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ORIGINAL REPORT

SHOULDER PAIN IN PRIMARY CARE – PART 2: PREDICTORS OF CLINICAL OUTCOME TO 12 MONTHS

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Objective: Identify predictor variables and models for clinical outcomes for primary care shoulder pain patients to 12 months follow-up.

Design: A non-randomized audit with 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, 87.0 and 83.9% follow-up at 3 weeks, 3, 6 and 12 months respectively. Treatment consisted of exercise and manual therapy-based physiotherapy and corticosteroid injection under specified selection criteria.

Methods: Potentially useful baseline variables were evaluated in univariate logistic regressions with the dependent variables determined by SPADI Questionnaire at 3 weeks, 3, 6 and 12 months. Variables associated (p-value ≤ 0.2) were retained for potential inclusion within multiple logistic regression analyses.

Results: Pain not improved by rest, intermittent pain, lower pain intensity with physical tests and absence of subacromial bursa pathology on ultrasound at the 3-week follow-up, constant pain and lower pain intensity with physical tests are predictors of excellent outcomes at the 3-month follow-up. Worse baseline pain and disability, no history of asthma, pain better with rest, better physical functioning, greater fear avoidance, male gender, no history of pain in the opposite shoulder, pain referred below the elbow, sleep disturbed by pain, smaller waist circumference, lower pain intensity with physical tests are factors predictive of excellent outcomes at the 12-month follow-up. Only higher pain intensity with physical tests was associated with a poor clinical outcome.

Conclusion: Predictive models for clinical outcomes in primary-care patients with shoulder pain were achieved for excellent clinical outcomes, successfully classifying 70–90% of cases.

INTRODUCTION

Shoulder pain is one of the most common musculoskeletal complaints presenting to primary care practitioners with the average medical practice serving 2,500 registrants reported to conduct a mean of 148 consultations per year for new episodes of shoulder pain (1, 2). Shoulder pain does not spontaneously resolve in a significant proportion of cases naturally (2, 3) or following different treatment methods (4–8) with approximately half of patients consulting more than once for the same episode of shoulder pain (9). Prognosis therefore is mixed depending on factors such as pathology, personal characteristics and specific circumstances of the individual patient and complaint of shoulder pain. The ability to identify prognostic indicators of a good or bad outcome following an episode of shoulder pain may enhance management of these patients.

In a large prospective study on prognostic indicators of outcome for shoulder pain patients in primary care, demographic, pain episode characteristics, patient physical characteristics, physical examination and psychosocial factors were prospectively assessed to determine what factors or combinations of factors predicted poor outcomes at 6 weeks, 3 and 6 months after presentation (10). In that study, longer duration of symptoms at baseline, gradual onset of shoulder pain and higher pain intensity were associated with a poorer prognosis at both 6 weeks and 6 months. Concomitant psychological complaints, performance of repetitive movements and higher neck pain scores at physical examination were associated with persistent symptoms at 6 weeks. A poor prognosis at 6 months was additionally predicted by concomitant back pain and higher shoulder pain scores at physical examination. The physical examination of patients was limited to simple measures of shoulder and neck range of movement and pain with movement. All patients were managed by general medical practitioners (GPs) according to the 1999 Dutch shoulder pain management guidelines (11, 12) which consisted of information on the prognosis of shoulder pain, advice regarding provoking activities and stepwise treatment consisting of paracetamol, non-steroidal anti-inflammatory drugs, corticosteroid injection or referral for physiotherapy. The GP determined the content of treatment, based on duration and severity of pain and disability. The current study offered the

opportunity to evaluate a different suite of outcome measures and the value of a much more extensive and standardized clinical examination that has been previously described in detail (13–17) over a longer follow-up period.

Part 1 of this report (18) presented an overview and results from a follow-up study of first contact primary care patients presenting to community physiotherapy and medical practices (13). Part 2 of this report focuses on in-depth analyses of potential predictors of outcome from baseline examination data derived from the Part 1 analysis plus variables identified by previous research for which analogues were available from the current dataset. The purpose of this report is to identify baseline variables associated with clinical outcomes at 3 weeks, 3, 6 and 12 months follow-up after initial presentation, and formulate potentially useful clinical prediction models. Identification of viable predictive models would assist the primary care clinician in utilizing management protocols similar to the model used in this study where an excellent outcome is expected. Also early referral for high-tech imaging and surgical review would be appropriate if the components of a predictive model suggesting a poor clinical outcome is likely.

METHODS

All patients inducted into a study of diagnostic accuracy among primary care shoulder pain patients (13) were invited to participate in a 12-month follow-up study. Outcomes were assessed at 3 weeks, 3, 6 and 12 months following completion of a comprehensive diagnostic workup. In Part 1, variables significantly associated with higher scores on the Shoulder Pain and Disability Index (SPADI) (19) questionnaire as completed by 84% of participants at the 12-month follow-up, were identified and evaluated for possible inclusion into multiple regression models. Other variables have been identified by previous authors as having an association with outcome at 6 months and 12 months, and where our data provided information on a similar dimension or construct, these were included in the initial list of variables for potential use in creating predictive models.

Outcome measures:

1. *SPADI questionnaire*: The SPADI questionnaire consists of 13 questions relating to pain and function with each question being scored in the range from 0 to 10 in single integer increments. There are two sections, with 5 questions relating to pain and 8 relating to function and disability. A zero score refers to no pain or disability and a 10 score refers to maximum pain and disability. The maximum score therefore is 130 representing maximum pain and disability. The scores acquired were converted to a percentage by the calculation (total SPADI score /130) × 100. The minimally clinically important difference (MCID) for the primary outcome measure, the SPADI Total (%) score, was set at ± 13 percentage points (20).

2. Categories of outcome were created by comparing baseline SPADI total percentage scores with those at each follow-up assessment. Using the MCID, categories of change were created in order to estimate the proportions of cases recovering, staying the same or worsening over time: *Excellent outcome:* Score reduced to zero between assessment points or improvement was 90% or more from baseline; *Better:* Percentage reduction in score larger than the MCID but less than 90%; *Poor Outcome:* Change (increase or decrease) in score was less than the MCID or increase in score was more than the MCID (Table I).

Statistical methods

Variables for inclusion in the initial evaluation for possible inclusion into predictive models were identified in two ways:
1. Those variables associated with SPADI Total score at 12 months ($p \geq 0.2$) from Part 1(18) of this report were included.
2. All other variables in our dataset that measured a similar conceptual construct as variables identified in previous research (3,10) as predictive of outcome at any time point.

All potential predictor variables were evaluated separately in univariate logistic regressions with the dependent variable being clinical outcomes: "Excellent", "Better" and "Poor" based on the SPADI Total at follow-up. Variables associated with the dependent variable (p-value ≤ 0.2) were initially retained for inclusion within multiple backwards logistic regression analyses. Models were considered statistically significant where p-value < 0.05. Where insufficient cases were available to construct models, the result was recorded as "not applicable" (N/A).

RESULTS

Demographic and clinical history details, and flow of patients through the study for the sample, respectively, have been previously reported (13). Of more than 160 variables considered as potential predictors of outcome, there were 26 having sufficient cases for analyses and had associations strong enough in univariate regression analyses for at least one of the outcomes at least one of the follow-up periods, and were retained for inclusion in multiple regression models (Table II). These variables were used to derive separate models for outcomes at the 3-week, 3-month, 6-month and 12-month follow-up periods.

Due to the low number of cases with poor outcomes surviving the multiple regression modelling, there were only two variables that emerged in a final model for the short term 3-month follow-up: Medium or large rotator cuff tears as identified by ultrasound imaging (OR 5.65, 95% CI 0.97–32.72, $p = 0.05$), and higher reported pain intensity with index physical tests carried out at the 3-week follow-up assessment (OR 5.65, 95% CI 0.0–1.05, $p = 0.07$). The analysis therefore was reduced to a dichotomous outcome: an excellent outcome versus all other outcomes. The results of the analyses for excellent outcomes for the short and medium term follow-ups are presented. "Better" or "Poor" outcomes are combined and produce the same but inverse results for an "excellent" outcome.

Table I. *Categorization of clinical outcomes*

Change in SPADI Total % between assessments		
+100% to –13%	–14% to –89%	–90% to –100%
"Poor" clinical outcome	"Better" clinical outcome	"Excellent" clinical outcome
SPADI increased, same or increased by<MCID	SPADI decreased by >MCID but <90%	SPADI decreased 90–100%

SPADI: Shoulder Pain and Disability Index questionnaire; MCID: Minimal Clinically Important Difference (13 percentage points). Zero represents the 'best' score (no pain or disability) on the SPADI, and 100% represents the 'worst' score (maximum pain and disability).

Table II. *Variables retained for multiple regression modelling*

SPADI Total Score (%) at baseline
SPADI Pain Score (%) at baseline
Gender
History of asthma
Past history shoulder pain in the opposite shoulder
Pain aggravated when reaching across the body
Pain is eased or at best when at rest
Ability to sleep on affected side
Pain disturbs sleep
Pain described as constant (24/7)
Pain is referred below the elbow
SF-8 Vitality at baseline
SF-8 General Health score at baseline
SF-8 Physical Functioning score at baseline
SF-8 Physical Component score at baseline
SF-8 Mental Component score at baseline
Baseline VAS (mm) lowest level of pain
Baseline VAS (mm) mean level of pain
Baseline VAS (mm) highest level of pain
FABQ General Sub-score (%) at baseline
Frozen shoulder: Clinical diagnosis
Pain intensity with index pain tests carried out at 3-week follow-up assessment
Waist circumference (cm)
Thickening, fluid or calcification of the SAB on ultrasound imaging
Moderate or major rotator cuff tears as identified on ultrasound imaging
ACJ arthropathy of any sort seen on X-ray

SPADI: Shoulder pain and disability Index Questionnaire; SF-8: Short Form 8 question questionnaire; FABQ: Fear Avoidance Beliefs Questionnaire; VAS: visual analogue scale; SAB: subacromial bursa; ACJ: acromioclavicular joint.

Predictors of an excellent outcome at short term (3 weeks and 3 months) follow-ups (Table III)

With an excellent clinical outcome as dependent variable, higher baseline SPADI pain sub-score, pain not eased or best at rest, pain reported as intermittent (versus constant), lower SF-8 Mental Component score (21), smaller waist circumference, lower pain intensity with index tests at 3-week follow-up, and the absence of Subacromial Bursa (SAB) pathology seen on ultrasound, were retained in the final equation for the 3-week follow-up, with 82% of the cases being correctly classified. Intermittent pain, patient report of not being woken by pain and lower pain intensity with index tests at 3-week follow-up were retained in the final equation for the 3-month follow-up, with 72% of the cases being correctly classified.

Predictors of an excellent outcome at medium term (6 and 12 months) follow-up (Table IV)

Constant pain, higher baseline SF-8 Physical Functioning sub-score, higher baseline FABQ General sub-score (22) and evidence of acromioclavicular joint (ACJ) arthropathy on X-ray were retained in the final equation for the 6 month follow-up, with 67.5% of the cases being correctly classified. For the 12 month follow-up, higher baseline SPADI Pain sub-score, no history of asthma, pain eased or best when at rest, higher baseline SF-8 Physical Functioning sub-score and Physical Component scores, higher baseline FABQ General sub-score, male gender, no history of pain in the opposite shoulder, referral of pain below the elbow, patient report of pain disturbing sleep, smaller waist circumference, lower pain intensity with index tests at the 3-week follow-up, a clinical diagnosis of adhesive capsulitis at baseline, were retained in the final model with 81.7% of the cases being correctly classified.

DISCUSSION

The emergent predictive models offer insights into factors that may help primary care clinicians in management. Male gender, smaller waist circumference, pain referred below the elbow, pain eased or better at rest, disturbed sleep, lower pain responses at physical examination, and higher physical function scores at baseline suggest a better outcome at 12 months. The opposite pattern would suggest poorer prognosis.

The strongest predictors of an excellent outcome at 12 months were "pain eased or best at rest" (OR 10, 95% CI 2–48) and pain referred below the elbow (OR 27, 95% CI 3–225), both of which suggest that though pain may be more severe at baseline, there is a good probability of an excellent outcome over the medium or long term. These data may provide valuable reassurance to patients in whom high pain severity at baseline may be distressing, and potentially provide a prognostic indication of the slow time-frame for recovery for some patients.

Some factors like disturbed sleep and pain referred below the elbow seem counter-intuitively associated with an excellent outcome, but may represent a proportion of cases with conditions like adhesive capsulitis that generally have a good natural history over 12 months and a good response to corticosteroid injection, yet typically report pain behaviours that are disruptive at initial assessment.

Table III. *Results of multiple logistic regression analyses for an excellent clinical outcome at short term (3 weeks and 3 months) clinical outcomes*

	3 weeks			3 months	
Variable	OR (95% CI)	*p*-value	Variable	OR (95% CI)	*p*-value
SPADI Pain sub-score at Baseline	1.04 (1.00–1.08)	0.03	Pain is constant	2.50 (0.89–6.00)	0.08
Best or eased when at rest	0.06 (0.01–0.32)	0.00	Patient report of night pain (disturbs sleep)	0.36 (0.14–0.94)	0.04
Pain is Constant	0.14 (0.03–0.72)	0.02	Pain intensity of index pain test at 3 weeks	0.98 (0.97–0.00)	0.03
SF8 Mental Component Score Baseline	0.93 (0.85–1.01)	0.08			
Waist circumference (cm)	0.95 (0.90–1.00)	0.05			
Pain intensity of index pain test at 3 weeks	0.93 (0.89–0.96)	0.00			
Any SAB pathology (ultrasound)	0.12 (0.02–0.74)	0.02			

SPADI: Shoulder Pain and Disability Index Questionnaire; 95% CI: 95% confidence interval; SF8: Short Form 8 question questionnaire; SAB: subacromial bursa. OR: odds ratio.

Table IV. *Results of multiple logistic regression analyses for an excellent clinical outcome at medium term (6 and 12 months) clinical outcomes*

Variable	6 months Odds ratio (95% CI)	*p*-value	Variable	12 months Odds ratio (95% CI)	*p*-value
Pain is constant	2.71 (0.92–8.05)	0.07	Baseline SPADI Pain sub score	1.03 (1.00–1.07)	0.08
Baseline SF8 Physical Functioning Score	1.00 (1.02–1.18)	0.02	History of asthma	0.13 (0.02–0.96)	0.05
Baseline FABQ General Score (%)	1.03 (1.00–1.07)	0.08	Pain eased or best when at rest	10.01 (2.09–48.05)	0.00
Any ACJ pathology (X-ray)	3.67 (0.86–15.68)	0.08	Baseline SF8 Physical Functioning Score	1.14 (1.03–1.25)	0.01
			Baseline SF8 Physical Component Score	1.11 (1.01–1.22)	0.04
			Baseline FABQ General Score (%)	1.01 (1.03–1.17)	0.00
			Male gender	0.18 (0.04–0.90)	0.04
			History of pain in the opposite shoulder	0.07 (0.01–0.46)	0.01
			Pain referred below the elbow	26.78 (3.19–225.11)	0.00
			Patient report of night pain (disturbs sleep)	5.17 (0.91–29.39)	0.06
			Waist circumference (cm)	0.94 (0.90–0.99)	0.02
			Pain intensity of index pain test at 3 weeks	0.97 (0.95–0.1.00)	0.03
			Diagnosis Adhesive capsulitis at baseline	23.19 (0.63–856.47)	0.09

SPADI: Shoulder pain and disability Index Questionnaire; 95% CI: 95% Confidence Interval; SF-8: Short Form 8 question questionnaire; FABQ: Fear Avoidance Beliefs Questionnaire; cm: centimetre; VAS: visual analogue scale; ACJ: acromioclavicular joint.

Predictors of poor outcome

While the ability to predict a 'poor' clinical outcome is of considerable value to inform decision makers regarding early intervention including the use of additional investigations, pain relief interventions, specialist consultations, allied health involvement (e.g occupational therapy) and vocational services, there were only a small number of cases in the 'poor' outcome category for the variables retained in the prediction models. This made it difficult to identify strong predictors of this outcome from our cohort.

A history of previous problems in the opposite shoulder was negatively associated with an excellent outcome at 12 months and positively associated with a poor outcome, which may suggest some individual susceptibility to shoulder pathologies such as rotator cuff disease (23). This susceptibility may be environmental, occupational or genetic separately or in combination, but this study design cannot offer any insights in that regard.

Comparison with other studies

While this study is not the first to observe and analyse progress of primary care shoulder patients, there appears to be differences in the New Zealand population compared to European counterparts. The differences between the present analysis and the study by Kuijpers et al. (24, 25) are likely because of different durations between assessments, in baseline clinical assessment and a different mix of treatment options. In addition, the small number of cases with a poor outcome at follow-ups that survived the multiple regression modelling in the current data made some direct comparisons impossible.

Some of the differences between the the study by Kuipjers et al. and the current results relate to the predictive nature of psychosocial factors which we found to be only weakly associated to poor outcomes (18). However we did find that a higher baseline FABQ General sub-score was associated with excellent outcomes at 6- and 12-month follow-ups.

In the current data 42, 21 and 37% could be classified as acute (up to 6 weeks), subacute (7–12 weeks) and chronic (13

weeks or more), respectively, similar to the results by Kuijpers et al. However, duration of symptoms at baseline was not a significant determinant of outcome in our study. We also found male gender was associated with an excellent outcome at 12 months. Kuijpers et al. found that lower pain severity at baseline and initial physical examination were related to an excellent outcome at 3 months. We observed a similar construct except that higher SPADI pain sub-scores were associated with excellent outcomes at 3 weeks. Lower pain intensity reported with physical test procedures carried out at the 3-week follow-up emerged in the final models for excellent clinical outcomes at 3 weeks, 3 months and 12 months, but not at the 6-month follow-up. Physical testing was only carried out at baseline, 3-week and 12-month follow-up. The results suggest that the clinician may guage progress by recording pain intensity with testing of the most painful active movements, passive tests, isometric tests and special tests at each follow-up. If the early trend is for reducing pain with testing, a better prognosis seems likely, whereas if pain intensity remains high in the first 3 months, a poorer outcome at 12 months seems likely.

Imaging findings

With respect to X-ray and ultrasound image findings, an absence of SAB pathology survived to the final model for an excellent outcome at 3 weeks, and an X-ray finding of ACJ pathology was retained in the final model for an excellent outcome at 6 months. MR arthrograms were acquired for the subset of patients (45%) reporting less than an 80% pain relief from guided diagnostic injections to the SAB and ACJ, and variables representing imaged pathology were included in the initial analyses. No MR arthrogram-related variables survived to the final models, but it is highly probable that the low frequencies of various disorders in an already diminished sample is responsible for this analytic outcome. Further research is required where all patients receive MR arthrography to determine relationships between MR imaged pathology and outcome in primary care populations.

New information

Other variables not previously identified emerged as predictors of outcome, were no history of asthma and smaller waist circumference being associated with an excellent outcome at 12 months. There is evidence that increased central adiposity may have systemic effects on musculoskeletal pathology and degenerative conditions – more than could be expected consequent on increased load from increased bodyweight (26), and there is evidence that obesity is a risk factor in non-weightbearing joints such as the carpometacarpal joints (27). The shoulder is not a weight bearing joint either, so it may be that increased waist circumference (central adiposity) is a risk factor for rotator cuff tendinopathy in the same way as it appears to be for patellar tendinopathy (28).

The clinical diagnosis of adhesive capulitis produced an OR of 23 in relation to an excellent outcome at 12 months, but the wide 95% CI (0.63–856) reflects the small number of cases in the initial sample ($n = 9$). A different issue occurs in relation to the patient report of pain disturbing sleep at night where the OR is 5.1 (95% CI 0.91–29). The large 95% CI was due to a larger number of patients being misclassified by this particular logistic regression model as opposed to some of the models for other significant variables.

Limitations of the study

This follow-up study was not a randomized controlled trial, and cause and effect relationships cannot be inferred from our results. However, these results provide valuable observations on the outcome of primary-care patients with shoulder pain providing clinicians with information regarding factors associated with poor and excellent outcomes and what may be expected throughout a 12-month period with steroid injection (using strict criteria), exercise and manual therapy-based physiotherapy management. Apart from specific criteria for the use of corticosteroid injection, other treatment throughout the period from the 3-week and 12-month follow-ups was not controlled or accurately determined. The value of physiotherapy or influence of medication on outcomes could not be assessed. Further study of these factors is warranted.

It is acknowledged that although the sample size is respectable, the large number of potential predictor variables collected may limit the robustness of conclusions because of our selection criteria for inclusion in multiple regression models. The lack of data for some patients with poor outcomes at the different follow-up periods caused them to be rejected in the analysis, limiting ability to provide models for poor outcomes.

The choice of 90% reduction of pain and disability as the cut-off point for an excellent clinical outcome is necessarily arbitrary and another value such as 75 or 50% could have been chosen. However, the authors considered that the primary objective of treatment is complete or near complete recovery, certainly by 12 months following presentation to primary care. From this perspective, anything other than complete or near-complete recovery can be considered as unsatisfactory.

Conclusion

This study identified variables associated with excellent clinical outcomes at 12 months after presentation to mostly physiotherapists at primary care level in New Zealand. The nature of care was not standardized except for a clear protocol for selection of cases for corticosteroid injection followed by firm post-injection instructions. Pain eased or best at rest and pain referred below the elbow were the strongest predictors of an excellent outcome in the medium term. Only higher pain scores with physical testing at the 3-week follow-up emerged as a predictor of poor clinical outcome, and only at 3 months. Duration of symptoms prior to presentation and psychosocial distress issues did not seem to influence outcomes meaningfully, but severity of pain at initial assessment is relevant.

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