EXTENDED REPORT

Predicting poor functional outcome in community-dwelling older adults with knee pain: prognostic value of generic indicators

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Background: In longitudinal studies across a range of regional musculoskeletal pain syndromes, certain prognostic factors consistently emerge. They are "generic" in the sense that they appear to apply regardless of the particular anatomical site or underlying cause of the pain.

Objective: To investigate the value of generic indicators of poor functional outcome for knee pain and osteoarthritis in the community.

Methods: We conducted a population-based cohort study of adults aged ≥ 50 years with knee pain as part of the Clinical Assessment Study (Knee) (CAS(K)). At baseline, participants completed a postal questionnaire and attended a research clinic where they completed a further questionnaire and underwent structured physical examination and x rays. The 18-month follow-up was via a self-completed questionnaire. Risk ratios were calculated using Cox regression with a fixed time period assigned to each participant.

Results: In total, 60% of participants experienced a poor outcome at 18 months. Twelve univariate associations were associated with poor outcome, with four variables remaining in the multivariate model (older age, being overweight or obese, having possible or probable anxiety, and more severe pain). Using a simple unweighted additive risk score (1 point each for age ≥ 60 years, body mass index ≥ 25 kg/m², possible or probable anxiety, Chronic Pain Grade II–IV), 90% of participants with all four generic indicators were correctly classified.

Conclusions: This study has demonstrated that generic prognostic indicators can be used to determine the prognosis of older people in the community with knee pain.

Studies investigating predictors of outcome are important for guidance of clinical decision-making, improving the design and analysis of clinical trials, and better understanding of the processes of illness and disease.^{1–2} The emphasis on diagnosis in clinical practice has arguably led to a sense that pathology is the major determinant of prognosis.³ Although this may be true for certain conditions, it can obscure the fact that sometimes there are general characteristics that are stronger or more useful indicators of prognosis in practice. Musculoskeletal pain is one such example. In longitudinal studies across a range of regional pain syndromes, certain prognostic factors consistently emerge. High initial pain intensity, longer duration of symptoms, and anxiety and depression are associated with poorer clinical outcome up to 1 year after baseline for lower back, neck, hip and shoulder pain.^{4–8} These appear to be "generic" prognostic indicators in the sense that they apply regardless of the particular anatomical site of the pain. There are, however, substantial gaps in the evidence. Most previous studies of musculoskeletal pain prognosis have been based in working-age adults and have investigated "non-specific" regional pain disorders.

Joint pain in older people represents an opportunity to investigate this further in a clear underlying disease model: osteoarthritis (OA). If the same generic prognostic indicators were also useful in predicting clinical outcomes in this population, it would strengthen the argument for a core set of features to be assessed in patients presenting with musculoskeletal pain, which would be capable of predicting the likely outcome, irrespective of the site of pain, age of the patient or the nature of the underlying disease. We investigated the prognostic value of generic indicators in a large population-based prospective study of knee pain and OA in older adults.

METHODS

The Clinical Assessment Study of the Knee (CAS(K)) study is a population-based prospective observational cohort study of 819 symptomatic individuals, aged ≥ 50 years of age, registered with three general practices (irrespective of their actual consultation pattern). The study was approved by the North Staffordshire local research ethics committee. Full details of the study design and methods have been previously presented.^{9–11} Between August 2002 and September 2003, respondents to two postal questionnaires who reported knee pain in the previous 12 months were invited to attend a research clinic, where they were given a standardised clinical interview and examination and plain radiographs (weight-bearing posteroanterior (PA) semiflexed, and supine skyline and lateral views) of both knees were taken. A single reader blinded to clinical status scored all films. Radiographic OA was defined as Kellgren and Lawrence (K-L) score ≥ 2 (posterior–anterior view), a score which basically requires the presence of at least one definite osteophyte, and/or K-L score ≥ 2 (skyline view) and/or the presence of superior or inferior patella osteophytes (lateral view) and/or posterior tibial osteophytes (lateral view).¹² Participants were sent a postal follow-up questionnaire 18 months after their baseline clinic attendance.¹¹

Of the 819 participants attending the research clinics, 745 were eligible for inclusion in the current analysis (74 exclusions: total knee replacement in index knee (16), existing

Abbreviations: OA, osteoarthritis; BMI, body mass index; CAS(K), Clinical Assessment Study (Knee); Chronic Pain Grade, CPG; HAD, Hospital Anxiety and Depression; K-L, Kellgren and Lawrence; PF, physical functioning; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index

diagnosis of inflammatory disease in the medical records (hospital and general practice) (14), incomplete x ray data (12), no pain reported in the previous 6 months on attending clinic (32)). No further exclusions were made for the presence of other possible non-OA diagnoses (eg fibromyalgia).

Outcome measurement

The primary outcome was change between baseline and 18-month follow-up in the physical functioning (PF) scale of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).¹³ The WOMAC-PF is a disease-specific (hip or knee OA) self-report instrument with 17 items yielding a score between 0 (good function) and 68 (poor function). It has been extensively validated and is widely recommended for use in studies of individuals with knee and hip OA.¹⁴ We used an adapted version that instructed participants to rate their difficulty “due to knee pain”.¹⁵ This questionnaire was completed prior to clinic attendance (mean (SD) time lag 60 (33) days).

Using WOMAC-PF scores at baseline and 18-month follow-up, we applied the same definition of “poor outcome” as in a recent analysis by Sharma *et al*¹⁶ to allow for direct comparison. Baseline and 18-month WOMAC-PF scores were categorised into five groups (0–7, 8–14, 15–22, 23–33 and 34–68). For each participant, a good functional outcome at 18 months was defined as moving down one group compared with baseline or remaining in one of the two lowest groups. A poor functional outcome was defined as moving into a higher group or remaining within the three highest groups.¹⁶

Prognostic indicators

Baseline variables were selected as prognostic indicators on the basis of their potential to be used generically. These covered sociodemographic characteristics (age, gender, occupation, marital status, social networks¹⁷), lifestyle (alcohol consumption, smoking status), self-rated health (single item from the Short Form (SF)-12¹⁸), body mass index (BMI; kg/m²; measured in clinic), number of selected comorbid health conditions (diabetes, raised blood pressure, eyesight problems, deafness, heart and chest problems), anxiety and depression (Hospital Anxiety and Depression (HAD) Scale¹⁹), pain location (whole-leg pain and widespread pain recorded on a full body manikin²⁰), temporal characteristics of knee pain (speed of onset, mode of onset, time since onset, episode duration²¹ pain days in the previous 6 months²²), and knee pain severity (Chronic Pain Grade²³ (CPG), a measure that combines severity of both pain and the associated restriction of activity on a scale of I–IV, with IV being the highest severity level).

Statistical analysis

Univariate analysis identified prognostic indicators of poor functional outcome at 18 months using Cox regression with a fixed time period assigned to each participant. Results were presented as risk ratios (RR) with 95% confidence intervals (95% CI). Prognostic indicators identified from the univariate analysis with $p < 0.10$ were entered into a backwards stepwise Cox regression ($p_r \geq 0.05$, $p_e \leq 0.01$) to produce a multivariate model.

We conducted two sensitivity analyses. The first was to investigate whether the model was helpful in predicting “incident poor function” as opposed to simply identifying individuals who had high WOMAC-PF scores both at baseline and 18-month follow-up. To do this we refitted the Cox multivariate regression model only to those with low baseline WOMAC-PF scores (0–14) and poor functional outcome (defined as WOMAC-PF scores of ≥ 15 at 18 months). The second analysis investigated whether the data reduction and

potential misclassification involved in dichotomising functional outcome and reducing continuous prognostic indicators to categorical variables had resulted in an inaccurate portrayal of the relationship between functional outcome and prognostic indicators. We conducted multiple linear regression with WOMAC-PF at 18 months as the dependent variable, and the 11 prognostic variables associated with poor functional outcome in the univariate analysis described above. Continuous variables were used for age and body mass index, and HAD anxiety and depression subscale scores.

RESULTS

In total, 6108 people responded to the baseline questionnaire (adjusted response 69.7%), of whom 3106 reported having knee pain in last 12 months. The regional pain questionnaire was mailed to 2226 responders (who gave consent to further contact) with 1949 responding (adjusted response 87.7%). A total of 819 participants attended the research clinic (42.2%) and 776 participants completed the 18-month questionnaire (adjusted response 96.8%). There were 745 participants eligible for inclusion in this analysis. Of these, 708 responded at the 18-month follow-up, with 621 having complete WOMAC-PF data at baseline and 18-month follow-up.

A small overall decline in physical function was observed between baseline and 18-month follow-up (mean difference in WOMAC-PF score: 1.61, 95% CI 0.75 to 2.46). Functional score at follow-up was strongly related to functional score at baseline (fig 1).

In total, 372 (60%) participants were classed as experiencing poor functional outcome at 18 months. Poor functional outcome was strongly associated in univariate analyses with the following baseline characteristics: poor self-rated health at baseline (fair/poor vs excellent/very good: RR 1.97, 95% CI 1.43 to 2.72), obesity (BMI >30 kg/m² vs <25 kg/m²: RR 1.83, 95% CI 1.28 to 2.60), more persistent knee pain in the 6 months prior to baseline assessment (90+ pain days vs 1–30 pain days: RR 1.53, 95% CI 1.21 to 1.95), and more severe knee pain (CPG IV vs I: RR 1.75, 95% CI 1.27 to 2.41). Gender, alcohol

Figure 1 Functional scores at baseline and 18-month follow-up (markers indicate functional outcome dichotomised as good or poor as per Sharma *et al*¹⁶).

Table 1 Prognostic indicators of poor functional outcome at 18 months, univariate analysis

Prognostic indicator at baseline	Total, n	Poor outcome, n (%)	RR (95% CI)*	p Value
Age† (years)				
50–59	187	89 (47.6)	1	
60–69	257	170 (66.1)	1.39 (1.08 to 1.77)	0.012
70+	177	113 (63.8)	1.34 (1.02 to 1.77)	0.038
Gender†				
Female	338	216 (63.9)	1	
Male	283	156 (55.1)	0.86 (0.70 to 1.06)	0.16
Occupation†‡				
Non-manual	234	123 (52.6)	1	
Self-employed	41	22 (53.7)	1.02 (0.65 to 1.61)	0.93
Manual	314	209 (66.6)	1.27 (1.01 to 1.58)	0.038
Data missing	32	18 (56.3)		
Married/cohabiting†				
Yes	459	269 (58.6)	1	
No	154	98 (63.6)	1.09 (0.89 to 1.37)	0.48
Data missing	8	5 (62.5)		
Social network index†				
Low	83	44 (53.0)	1	
Medium	189	126 (66.7)	1.26 (0.89 to 1.77)	0.19
Medium-high	73	41 (56.2)	1.06 (0.69 to 1.62)	0.79
High	164	93 (56.7)	1.07 (0.75 to 1.53)	0.71
Data missing	112	68 (60.7)		
Alcohol†				
Daily	148	78 (52.7)	1	
1–2 times a week	215	130 (60.5)	1.15 (0.87 to 1.52)	0.34
1–2 times a month	113	73 (64.6)	1.23 (0.89 to 1.69)	0.211
1–2 times a year	90	58 (64.4)	1.22 (0.87 to 1.72)	0.25
Never	51	30 (58.8)	1.12 (0.61 to 1.70)	0.61
Data missing	4	3 (75.0)		
Smoking status†				
Never	266	151 (56.8)	1	
Previous smoker	280	172 (61.4)	1.08 (0.87 to 1.35)	0.48
Current	65	42 (64.6)	1.14 (0.81 to 1.60)	0.46
Data missing	10	7 (70.0)		
Body mass index§ (kg/m ²)				
Underweight/desirable (<25)	98	37 (37.8)	1	
Overweight (25–29.9)	276	165 (59.8)	1.58 (1.11 to 2.26)	0.011
Obese (30+)	246	169 (68.7)	1.82 (1.28 to 2.60)	0.001
Data missing	1	1 (100)		
Self-rated health†				
Excellent/very good	126	47 (37.3)	1	
Good	277	164 (59.2)	1.59 (1.15 to 2.20)	0.005
Fair/poor	211	156 (73.9)	1.98 (1.43 to 2.75)	<0.001
Data missing	7	5 (71.4)		
No. of selected comorbid health conditions†				
0	248	130 (52.4)	1	
1	233	146 (62.7)	1.20 (0.94 to 1.51)	0.14
2+	140	96 (68.6)	1.31 (1.01 to 1.70)	0.05
HAD Anxiety† (0–21)				
None (0–7)	380	194 (51.1)	1	
Possible (8–11)	160	114 (71.3)	1.40 (1.11 to 1.76)	0.005
Probable (12–21)	67	52 (77.6)	1.52 (1.12 to 2.07)	0.007
Data missing	14	12 (85.7)		
HAD Depression† (0–21)				
None (0–7)	506	283 (55.9)	1	
Possible (8–11)	70	51 (72.9)	1.30 (0.97 to 1.76)	0.082
Probable (12–21)	31	26 (83.9)	1.50 (1.00 to 2.24)	0.048
Data missing	14	12 (85.7)		
Chronic Pain Grades				
I	342	165 (48.2)	1	
II	169	113 (66.9)	1.39 (1.09 to 1.76)	0.008
III	53	46 (86.8)	1.80 (1.30 to 2.49)	<0.001
IV	57	48 (84.2)	1.75 (1.27 to 2.41)	0.001
Whole leg pain†				
No	548	326 (59.5)	1	
Yes	73	46 (63.0)	1.06 (0.78 to 1.44)	0.72
Widespread pain†				
No	379	221 (58.3)	1	
Yes	136	104 (76.5)	1.31 (1.04 to 1.66)	0.023
Data missing	106	47 (44.3)		
Days in pain§ (last 6 months)				
1–30	294	142 (48.3)	1	
31–89	158	104 (65.8)	1.36 (1.06 to 1.76)	0.016
90+	169	126 (74.6)	1.54 (1.21 to 1.96)	<0.001
Episode duration§				
<3 years	370	201 (54.3)	1	
≥3 years	251	171 (68.1)	1.25 (1.02 to 1.54)	0.03

Table 1 Continued

Prognostic indicator at baseline	Total, n	Poor outcome, n (%)	RR (95% CI)*	p Value
Sudden onset§				
No	426	269 (63.1)	1	
Yes	193	102 (52.8)	1.19 (0.95 to 1.50)	0.13
Ambiguous	2	1 (50.0)		
Onset following injury§				
No	526	315 (59.9)	1	
Yes	95	57 (60.0)	1.00 (0.75 to 1.32)	0.99
Time since onset§				
<1 year	69	29 (42.0)	1	
1–5 years	216	128 (59.3)	1.41 (0.94 to 2.11)	0.095
5–10 years	127	88 (69.3)	1.65 (1.08 to 2.51)	0.020
10+ years	209	127 (60.8)	1.45 (0.97 to 2.16)	0.073

HAD, Hospital Anxiety and Depression scale.¹⁹

*Crude risk ratio, 95% confidence interval.

‡Current occupation, or if no longer working, most recent occupation.

†Information collected from baseline health survey.

§Information gathered at clinic.

consumption, smoking, whole-leg pain and mode of onset at baseline were not associated with functional outcome at 18-months (table 1).

Of the remaining 12 variables with $p < 0.10$, widespread pain was not entered into the multivariate model because of high levels of missing data ($n = 106$). The multivariate model was conducted on 568 participants with complete data on the 11 indicators. Four indicators were retained in the final model and refitted to all 606 participants with complete data on these four indicators (table 2). The baseline indicators of poor functional outcome at 18 months were older age, being overweight or obese, having possible or probable anxiety, and more severe pain.

A simple non-weighted additive risk score (1 point each for age ≥ 60 years, BMI 25 kg/m^2 , possible or probable anxiety, CPG II–IV) was calculated to illustrate the range of absolute risk of poor functional outcome in relation to multiple risk factors. Of 20 participants with no risk factors, 3 (15%) experienced poor functional outcome. The numbers of participants in the current study with 1, 2, 3 and risk factors were 89, 218, 207 and 72, and the proportions experiencing poor functional outcome were 28%, 54%, 71% and 90%, respectively. Figure 2 shows that the relationship between risk-factor score and functional outcome was similar for those with and without

radiographic knee OA in the index knee. Individuals with radiographic OA and one or two risk factors appeared more likely to experience a poor functional outcome at 18 months, although the differences were non-significant.

In the subgroup analysis of 241 participants with low baseline WOMAC-PF scores, 68 (28%) reported WOMAC-PF scores of ≥ 15 at 18-month follow-up (table 3). The four prognostic indicators identified earlier were also strongly associated with this “incident poor function”: age (70+ vs 50–59 years: adjusted RR 3.45, 95% CI 1.61 to 7.37), BMI (30+ vs $< 25 \text{ kg/m}^2$: adjusted RR 3.63, 95% CI 1.40 to 79.40), HAD anxiety (probable vs none: adjusted RR 2.56; 95% CI 1.13 to 75.80), and CPG (IV vs I: adjusted RR 7.19; 95% CI 0.78 to 766.01).

DISCUSSION

This study confirms that generic factors previously found to be associated with poor outcome for a range of non-specific regional musculoskeletal disorders in working-age adults also predict poor functional outcome in a longitudinal study of older adults with knee pain. In our analysis, older age, being overweight or obese, anxiety and high initial pain intensity were indicative of functional decline or remaining significantly disabled 18 months later. Although these were the indicators

Table 2 Prognostic indicators of poor functional outcome at 18 months, multivariate analysis

Variable at baseline	Total, n	Poor outcome, n	Adjusted RR (95%CI)*	p Value
Age (years)				
50–59	181	84	1	
60–69	251	165	1.38 (1.06 to 1.80)	0.017
70+	174	110	1.44 (1.08 to 1.92)	0.014
Body mass index (kg/m^2)				
Underweight/normal weight (< 25)	97	36	1	
Overweight (25–29.9)	268	159	1.50 (1.04 to 2.15)	0.029
Obese (30+)	241	164	1.64 (1.14 to 2.38)	0.008
HAD anxiety (0–21)				
None (0–7)	379	193	1	
Possible (8–11)	160	114	1.34 (1.06 to 1.71)	0.015
Probable (12–21)	67	52	1.44 (1.04 to 1.98)	0.027
Chronic Pain Grade				
I	333	158	1	
II	167	111	1.34 (1.05 to 1.71)	0.023
III	53	46	1.55 (1.10 to 2.17)	0.013
IV	53	44	1.42 (1.00 to 2.03)	0.051

*Risk ratio, 95% confidence interval, adjusted for the variables listed
Hospital Anxiety and Depression scale.¹⁹

Figure 2 Absolute risk of poor functional outcome at 18 months by number of risk factors, stratified by presence or absence of radiographic knee OA.

with the strongest independent association with functional outcome, several other baseline factors (longer duration of pain, more persistent pain, depression, poorer general health) were also associated with poor functional outcome.

Relationship to previous studies

Our choice of candidate prognostic indicators was based on findings from previous studies of musculoskeletal pain and OA. Some (eg pain severity,^{24, 25} age,²⁵ anxiety²⁶) had previously been shown to be associated with self-reported function in cross-sectional studies. Being overweight or obese has been linked to the persistence or onset of significant functional difficulties in

adults with knee OA.^{16, 27, 28} Anxiety has been shown to be a significant risk factor for the progression of disability in older women²⁹ and is associated with self-reported knee pain in the community.³⁰

The CPG is a measure of pain severity and disability. These two factors have consistently been associated with a poor prognosis for knee pain.^{16, 31–33} In our study the increased risk of poor functional outcome was associated with CPG level II or greater. The common feature of these grades is high pain intensity.

In contrast to other research,³² knee trauma or injury was not a prognostic indicator in this analysis. We sampled prevalent, not incident, cases in the population and it is likely that any trauma or injury reported by participants as having occurred before the onset of their knee problem, often several years earlier, may no longer be relevant to the current course of their problem.

Strengths and limitations

These findings come from a large cohort with a very high follow-up rate at 18 months. Bias due to attrition is less of a concern than selective non-participation at the time of recruitment and missing data. Only a minority of potentially eligible individuals was recruited into the baseline research clinics. Although selective non-participation at baseline has been carefully investigated previously,¹¹ its effect on the prognostic relationships is difficult to estimate, and so caution is needed in generalising our findings to all adults aged ≥ 50 years with knee pain. Nevertheless, the WOMAC scores of participants at baseline are very similar to those obtained from a recent large population survey of people with knee pain.¹⁵ Furthermore, the proportion experiencing poor functional outcome at 18 months (60%) was similar to American cohort of Sharma *et al* at 3 years using the same definition (52%)¹⁶ and with a similar baseline distribution of age, BMI and WOMAC scores.

Missing data on both outcomes and prognostic indicators, particularly from the postal questionnaires, reduced the number of participants available for analysis. Having missing WOMAC-PF data was not associated with any of the prognostic indicators. However, missing manikin data meant that we were unable to include widespread pain in our multivariate model. The incidence of missing data was associated with a lower likelihood of poor functional outcome, suggesting that this item was more often missed in those without widespread pain. We feel that this remains a likely candidate for generic prognostic assessment. Studies on other anatomical areas^{34, 35} have found that widespread pain is often associated with a poor prognosis, and this should be considered in future work.

Entry criteria to this study were deliberately broad. Our findings appeared to hold whether radiographic evidence of OA was present or not. Many individuals without radiographic knee OA might nevertheless be expected to exhibit pre-radiographic disease.³⁶ To the extent that this is true, age, obesity, anxiety and pain severity indicate poor functional outcome even in this early stage of disease.

Our study is based on prevalent cases in the general population. One use of generic prognostic indicators for musculoskeletal disorders is to develop a simple generic assessment tool to assess the prognosis of older people with joint pain as part of routine consultation in primary care. Patients with a higher probability of experiencing a poor outcome could potentially be targeted at an earlier stage. We cannot be sure that our population-based findings will translate to estimating prognosis in the primary care consultation. However, the factors we identified are consistent with those found in a recent systematic review of prognostic indicators for

Table 3 Subgroup analysis: the multivariate model fitted to those experiencing incident disability at 18 months

Variable at baseline	Adjusted RR (95%CI)†	p Value
Age (years)		
50–59	1	
60–69	2.91 (1.44, 6.01)	0.003
70+	3.45 (1.61, 7.37)	0.001
Body mass index (kg/m ²)		
Underweight/normal (<25)	1	
Overweight (25–29.9)	2.29 (0.88, 5.94)	0.089
Obese (30+)	3.63 (1.40, 9.40)	0.008
HAD‡ Anxiety (0–21)		
None (0–7)	1	
Possible (8–11)	1.25 (0.68, 2.30)	0.476
Probable (12–21)	2.56 (1.13, 5.80)	0.024
Chronic Pain Grade		
I	1	
II	1.62 (0.93, 2.82)	0.086
III	2.68 (0.34, 21.52)	0.353
IV	7.19 (0.78, 66.01)	0.081

†Risk ratio, 95% confidence interval, adjusted for the variables listed.

‡Hospital Anxiety and Depression scale.¹⁹

Multiple linear regression analysis retained the same four prognostic variables as the Cox regression model (data not shown).

musculoskeletal pain in primary care³⁷ and this is currently being investigated in the PROG-RES study.³⁸

CONCLUSION

The convergence of findings from prognostic studies of various musculoskeletal disorders across the age ranges and in the presence of demonstrable disease points to a clear challenge: to dispense with the preponderance of site-specific "clinical prediction rules" and to move towards a core set of features for the assessment of all musculoskeletal pain. The latter may still highlight strongly site-specific, perhaps even disease-specific mechanisms to explain the variable course of musculoskeletal disorders (eg misalignment, joint laxity).^{16–39}

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