified by anaesthetic response using either ultrasound or fluoroscopic guidance.

Patients were followed up at 3 weeks, 3, 6 and 12 months. All follow-up assessments were carried out by the lead author (ML) except for two that were carried out by a co-author (AC). For patients receiving guided CSI procedures, the first follow-up assessment occurred approximately three weeks after the CSI procedure during which time firm instructions to engage in "relative rest", i.e. no vigorous shoulder activity or high loads, was emphasized. At the 3 week follow-up, patients were referred back to the referring clinician for on-going management. All management after the 3 week follow-up was uncontrolled and followed usual community based conservative care in the form of physiotherapy (exercise, soft tissue and joint mobilisation, guidance on return to usual work and physical activities), corticosteroid injection or no treatment at all. Documentation of received treatments were based on patient self-reports only. No formal advice was given to patients by the researchers after the 3-week follow-up.

Outcome measures

Measures used at baseline, 3 weeks, 3, 6 and 12 months follow-up:
1. Shoulder Pain and Disability Index (SPADI) questionnaire (32, 33). This questionnaire has 5 pain- and 8 function-related questions scored from 0 to 10 where 0 = no pain or disability and 10 = maximum pain or disability. These scores generate pain and disability subscales and a total score, which were all percentalized.
2. Three 100-mm visual analogue scales (VAS) for pain intensity (pain at lowest, mean and worst in last 48 h) (34).
3. Fear Avoidance Beliefs Questionnaire (FABQ). This questionnaire generates "general", "physical activity" and "work" subscales and a total score is also calculated (35).
4. Short Form 8 item general health questionnaire (SF-8) with two subscales: Physical Component Score (PCS) and Mental Component Score (MCS) used to reflect two distinct dimensions of general health (36).
5. Global disability rating scale (33). This Likert scale has 7 options: "No disability", "Almost no disability", "Minimal disability", "Some disability", "Moderate disability", "A lot of disability", and "Maximum disability" which were coded 1–7, respectively.

Data analysis

Baseline and all follow-up assessment data were acquired on standardized forms and data transferred to a SPSS version 20 database. All analyses were carried out using SPSS statistical software with the alpha level set to $p < 0.05$. To determine which baseline variables were significantly associated with SPADI results, correlations were calculated for continuous baseline variables and independent sample t-tests or 1-way ANOVAs were calculated for discrete baseline variables. A repeated measures ANOVA was used to determine if the SPADI scores changed significantly over the 5 time periods.

The minimally clinically important difference (MCID) for the primary outcome measure, the SPADI Total (%) score, was set at ±

13 percentage points (37). Typically, patients seek complete recovery from pain and a return to normal activities, but this has been reported to be achieved in only 50% by 6 months (21). In this study we created categories enabling identification of those achieving clinically relevant outcomes. The MCID was used to identify those cases achieving less than highly satisfactory outcomes. The categories were based on changes in SPADI Total percentage scores between assessments:
1. Excellent outcome: Score reduced to zero between assessment points or improvement was 90% or more from baseline;
2. Better: Percentage reduction in score larger than the MCID but less than 90%;
3. Poor outcome: Change (increase or decrease) in score was less than the MCID or increase in score was more than the MCID.

All appropriate variables were considered for possible inclusion into predictive models of 12 month outcome, and were identified in two ways:
1. Those variables associated with SPADI Total score at 3 and 12 months ($p \leq 0.2$).
2. All other variables in our dataset that measured a similar conceptual construct as variables identified in previous research (5, 21) as predictive of outcome at any time point were included. See Appendix I for full list of initial selection of variables.

All potential predictor variables were evaluated separately in univariate logistic regressions with the dependent variables being the three different clinical outcomes: excellent; better; poor. Statistical significance was set where $p < 0.05$.

RESULTS

Two hundred and eight participants were enrolled in the diagnostic study and received baseline diagnostic tests. One hundred and sixty-one subjects (77.4%) agreed to participate in the follow-up study with 156 (96.9%) followed up at 3 weeks, 158 (98.1%) at 3 months, 139 (86.3%) at 6 months and 135 (83.9%) at 12 months (Fig. 1). There was no significant gender difference between those declining participation and those enrolling in the follow-up study (Pearson Chi-square $p = 0.2$). One way ANOVA of mean values for baseline age, SPADI subscale and total scores, SF-8 mental and physical component scores, mean and worst pain VAS scores, FABQ Work general and total scores were not significantly different between participants and non-participants ($p > 0.1$). Mean FABQ Physical Activity subscale and the VAS score for lowest pain intensity in the preceding 48 h were lower ($p = 0.005$ and 0.02, respectively) for those declining participation. Table I presents basic demographic profiles for included patients. Table II presents mean values for key outcome measures taken at baseline, 3 weeks, 3, 6 and 12 months. During the 12-month follow-up period, some patients were not followed up for a variety of reasons. Three patients withdrew because of time constraints, one patient withdrew because the researchers were not 'doing anything'. The remainder of the cases where data are missing reflect patients failing to show for scheduled appointments and being unable to be contacted. In these cases multiple attempts over several weeks were made to contact patients and often contact was re-established.

Of the 161 patients enrolled, 37%, 15% and 9% reported a PAR to diagnostic injection to the SAB, ACJ and GHJ, respectively. There was no significant gender difference between those reporting a PAR or negative anaesthetic response (NAR)
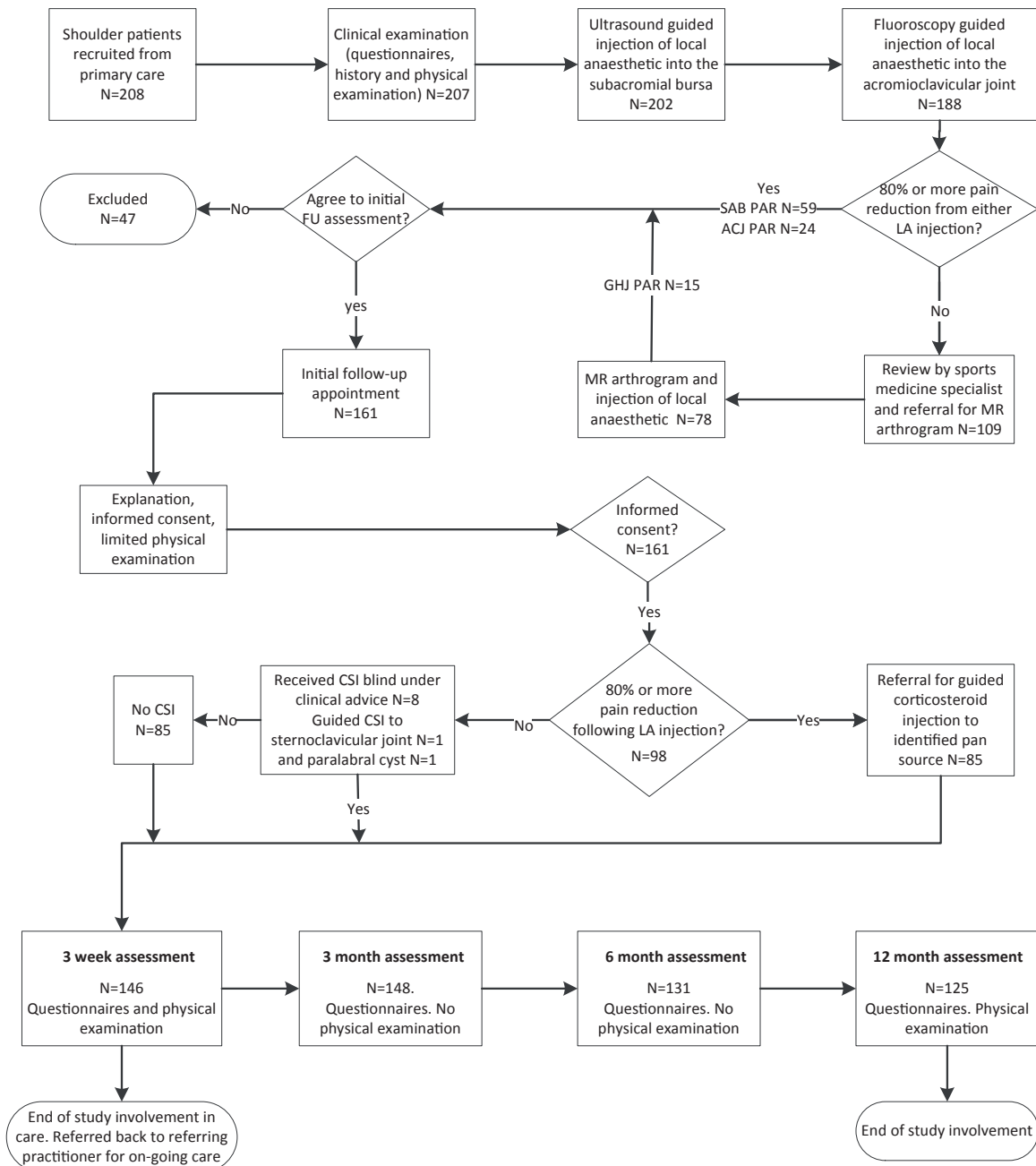
Fig. 1. Diagram of flow of patients through diagnostic and follow-up studies. LA: guided local anaesthetic injection; CSI: corticosteroid injection; PAR: positive anaesthetic response, i.e. ≥80% relief of pain. Source participants derived from Cadogan 2011 (28).

(Pearson chi-square $p > 0.3$). One way ANOVA analyses of SPADI Total and subscales, pain intensity VAS scores, SF-8 PCS and MCS, Global Disability rating, and FABQ total and subscales for those reporting PAR from at least one structure injection, showed no significant differences from those reporting a negative anaesthetic response (NAR) ($p > 0.1$).

The majority of patients were managed with physiotherapy interventions (mostly exercise, mobilization and guidance on activity modification), and corticosteroid injection. Corticosteroid injection (CSI) was arranged at the initial interview by

the principal author (ML) in accordance with reported PAR, i.e. ≥80% pain reduction criterion used to identify the source of pain (28). Fifty-five, 18 and 16 patients received guided CSI to the SAB, ACJ and GHJ, respectively. Of the 13 patients with both SAB and ACJ sources of pain, one received guided CSI to both structures, 4 and 6 received CSI to the ACJ and SAB respectively based on the clinical judgement of the lead author or Sports Medicine specialist, and two declined further injections. One patient received guided CSI into a paralabral synovial cyst and another, an injection into

Table I. *Demographic profile of patients included in shoulder pain follow-up study*

	n (%)	Missing, n	Min–Max	Mean (SD)
Age, years	161	0	18–81	44.00 (13.88)
Duration of symptoms, days	158	3	2–1,697	108.35 (193.88)
SPADI Pain subscale, %	161	0	0–100	50.56 (21.72)
SPADI Disability subscale, %	161	0	0–93	30.25 (21.10)
SPADI Total, %	161	0	0–94	38.03 (20.11)
Pain intensity in last 48 h, 100 mmVAS				
Lowest	157	4	0–66	7.30 (14.33)
Mean	157	4	0–84	36.35 (20.65)
Worst	159	2	0–100	62.42 (23.50)
Global Disability Rating Score (1–7)	161		1–6	3.64 (1.45)
FABQ General Score, %	155	6	0–74	25.11 (22.68)
FABQ Physical Activity Score, %	158	3	0–100	61.89 (23.37)
FABQ Total (Work + Physical Activity Subscales), %	158	3	0–78	27.01 (16.69)
FABQ Work Score, %)	156	5	0–82	38.48 (18.60)
SF-8 Mental Component Score	160	1	0–61	44.02 (8.64)
SF-8 Physical Component Score	160	1	0–66	52.38 (9.07)
Male gender	79 (49.1)	0		
Right side affected	88 (54.7)	0		
Dominant right hand	142 (88.2)	0		
Diabetes	– (0.0)	0		
Heart disease	3 (1.9)	3		
Asthma	29 (18.0)	4		
Smoker	31 (19.3)	4		
Pain at night	87 (54.0)	7		
Unable to sleep on painful side	87 (54.0)	10		
Occupational demand on shoulder	– (13.0)	21		
Low	52 (32.3)			
Moderate	50 (31.1)			
High	38 (23.6)			
Sport/recreational demand on shoulder	– (13.7)	22		
Low	28 (17.4)			
Moderate	37 (23.0)			
High	74 (46.0)			
Description of current episode	– (0.7)	1		
Recurrent episode	132 (82.0)			
New episode	28 (17.4)			
Mechanism/cause of pain onset	– (1.2)	2		
Trauma	57 (35.4)			
Strain	70 (43.5)			
Repetitive/overuse	16 (9.9)			
Unknown/spontaneous	16 (9.9)			
Employment	– (2.5)	4		
In paid employment	128 (79.5)			
Retired	13 (8.1)			
Home with children/maternity leave	2 (1.2)			
Unable to work/sickness benefit	1 (0.6)			
Unemployed	4 (2.5)			
Student	8 (5.0)			
Other	1 (0.6)			

Min: Minimum; Max: Maximum; SD: standard deviation; SPADI: Shoulder Pain and Disability Index; VAS: visual analogue scale; FABQ: Fear Avoidance beliefs Questionnaire; SF-8: Short Form 8.

the sternoclavicular joint. After the 3 weeks follow-up, two patients were managed by rheumatology specialists. Other interventions used were: hydraulic distension combined with CSI to the glenohumeral joint (*n* = 4), aspiration followed by CSI to synovial cysts associated with labral pathology (*n* = 2), fenestration and barbotage to calcific tendinopathies in conjunction with CSI to the subacromial bursa (*n* = 2), and one patient received prolotherapy. By the 12-month follow-up assessment, 29 patients had been offered and 19 had undergone

surgical intervention. At the 12-month assessment 5 were scheduled to have surgery. Insurance coverage for surgery was declined in 3 cases so it did not proceed, and one patient chose not to proceed because of clinical improvement. To determine if there were significant baseline differences between those patients offered or had received surgery compared with those not considered surgical candidates, one way ANOVA analyses were carried out on relevant measures (SPADI Total % and Pain and Disability sub-scales, pain intensity VAS scores,

Table II. *Outcome measure scores from baseline to 12 month follow-up*

	Baseline Mean (SD)	3 week FU Mean (SD)	3 Month FU Mean (SD)	6 month FU Mean (SD)	12 month FU Mean (SD)
SPADI Pain %	50.6 (21.72)	21.9 (23.13)	24.6 (25.42)	24.2 (25.28)	15.0 (21.34)
SPADI Disability %	30.2 (21.10)	12.3 (17.89)	12.8 (19.12)	12.6 (18.13)	7.0 (14.47)
SPADI Total %	38.0 (20.11)	16.1 (19.22)	17.5 (20.96)	17.0 (20.16)	10.1 (16.43)
100 mm Pain VAS					
Lowest	7.3 (14.33)	4.7 (12.12)	4.8 (11.46)	3.6 (10.51)	1.8 (7.26)
Mean	36.4 (20.65)	13.2 (20.02)	14.7 (20.41)	15.0 (21.56)	8.4 (17.65)
Worst	62.4 (23.50)	25.3 (29.85)	27.9 (30.48)	29.2 (32.27)	17.3 (28.13)
Global Disability Rating (1–7)	3.6 (1.45)	2.4 (1.52)	2.3 (1.57)	2.4 (1.68)	1.7 (1.23)

Visual analogue scale (VAS) scores are the subjects rating from 0 to 100 in previous 48 h, where 0=no pain and 100=worst imaginable pain.
FU: follow-up; SD: standard deviation.

Global Disability Rating, FABQ Total and subscales, SF-8 Mental and Physical Component scores, and age). Only baseline FABQ Physical Activity subscale and Total scores were significantly higher for the surgical group ($p > 0.02$ and 0.03, respectively). However, with the exception of SF-8 mental component and physical component scores at 3 weeks, the physical component scores at 3 months and both component scores at 6 months, all scales of the SPADI questionnaire were significantly higher for the surgical group at 3 week, 3 month and 6 month follow-up ($p < 0.05$).

Physiotherapy treatment

Of the 152 patients where data are available, 76.6% received physiotherapy (mean number of treatments 6.9, (standard deviation (SD) 8.91)). During the 12-month study period, 39.5% received between one and 5 treatments, and 29.6% received 15 or more treatments. The maximum number of treatments was 55, with 3 surgical patients (2.6%) receiving more than 40 pre and post-operative treatments combined. The percentage subsidized by the universal Accident Compensation and Rehabilitation insurance scheme (ACC) was 90.1%.

Therapeutic outcomes

At baseline SPADI pain and disability sub-scales showed significant gender differences with females reporting higher scores (One way ANOVA, $p = 0.009$ and $p < 0.001$ respectively). These differences were not retained at subsequent follow-up assessments ($p > 0.05$). Repeated measures ANOVA analysis with 5 levels of SPADI scores (baseline, 3 weeks, 3 months, 6 months and 12 months) with gender and duration of symptoms as factors, and baseline pain intensity VAS (average), SF-8 PCS and MCS, FABQ (total%), GDR and age (years) as covariates, revealed a consistent pattern of change over time. For this reason, only the SPADI Total percentage score values are reported here. There was a significant reduction in SPADI total scores expressed as mean percentage values between the baseline assessment and all follow-up assessments ($p < 0.001$). Fig. 2 shows the pattern of change over 12 months for both genders, SPADI Total percentage scores, and for the SPADI subscales of pain and disability. The change in SPADI scores was significant between baseline and the 3-week assessment ($p < 0.001$), and between the 6- and 12-month assessments

($p < 0.001$), but non-significant between the 3-week and 6-month assessments ($p > 0.1$).

Fig. 3 presents data for proportions of change categories at 3 weeks, 3, 6 and 12 months. Thus at 12 months, 16.1% were lost to follow-up leaving a total sample size of 135. Using an intention-to-treat approach, 45.3% achieved an excellent clinical result, about 28.6% were improved more than the MCID but less than 90% better, 13.0% were not clinically different and 1.9% had worsened. The status of patients was generally poorest at the 3 month follow-up, with 63.3% of patients improved beyond the MCID and 34.8% either unchanged or worse (Fig. 4).

A large number of variables were assessed by univariate logistic regression analyses for a relationship with 3 clinical outcomes (excellent, better, poor) at 3- and 12-month follow-up, and the results for key variables are presented in the appendix.
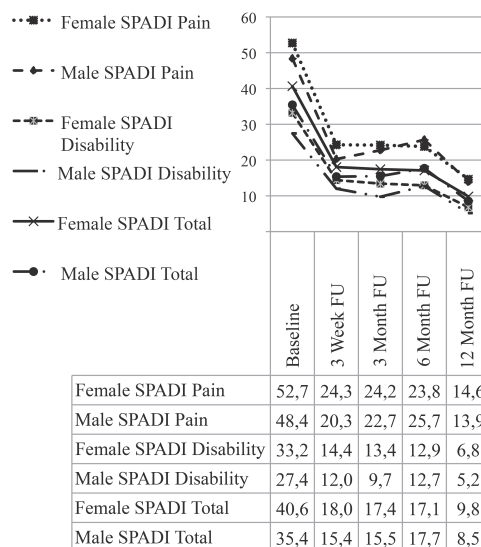

	Baseline	3 Week FU	3 Month FU	6 Month FU	12 Month FU
Female SPADI Pain	52,7	24,3	24,2	23,8	14,6
Male SPADI Pain	48,4	20,3	22,7	25,7	13,9
Female SPADI Disability	33,2	14,4	13,4	12,9	6,8
Male SPADI Disability	27,4	12,0	9,7	12,7	5,2
Female SPADI Total	40,6	18,0	17,4	17,1	9,8
Male SPADI Total	35,4	15,4	15,5	17,7	8,5

Fig. 2. Change in mean Shoulder Pain and Disability Index (SPADI) subscales and total percentage scores from baseline to 12 month follow-up (FU) assessments. Covariates appearing in the model are evaluated at the following values: Global Disability Rating at baseline=3.68, FABQ (Fear-Avoidance Beliefs Questionnaire) Total (%) (Work+Physical Activity Subscales) at baseline=37.84, Short Form 8 (SF-8) Physical Component Score at baseline=43.68, SF-8_Mental Component Score at baseline=53.42, SC: average VAS Score (0-100) in last 48 h (mm) at baseline=36.58.
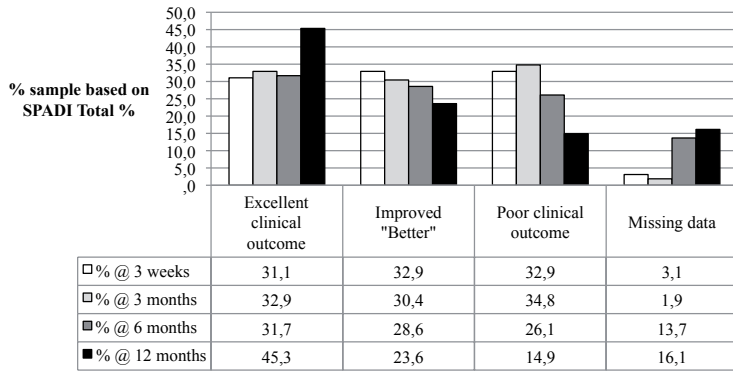
% sample based on SPADI Total %	Excellent clinical outcome	Improved "Better"	Poor clinical outcome	Missing data
□ % @ 3 weeks	31,1	32,9	32,9	3,1
□ % @ 3 months	32,9	30,4	34,8	1,9
■ % @ 6 months	31,7	28,6	26,1	13,7
■ % @ 12 months	45,3	23,6	14,9	16,1

Fig. 3. Proportions of change categories in shoulder pain patients at follow-up assessments. SPADI: Shoulder Pain and Disability Index.

Excellent outcomes at 3 months were associated with: Higher total SPADI scores at baseline, lower maximum reported pain VAS scores in the 48 h prior to enrolment in the study, lower pain scores with painful index tests carried out at the 3-week follow-up assessment, a PAR following diagnostic injection of local anaesthetic into the GHJ and the presence of subacromial bursa pathology(ultrasound imaging of thickening, fluid or calcification). Excellent outcomes at 12 months were associated with: Report of pain not being eased or 'best' when at rest, lower reported pain scores with painful index tests carried out at the 3-week follow-up assessment and a PAR following block of the ACJ. Only a PAR to diagnostic block to the SAB was associated with being classified as "Better" (improved beyond the MCID but less than 90% better) at 3-month follow up (*p*=0.009). Being "Better" at 12-months follow-up was associated with: A report of pain being eased at best when at rest, higher reported pain scores with painful index tests carried out at the three week follow up assessment, and a PAR to diagnostic block to the ACJ. A poor outcome at 3-month follow-up was

% sample based on SPADI Total %	3 weeks	3 months	6 months	12 months
···◆··· Excellent clinical outcome	31,1	32,9	31,7	45,3
− ■ · Improved	32,9	30,4	28,6	23,6
──▲── Poor clinical outcome	32,9	34,8	26,1	14,9
−■− Missing data	3,1	1,9	13,7	16,1

Fig. 4. Clinical outcomes based on Shoulder Pain and Disability Index (SPADI) Total % at follow-up assessments. Excellent clinical outcome: SPADI Total % reduced by 90% or more. Improved: SPADI Total % reduced more than MCID but less than 90% improvement. Poor clinical outcome: SPADI Total % not reduced by MCID (13 points) or worse.

associated with: Higher FABQ Work subscale scores at baseline and higher reported pain scores with painful index tests carried out at the three week follow up assessment. A poor outcome at 12-month follow-up was associated with a lower SF-8 General Health subscale score at baseline and a PAR to diagnostic block of the ACJ.

Recurrences and re-injury rates

At each follow-up subjects were asked to recall and report recurrences of pain and re-injuries that may have occurred (Table III), with nearly half of all pain recurrences related to re-injury. Re-injury was defined as a significant traumatic event or a significant repetitive overload situation that the patient clearly connected to a rapid return or increase in the typical shoulder pain.

DISCUSSION

This study provides the first detailed report of outcomes for patients receiving community based primary care interventions for shoulder pain in a New Zealand environment. Management of patients throughout the follow-up period was broadly consistent with recommended guidelines (7, 17, 18) and with treatments recommended in a recent systematic review of studies of impingement syndrome (38–40), but were not directed. The outcomes at 12 months are broadly consistent with those established in previous reports (1, 3, 7). Also consistent with previous reports, recurrences were reported by 13.5% by the 3-month follow-up and 24% by the 12-month follow-up. However, in the current study about half of these recurrences were related to re-injury, so the spontaneous recurrence rate at 12 months was 14% in this study.

Corticosteroid anti-inflammatory injection is reported to be effective for short term relief of shoulder pain (41). In the current study, the majority of patients receiving corticosteroid injection were selected for this procedure based on a highly standardized criterion, i.e. ≥80% reduction of pain following a guided diagnostic injection into the subacromial bursa, acromioclavicular joint or glenohumeral joint. Though diagnostic block has been incorporated into the diagnostic work up in one previous study (42), to our knowledge, this is the first report of outcomes where such a stringent criterion for CSI has been used for the great majority of patients which were carried out within the first 3 weeks of the study. No other interventions had commenced until after the 3-week assessment.

Previous reports established a significant relationship between a shorter duration of symptoms at presentation and better outcome at 6 weeks and 6 months (43). This relationship was not supported by our data as there was no association between duration of symptoms prior to baseline assessment and the likelihood of an excellent
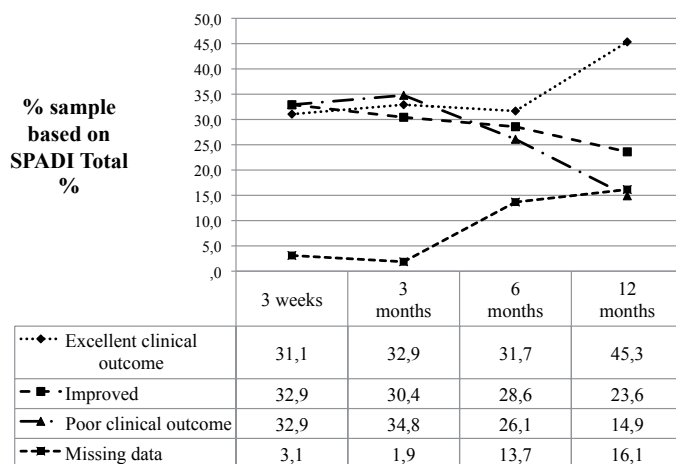
Table III. *Number of cases reporting recurrences and re-injuries during intervals between follow-up assessments*

	Interval between 3-week and 3-month follow-up	Interval between 3-month and 6-month follow-up	Interval between 6-month and 12-month follow-up	Total incidents/events
Recurrence no re-injury	10	12	19	41
Recurrence with re-injury	8	2	9	19
Re-injury without recurrence	1	7	4	12
No recurrence or re-injury	122	115	103	N/A
Totals	141	136	135	72

N/A: not applicable.

outcome at 3 weeks or 3 months. These findings suggest that the structured timing of steroid injection carried out on 54% of the 156 patients assessed at 3 weeks was a factor in the observed rapid change, and may also account for the differences with previous reports (3, 43). It is noted that reports in 2009 and 2012 suggest that the added specificity provided by image guidance does not provide additional benefit in terms of accuracy of injectate placement or clinical outcome (44, 45). However, in 2008 we chose to use ultrasound or fluoroscopic guidance for diagnostic and therapeutic injections to assist in validation of injectate placement.

The profile of treatment in the current study differed substantially from the study by Kuijpers et al. (43) in that over 50% versus 12%, respectively, received corticosteroid injection and 77% versus 10%, respectively, received physiotherapy treatment. In addition, the great majority of CSI interventions occurred in the first 3 weeks. It seems reasonable to argue that the improvement observed in the first 3 weeks was related to corticosteroid injection independently of the duration of symptoms. The reason for the plateau in improvement between 3-week and 3-month follow-ups, and the subsequent significant improvement between the 6-month and 12-month follow-ups cannot be determined based on our data. Examination of these observations was beyond the design and scope of this study and should receive attention in future research. A proportion of patients received steroid injection after the 3 week assessment: 15 between the 3-week and 3-month assessments, 8 between 3-month and 6-month follow-ups and 9 patients between 6- and 12-month follow-up. The contribution of these interventions on the average clinical course could not be distinguished from improvement over time and the community-based interventions (mostly physiotherapy) employed in the majority of cases. Medication use during this period was not accurately assessed and it is also possible that during this period the use of oral medications may have had an effect on overall decline in pain and disability.

Patients who were offered or had received surgery for their shoulder problem were not significantly more painful or disabled at baseline, but did have elevated fear avoidance with regard to physical activity. However, significant differences emerged throughout the first 6 months of follow-up suggesting that failure to improve with conservative care or steroid injection were important factors in selection for surgical intervention.

Mean pain and disability generally (but not significantly) increased or stayed about the same between the 3-week and 6-month assessments and then significantly declined between

the 6- and 12-month follow-up. This finding is contrasted to previous reports and opinion that suggest that reductions in pain and disability are not expected after 6 months (3, 22, 43). The reason for the difference in findings is unclear. It is important to acknowledge that during this period, some patients improved, some remained unchanged and others worsened. Some patients received surgical interventions ($n = 17$), which typically caused a major increase in pain for a variable amount of time in the post-surgery period.

The predictive value of findings from imaging studies such as x-ray, ultrasound and magnetic resonance imageing (MRI) was limited. Though the presence of SAB thickening, fluid or calcification is associated with an excellent outcome or being "better" at 3 months, it must also be remembered that those patients being offered guided corticosteroid injections into the bursa were those that had a positive response to guided diagnostic block to the SAB. Curiously, a PAR block to the SAB was not predictive of a good outcome. It is intended to examine this apparent paradox in future analyses. Another paradox that emerged needs further detailed examination: A positive response to anaesthetic block into the ACJ was associated with an excellent clinical outcome at 12 months, *and* a poor outcome at 12 months, suggesting that there are at least two different types of painful ACJ pathologies. The presence of ultrasound verified large or medium sized rotator cuff tear, MRI verified bursitis, MR verified labrum tears and X-ray verified pathology of any kind did not predict poor or good clinical outcomes.

The identification of data acquired at baseline or at three weeks post induction into the study for association with outcomes at 3 and 6 months, will inform the secondary analysis for potential predictive models and will be reported on in Part 2 of this report. Consistent with previous research on other painful musculoskeletal disorders, we have found that a poor outcome was associated with lower self-reported general health scores, and fear avoidance as it relates to work activities. In contrast, the instruments we employed for measuring other psychosocial factors were not strongly associated with 3- or 12-month outcomes.

Limitations

The current study was not a randomized controlled trial and cause/effect relationships are outside the scope of the design. Treatment methods by GPs and physiotherapists after the 3-week assessment were not standardized or controlled, so causal relationships between different oral medications or physiotherapy interventions and outcomes cannot be estab-

lished. Nevertheless, the current design allowed us to evaluate outcomes associated with current practice in a pragmatic fashion. This would not have been possible with a more rigid design that did not allow clinicians the option to make appropriate treatment choices based upon the individual patient. In general the main treatment choices reflected nationally based guidelines.

Conclusion

Patients managed in a manner broadly consistent with guidelines for shoulder pain in primary care, demonstrate improvement in pain and disability over a 12-month period. However, a moderate proportion still reported pain and disability at 12 months and many reported recurrence of pain during this period. While 30% show dramatic improvement with a structured corticosteroid injection protocol at the 3-week follow-up, mean pain and disability stayed rather static over the next few months, but improved in the 6–12-month period, regardless of symptom duration at presentation. There is evidence to support the hypotheses that a corticosteroid injection is a valuable treatment modality for selected patients in the short term. The prolonged course of recovery for many with shoulder pain requires further investigation to determine whether improvements in diagnostic and/or treatment processes may reduce recovery time, reduce costs and result in more rapid return of shoulder function. Part two of this report will present results of multivariate predictive modelling for clinical outcomes.

The authors declare no conflicts of interest.

REFERENCES

1. van der Windt DA, Koes BW, de Jong BA, Bouter LM. Shoulder disorders in general practice: incidence, patient characteristics, and management. Ann Rheum Dis 1995; 54: 959–964.
2. Luime JJ, Koes BW, Hendriksen IJ, Burdorf A, Verhagen AP, Miedema HS, Verhaar JA. Prevalence and incidence of shoulder pain in the general population; a systematic review. Scand J Rheumatol 2004; 33: 73–81.
3. Croft P, Pope D, Silman A. The clinical course of shoulder pain: prospective cohort study in primary care. Primary Care Rheumatology Society Shoulder Study Group. BMJ 1996; 313: 601–602.
4. Urwin M, Symmons D, Allison T, Brammah T, Busby H, Roxby M, Simmons A, Williams G. Estimating the burden of musculoskeletal disorders in the community: the comparative prevalence of symptoms at different anatomical sites, and the relation to social deprivation. Ann Rheum Dis 1998; 57: 649–655.
5. van der Windt DA, Koes BW, Boeke AJ, Deville W, de Jong BA, Bouter LM. Shoulder disorders in general practice: prognostic indicators of outcome. Br J Gen Pract 1996; 46: 519–523.
6. Philadelphia Panel evidence-based clinical practice guidelines on selected rehabilitation interventions for shoulder pain. Phys Ther 2001; 81: 1719–1730.
7. Accident Compensation and Rehabilitation Corporation of New Zealand. The diagnosis and management of soft tissue shoulder injuries and related disorders: Best practice evidence-based guideline. Arroll B, Robb G, editors. Wellington: ACC; 2004.
8. Bonafede RP, Bennett RM. Shoulder pain. Guidelines to diagnosis and management. Postgrad Med 1987; 82: 185–183.
9. Buchbinder R, Goel V, Bombardier C, Hogg-Johnson S. Classification systems of soft tissue disorders of the neck and upper

limb: do they satisfy methodological guidelines? J Clin Epidemiol 1996; 49: 141–149.
10. Iannotti JP, Kwon YW. Management of persistent shoulder pain: a treatment algorithm. Am J Orthop 2005; 34: 16–23.
11. Johal P, Martin D, Broadhurst N. Managing shoulder pain in general practice - assessment, imaging and referral. Aust Fam Physician 2008; 37: 263–265.
12. Kelley MJ, McClure PW, Leggin BG. Frozen shoulder: evidence and a proposed model guiding rehabilitation. J Orthop Sports Phys Ther 2009; 39: 135–148.
13. Michener LA, Walsworth MK, Burnet EN. Effectiveness of rehabilitation for patients with subacromial impingement syndrome: a systematic review. J Hand Ther 2004; 17: 152–164.
14. Parentis MA, Mohr KJ, Elattrache NS. Disorders of the superior labrum: review and treatment guidelines. Clin Orthop Relat Res 2002; 400: 77–87.
15. van der Heijden GJ. Shoulder disorders: a state-of-the-art review. Baillieres Best Pract Res Clin Rheumatol 1999; 13: 287–309.
16. Wilk KE, Reinold MM, Dugas JR, Arrigo CA, Moser MW, Andrews JR. Current concepts in the recognition and treatment of superior labral (SLAP) lesions. J Orthop Sports Phys Ther 2005; 35: 273–291.
17. Robb G, Arroll B, Reid D, Goodyear-Smith F. Summary of an evidence-based guideline on soft tissue shoulder injuries and related disorders – Part 1: Assessment. J Prim Health Care 2009; 1: 36–41.
18. Robb G, Arroll B, Reid D, Goodyear-Smith F. Summary of an evidence-based guideline on soft tissue shoulder injuries and related disorders – Part 2: Management. J Prim Health Care 2009; 1: 42–49.
19. Arroll B, Goodyear-Smith F. Corticosteroid injections for painful shoulder: a meta-analysis. Br J Gen Pract 2005; 55: 224–228.
20. Kuijpers T, van der Windt DA, van der Heijden GJ, Twisk JW, Vergouwe Y, Bouter LM. A prediction rule for shoulder pain related sick leave: a prospective cohort study. BMC Musculoskelet Disord 2006; 7: 97.
21. Kuijpers T, van der Windt DA, Boeke AJ, Twisk JW, Vergouwe Y, Bouter LM, van der Heijden GJ. Clinical prediction rules for the prognosis of shoulder pain in general practice. Pain 2006; 120: 276–285.
22. Kuijpers T, van der Windt DA, van der Heijden GJ, Bouter LM. Systematic review of prognostic cohort studies on shoulder disorders. Pain 2004; 109: 420–431.
23. Kuijpers T, Vergouwe Y, van der Heijden GJ, Bot SD, Twisk JW, van der Windt DA, Bouter LM. Generalizability of a prediction rule for sick leave due to shoulder pain. Scand J Work Environ Health 2007; 33: 440–446.
24. Thomas E, van der Windt DA, Hay EM, Smidt N, Dziedzic K, Bouter LM, Croft PR. Two pragmatic trials of treatment for shoulder disorders in primary care: generalisability, course, and prognostic indicators. Ann Rheum Dis 2005; 64: 1056–1061.
25. van der Heijden GJ, van der Windt DA, de Winter AF. Physiotherapy for patients with soft tissue shoulder disorders: a systematic review of randomised clinical trials. BMJ 1997; 315: 25–30.
26. van der Heijden GJ, van der Windt DA, Kleijnen J, Koes BW, Bouter LM. Steroid injections for shoulder disorders: a systematic review of randomized clinical trials. Br J Gen Pract 1996; 46: 309–316.
27. van der Windt DAWM, van der Heijden GJMG, van den Berg SGM, ter Riet G, de Winter AF, Bouter LM. Ultrasound therapy for musculoskeletal disorders: a systematic review. Pain 1999; 81: 257–271.
28. Cadogan A, Laslett M, Hing WA, McNair PJ, Coates MH. A prospective study of shoulder pain in primary care: Prevalence of imaged pathology and response to guided diagnostic blocks. BMC Musculoskelet Disord 2011; 12: 119.
29. Cadogan A, Laslett M, Hing W, McNair P, Taylor S. Clinical predictors of a positive response to guided diagnostic block into the subacromial bursa. J Rehabil Med 2012; 44: 877–884.
30. Cadogan A, McNair P, Laslett M, Hing W. Shoulder pain in pri-

mary care: diagnostic accuracy of clinical examination tests for non-traumatic acromioclavicular joint pain. BMC Musculoskelet Disord 2013; 14: 156.

31. Cadogan A, McNair P, Laslett M, Hing W, Taylor S. Diagnostic accuracy of clinical examination features for identifying large rotator cuff tears in primary health care. J Man Manip Ther 2013; 21: 148–159.

32. Roach KE, Budiman-Mak E, Songsiridej N, Lertratanakul Y. Development of a shoulder pain and disability index. Arthritis Care Res 1991; 4: 143–149.

33. Schmitt JS, Di Fabio RP. Reliable change and minimum important difference (MID) proportions facilitated group responsiveness comparisons using individual threshold criteria. J Clin Epidemiol 2004; 57: 1008–1018.

34. Scott J, Huskisson EC. Graphic representation of pain. Pain 1976; 2: 175–184.

35. Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. Pain 1993; 52: 157–168.

36. Turner-Bowker DM, Bayliss MS, Ware JE, Jr., Kosinski M. Usefulness of the SF-8 Health Survey for comparing the impact of migraine and other conditions. Qual Life Res 2003; 12: 1003–1012.

37. Roy JS, MacDermid JC, Woodhouse LJ. Measuring shoulder function: a systematic review of four questionnaires. Arthritis Rheum 2009; 61: 623–632.

38. Kromer TO, de Bie RA, Bastiaenen CH. Physiotherapy in patients with clinical signs of shoulder impingement syndrome: A

39. Kromer TO, de Bie RA, Bastiaenen CH. Effectiveness of individualized physiotherapy on pain and functioning compared to a standard exercise protocol in patients presenting with clinical signs of subacromial impingement syndrome. A randomized controlled trial. BMC Musculoskelet Disord 2010; 11: 114.

40. Kromer TO, Tautenhahn UG, de Bie RA, Staal JB, Bastiaenen CH. Effects of physiotherapy in patients with shoulder impingement syndrome: a systematic review of the literature. J Rehabil Med 2009; 41: 870–880.

41. Buchbinder R, Green S, Youd JM. Corticosteroid injections for shoulder pain. Cochrane Database Syst Rev 2003; (1): CD004016.

42. Johansson K, Bergstrom A, Schroder K, Foldevi M. Subacromial corticosteroid injection or acupuncture with home exercises when treating patients with subacromial impingement in primary care – a randomized clinical trial. Fam Pract 2011; 28: 355–365.

43. Kuijpers T, VAN DER Windt DA, Boeke AJ, Twisk JW, Vergouwe Y, Bouter LM, van der Heijden GJ. Clinical prediction rules for the prognosis of shoulder pain in general practice. Pain 2006; 120: 276–285.

44. Ekeberg OM, Bautz-Holter E, Tveita EK, Juel NG, Kvalheim S, Brox JI. Subacromial ultrasound guided or systemic steroid injection for rotator cuff disease: randomised double blind study. BMJ 2009; 338: a3112.

45. Dogu B, Yucel SD, Sag SY, Bankaoglu M, Kuran B. Blind or ultrasound-guided corticosteroid injections and short-term response in subacromial impingement syndrome: a randomized, double-blind, prospective study. Am J Phys Med Rehabil 2012; 91: 658–665.

APPENDIX I. Association of variables to clinical outcome at 3 and 12 months

	Excellent outcome		Better		Poor outcome	
	3 months OR (*p*-value)	12 months OR (*p*-value)	3 months OR (*p*-value)	12 months OR (*p*-value)	3 months OR (*p*-value)	12 months OR (*p*-value)
Variables derived from Part-1 analysis						
SPADI Total Score (%) at baseline	1.018 (0.032)	1.000 (0.990)	0.988 (0.124)	0.997 (0.687)	0.983 (0.294)	1.032 (0.210)
SPADI Pain Score (%) at baseline	1.016 (0.055)	0.995 (0.548)	0.990 (0.192)	1.003 (0.705)	0.984 (0.289)	1.020 (0.458)
SPADI Disability Score (%) at baseline	0.994 (0.460)	0.995 (0.530)	1.010 (0.230)	1.006 (0.465)	0.984 (0.343)	0.990 (0.737)
History of Asthma	0.573 (0.238)	0.438 (0.075)	1.379 (0.455)	2.068 (0.112)	1.702 (0.454)	2.326 (0.498)
Past history shoulder pain in the same shoulder	0.825 (0.605)	0.637 (0.236)	1.257 (0.521)	1.163 (0.693)	0.825 (0.784)	N/A
Pain aggravated when reaching across the body	0.520 (0.058)	0.705 (0.326)	1.479 (0.237)	1.197 (0.615)	2.316 (0.229)	N/A
Pain is eased or at best when at rest	0.553 (0.154)	0.350 (0.014)	1.467 (0.329)	2.919 (0.012)	1.733 (0.467)	0.880 (0.929)
Pain described as constant (24/7)	2.057 (0.054)	1.291 (0.510)	0.569 (0.124)	0.756 (0.474)	0.604 (0.531)	1.257 (0.854)
SF-8_Bodily Pain Score at baseline	0.991 (0.656)	0.998 (0.940)	0.990 (0.617)	0.995 (0.811)	1.070 (0.080)	1.079 (0.302)
SF-8_General Health Score at baseline	1.048 (0.067)	1.032 (0.215)	0.954 (0.056)	0.986 (0.584)	1.014 (0.763)	0.836 (0.040)
SF-8_Physical Functioning Score at baseline	0.973 (0.176)	0.993 (0.744)	1.007 (0.737)	1.007 (0.752)	1.106 (0.077)	1.003 (0.967)
SF-8_Role Physical Score at baseline	1.003 (0.903)	1.013 (0.544)	1.005 (0.813)	0.995 (0.813)	0.976 (0.498)	0.923 (0.232)
SF-8_Vitality at baseline	1.035 (0.183)	0.996 (0.886)	0.964 (0.137)	1.018 (0.501)	1.019 (0.693)	0.883 (0.105)
SF-8_Physical Component Score at baseline	1.028 (0.186)	1.021 (0.284)	0.980 (0.308)	0.988 (0.537)	0.984 (0.624)	0.934 (0.133)
Baseline VAS (mm) lowest level of pain	0.985 (0.263)	0.978 (0.092)	1.009 (0.464)	1.026 (0.053)	1.013 (0.505)	0.006 (0.992)
Baseline VAS (mm) highest level of pain	0.985 (0.045)	0.991 (0.230)	1.013 (0.060)	1.009 (0.264)	1.001 (0.924)	1.008 (0.758)
FABQ Work Score (%) at baseline	1.001 (0.926)	0.993 (0.405)	0.990 (0.188)	1.002 (0.823)	1.032 (0.027)	1.059 (0.081)
Baseline FABQ Total (%)	1.000 (0.977)	0.997 (0.731)	0.990 (0.258)	0.995 (0.641)	1.038 (0.034)	1.116 (0.035)
Frozen shoulder: Clinical diagnosis	0.980 (0.978)	3.182 (0.159)	1.402 (0.642)	0.346 (0.196)	N/A	N/A
Pain intensity of index test pain at 3 weeks	0.982 (0.003)	0.987 (0.024)	1.009 (0.085)	1.017 (0.005)	1.022 (0.041)	0.895 (0.290)
Variables suggested by previous studies						
SF-8 Mental Component Score at baseline	0.973 (0.174)	0.993 (0.727)	1.024 (0.225)	1.007 (0.737)	1.007 (0.851)	1.003 (0.960)
FABQ General Score (%) at baseline	1.011 (0.270)	1.015 (0.175)	0.986 (0.140)	0.982 (0.124)	1.014 (0.418)	1.020 (0.542)
Duration of symptoms (pain onset to initial clinical examination in days)	0.998 (0.207)	1.000 (0.913)	1.000 (0.791)	1.000 (0.915)	1.002 (0.088)	0.969 (0.267)
Gender is female	1.329 (0.401)	0.615 (0.165)	0.745 (0.367)	1.565 (0.203)	1.121 (0.856)	1.667 (0.680)
Concurrent cervical spine symptoms	0.727 (0.435)	0.868 (0.724)	1.230 (0.592)	1.008 (0.985)	1.314 (0.696)	3.282 (0.338)

APPENDIX I. Contd.

	Excellent outcome		Better		Poor outcome	
	3 months OR (*p*-value)	12 months OR (*p*-value)	3 months OR (*p*-value)	12 months OR (*p*-value)	3 months OR (*p*-value)	12 months OR (*p*-value)
History of pain in the opposite shoulder	1.090 (0.814)	1.767 (0.126)	1.116 (0.753)	0.564 (0.125)	0.523 (0.305)	0.989 (0.993)
Pain is referred below the elbow	0.695 (0.448)	2.203 (0.109)	1.479 (0.237)	0.508 (0.168)	1.093 (0.913)	0.000 (0.998)
Shoulder pain disturbs sleep	0.620 (0.167)	0.576 (0.128)	1.283 (0.454)	1.700 (0.146)	2.127 (0.280)	1.368 (0.800)
Waist Circumference (cm)	0.983 (0.178)	0.985 (0.196)	1.014 (0.237)	1.018 (0.146)	1.005 (0.828)	0.975 (0.599)
Pain is aggravated by reaching above the head	1.162 (0.733)	0.674 (0.385)	1.036 (0.934)	1.665 (0.262)	0.442 (0.446)	N/A
Shoulder pain provoked by neck movement testing	0.995 (0.977)	0.876 (0.458)	0.893 (0.494)	1.109 (0.563)	1.440 (0.181)	1.323 (0.581)
Variables derived from imaging studies						
PAR to diagnostic injection to the SAB (≥80%)	0.768 (0.462)	0.800 (0.531)	1.451 (0.279)	0.991 (0.981)	0.607 (0.474)	N/A
Positive anaesthetic response to diagnostic injection to the ACJ joint (≥80%)	1.390 (0.525)	0.219 (0.026)	1.102 (0.850)	3.372 (0.052)	N/A	3.808 (0.020)
PAR to diagnostic injection to the GHJ joint (≥80%)	5.444 (0.009)	0.556 (0.352)	0.366 (0.085)	1.800 (0.352)	0.400 (0.405)	N/A
Thickening, fluid or calcification of the SAB on ultrasound imaging	0.307 (0.005)	1.029 (0.939)	2.662 (0.009)	0.969 (0.932)	1.216 (0.764)	1.035 (0.978)
ACJ arthropathy of any sort seen on x-ray	0.653 (0.402)	0.662 (0.398)	1.692 (0.279)	1.681 (0.287)	0.564 (0.593)	N/A
ACJ arthropathy of any sort seen on MRI	0.765 (0.618)	0.437 (0.105)	0.773 (0.594)	2.291 (0.105)	3.208 (0.164)	N/A
Subacromial 'bursitis' seen on MRI	0.809 (0.728)	0.778 (0.665)	1.197 (0.744)	1.286 (0.665)	0.981 (0.982)	N/A
Labrum tear seen on MRI	1.528 (0.433)	0.941 (0.903)	0.607 (0.298)	1.062 (0.903)	1.445 (0.605)	N/A
Frozen shoulder: clinical diagnosis	0.980 (0.978)	3.182 (0.159)	1.402 (0.642)	0.346 (0.196)	N/A	N/A
Moderate or major rotator cuff tears as identified on ultrasound imaging	0.390 (0.154)	0.967 (0.951)	1.281 (0.644)	1.144 (0.806)	3.562 (0.083)	N/A
GHJ synovitis (generalized or local) seen on MRI	1.308 (0.618)	0.384 (0.065)	1.293 (0.594)	2.607 (0.065)	0.312 (0.164)	N/A

Diagnostic anaesthetic injection only provided to a subset of patients referred for MR arthrogram i.e. those who reported less than 80% pain reduction following diagnostic blocks to the subacromial bursa and the acromioclavicular joint.

Classification of cases as having a "frozen shoulder" was derived from the physical examination findings at baseline and based on 50% or more reduction in passive range of motion (compared with other side) in two or more of the following planes: abduction, external rotation, internal rotation.

N/A: insufficient data and/or no variation in the variable (e.g. all values the same for a particular variable); SPADI: Shoulder Pain and Disability Index Questionnaire; SF-8: Short Form 8 questionnaire; FABQ: Fear Avoidance Beliefs Questionnaire; VAS:visual analog scale; GHJ: glenohumeral joint; SAB: subacromial bursa; ACJ: acromioclavicular joint; MRI: magnetic resonance imaging.