

STUDY PROTOCOL

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A study protocol for the profile of pain in older women: assessing the multi dimensional nature of the experience of pain in arthritis

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Abstract

Background: Arthritis is a significant contributor to illness, pain and disability and imposes a considerable burden upon the community. Pain is a cardinal symptom of arthritis and has significant implications on biopsychosocial wellbeing. The multidimensional nature of the experience of pain in arthritis has not been well defined in community-based samples.

Aims: The two aims of this study are to generate profiles of pain from a community sample of older women and to compare profiles for women with and without arthritis.

Methods: The sub study is a cross-sectional postal survey of 700 Australian community-based women. The survey includes a range of measures on health, arthritis and pain that will be used to examine the multidimensional nature of the experience of pain in arthritis and generate profiles of pain.

Discussion: With no core set of measures for the evaluation of arthritis pain, this survey was created from an amalgamation of measures to capture multiple dimensions of pain. Findings from this study will assist in defining the symptom of pain in arthritis and may lead to further research in evidence-based treatment options for people with arthritis.

Keywords: Research design, Cross-sectional studies, Health status, Arthritis, Pain

Background

Arthritis is a major contributor to individual illness, pain and disability and imposes a significant social and economic burden on the community [1]. Arthritis is common among older people, with at least 50% of people over the age of 65 having clinical arthritis [2]. Arthritis is also more common in women, with 50% of Australian women aged over 85 years reporting symptomatic osteoarthritis [3]. In 2005, 56% of Australians who reported arthritis as their main disabling condition reported chronic or recurrent pain [4]. Arthritis pain, whether acute or chronic, is the key disabling symptom of this disease [5].

Pain is an internal, subjective experience that cannot be directly observed by others and therefore assessment

relies upon self-report [6]. The experience of pain in arthritis is multi-dimensional in nature, encompassing dimensions such as intensity, quality, location, frequency, duration, variability, and trajectory; as well as onset, mechanism, aetiology, sensory and affective qualities, exacerbating or alleviating factors, activity limitations, and effect on sleep [7-11]. Biopsychosocial aspects such as biological ageing, attitudes, beliefs, coping, expectations, prior experiences, fear, mood, presence and response of social support, and social context are among the many variables that will influence an individual's experience and report of pain [10,12]. These dimensions and aspects of pain should be considered in the assessment of pain in people with arthritis. Notably Melzack and Casey defined three dimensions of pain: sensory-discriminative, affective-motivational and cognitive-evaluative [13,14]. Each dimension has differing neural circuitry involved in processing, with the nociceptive, limbic and frontal cerebral cortex involved in each dimension respectively

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[14]. This model for the dimensions of pain is widely accepted, and whilst termed in the 1960's, is still relevant to the experience of pain today.

The experience of pain in osteoarthritis is not well understood [15] nor captured by existing measures [16]. The assessment of osteoarthritis pain in clinical trials is mostly one dimensional, limited to the measure of pain intensity [17]. The Osteoarthritis Research Society International (OARSI) has invited further research into the experience of pain in arthritis [18]. Of interest is the mechanism of central sensitization and neuropathic pain in arthritis. Acute, painful activation of the nociceptive pain pathway instigates a cascade of inflammatory and hyperalgesic substances in the joint [19]. Repeated, persistent excitation results in the peripheral sensitisation of surrounding musculoskeletal structures [20], modifying neuronal activity arriving at the spinal cord dorsal laminae. This leads to altered gene expression and central sensitisation [21,22]. Central sensitisation causes increases in neuronal excitability and decreases inhibition of painful sensory input which results in altered responses of the nervous system [23,24]. Modulation of the sensory response can cause plasticity of the nervous system, and result in what is now being recognised as the occurrence of neuropathic pain in arthritis [25]. A subgroup of people with osteoarthritis have been recognised as having troubling persistent pain and lower pain thresholds, as well as experiencing enhanced duration and temporal summation of pain [25]. This study highlights local and central sensitization as important underlying pain mechanisms in the experience of pain in knee OA. Increased pin-prick hyperalgesia has also been shown in people with rheumatoid arthritis [26]. A psychophysical and functional magnetic resonance imaging of a cohort of people with hip osteoarthritis found significantly lower pain thresholds than the general population in response to noxious stimuli in referred pain areas [27]. Gwilym et al. demonstrated increased activity in the periaqueductal grey matter associated with pin-prick stimulus [27]. Such evidence advocates for further research on the role of neuropathic pain in the traditionally peripheral disease of arthritis. Research is warranted to investigate the multidimensional nature of the experience of pain, and findings may have significant implications for the improvement of pharmacological responses and therapeutic outcomes in people who have arthritis [28].

The two aims of this study are to generate profiles of pain from a community sample of older women and to compare profiles for women with and without arthritis. Factors associated with different profiles of pain will be identified and the role of arthritis as a modifier will be investigated. It is hypothesized that women will group into unique profiles based on their multidimensional experience of pain.

Methods

The Australian longitudinal study on womens health

ALSWH is a longitudinal population-based survey which has been studying the health of a national sample of over 40 000 Australian women since 1996. This survey examines the relationships between biological, psychological, social and lifestyle factors and women's physical health, emotional well-being and their use of and satisfaction with health care. Detailed methods for the recruitment and maintenance of the ALSWH cohorts have been described elsewhere [29,30] and are available at <http://www.alswh.org.au>.

Profile of pain in older women Sub study

ALSWH participants are often invited to answer additional surveys between the major three yearly surveys. These smaller, separately funded sub studies have specific aims to investigate particular areas of health beyond the questions asked in the main surveys. The sample for this sub study consists of community-based women from the 1946–1951, mid aged cohort. Arthritis was found to be common in this group, with 32% of women reporting arthritis in 2006 when they were aged between 55–66 years [31]. In 2010, when the mid-aged cohort was aged between 59–64 years 17.9% of women reported osteoarthritis, 4.7% reported rheumatoid arthritis and 13.3% reported 'other' arthritis [32]. In 2012, at the time of the sub study survey, women from the mid-aged cohort will be aged 61–66 years.

A postal survey will be sent to two sub-samples of the 1946–51 cohort. One subsample will consist of 350 random women who answered 'yes' to "arthritis/rheumatism", for the item "In the past THREE years, have you been diagnosed or treated for:" in ALSWH Survey 3 (2001) or ALSWH Survey 4 (2004). The other subsample will consist of 350 random women who have never reported any form of arthritis in ALSWH Surveys 3–6 (2001–2010). An information letter and survey will be sent to women; those who wish to participate are instructed to provide written consent, complete the survey and return it to the ALSWH office. The survey materials will be scanned and stored electronically at the University of Newcastle, Australia.

Profile of pain in older women Sub study survey

The survey will use measures of health, arthritis and pain as recommended by international bodies OARSI and Outcome Measures in Rheumatology (OMERACT) [15,18,33-41], and reports from expert panels [12]. The measures and their appropriateness for inclusion are discussed below (see Table 1).

Health measures

Health measures include the Medical Outcomes Study: 36 Item Short Form Survey (SF-36), Health Assessment

Table 1 Health, arthritis and pain measures used to assess multiple dimensions of pain in arthritis in this study

Measure		Dimensions of pain
Health measures	Medical Outcomes Study: 36 Item Short Form Survey [42]	General health, role emotional, mental health, social functioning, vitality, mental health
	Heath Assessment Questionnaire [47]	Functional disability
	Fatigue Severity Scale [51]	Fatigue
Arthritis specific measures	Western Ontario and MacMaster Universities Arthritis Index [52]	Pain severity in hip and knee arthritis
	Australian/Canadian Osteoarthritis Hand Index [54]	Pain severity in hand arthritis
	quickDASH [58]	Pain severity in upper limb
Pain measures	Brief Pain Inventory [64]	Pain severity
		Mood
		Relations
	McGill Pain Questionnaire - Short Form [59]	Sleep
		Interference
		Sensory qualities
	Chronic Graded Pain Scale [72]	Affective qualities
		Pain intensity
		Severity of chronic pain
Pain Catastrophizing Scale [67]	Duration	
	Catastrophizing	
PainDETECT [73]	Neuropathic qualities	
	Course and variability	

Questionnaire (HAQ) and Fatigue Severity Scale (FSS). The SF-36 is a self-report, 36 item survey measuring health-related quality of life [42], recommended where a detailed and broad ranging assessment of health is required. It is specifically applicable for this study as it will examine changes in health status over time [43]. The HAQ is the most widely used general functional measure in rheumatology [44,45], specifically developed for use among adults with arthritis [46,47]; it shows a strong correlation with physical capacity in older adults [48], and is supported for use in observational studies [44]. The FSS measures the impact of fatigue in a variety of rheumatologic and neurologic disorders [49,50], and will enable comparison of fatigue symptomatology in populations of older women with arthritis [51].

Arthritis measures

Arthritis specific measures in the sub study survey include the Western Ontario and McMaster Universities Arthritis Index (WOMAC), Australian/Canadian (AUSCAN) Osteoarthritis Hand Index and the quickDASH. The WOMAC assesses health status and health outcomes in women who have arthritis of the knee and/or hip [52]. It is a health measurement tool which is valid, reliable and responsive, easy to complete and simple to score [53]. The AUSCAN Osteoarthritis Hand Index and quickDASH (Disabilities of the Arm, Shoulder and

Hand) will assess health status and health outcomes in arthritis of the upper limb (shoulder, elbow, wrist and hand) [54-59].

Pain measures

Pain measures will include the McGill Pain Questionnaire (Short Form) (SF-MPQ), Brief Pain Inventory (BPI), Pain Catastrophizing Scale (PCS), Graded Chronic Pain-Primary Care Scale (GCP-PCS) and the painDETECT. The SF-MPQ is a short form of the McGill Pain Questionnaire that will be used to assess the affective and sensory qualities of arthritis pain [60]. It is the most widely used, accepted and comprehensive assessment of the pain experience in older persons [12,61-63]. The BPI allows patients to rate the severity of their pain and measure pain severity and interference on daily activities, including sleep [64]. First versions were developed for patients with rheumatoid arthritis [65], and reliability, validity and responsiveness has since been confirmed for patients with osteoarthritis [66-68]. The BPI is a measure recommended by an interdisciplinary consensus of experts to measure pain [12,62]. The PCS was developed to assess three components of catastrophizing: rumination, magnification, and helplessness [69]. Pain catastrophizing is significantly related to pain outcomes in patients with rheumatoid arthritis [70], osteoarthritis [71] and neuropathic pain [72], with higher scores

predicting chronicity [73]. The GCP-PCS will be used to obtain measures of chronic pain intensity, interference with activities and pain duration, as well as an ordinal classification of chronic pain severity [74]. The painDETECT has been selected as a measure of neuropathic pain components. It was initially developed and validated in 8000 low back pain patients [75] and has been used in studies for arthritis [27,76-79].

Dimensions of pain

The measures of health, arthritis and pain have also been chosen to assess the multi-dimensional nature as pain as defined by Melzack and Casey [13,14]. Sensory-discriminative dimensions of pain to be assessed include the location, intensity, severity, sensory and affective qualities, duration, course or variability and frequency. Affective-motivational dimensions of pain to be assessed include mood, catastrophizing, fatigue, interference and affect on sleep. Cognitive-evaluative dimensions of pain to be assessed include role social and role emotional. The measures used to assess these dimensions can be seen in Table 1.

The Australian longitudinal study on womens health linked data

For all consenting women, data from ALSWH Survey 6 (2010) will be accessed and linked to the sub study survey data. Linked survey information will include: body mass index; care information; cognition; conditions and comorbidities; demographic information; education and employment; health care utilization; health measures; life satisfaction; lifestyle choices; marital status; medical history; medication use; physical activity; psychological wellbeing; residency and retirement; social ability; and stiff and painful joint data.

Statistical analysis

Descriptive statistics will be used to characterize the demographic, health and pain characteristics of women with and without arthritis, and groups will be compared with χ^2 tests and t tests as appropriate. Descriptive profiles of pain will be generated across the sample using latent class analysis. Associations between risk factors and health, arthritis, and pain profile will be evaluated by appropriate regression methods.

Ethics, funding and dissemination

This study was approved by the Human Research Ethics Committee of the University of Newcastle; Approval number: H-2012-0144. Funding for this project was competitively gained through peer-review from Hunter Medical Research Institute. The findings of the study will be disseminated through peer-reviewed journals, national and international conference presentations.

Discussion

This is a large, cross-sectional sub study of 700 older women that will gather data on the multi-dimensional nature of the experience of pain in arthritis. With no core set of measures to evaluate the spectrum of arthritis pain beyond intensity and disability [18] this study amalgamated measures to capture individual dimensions of pain needed to describe different profiles of pain. Whilst intensity is the most common dimension of pain measured, it is important to measure the different qualities of pain. While focus groups have begun to analyze pain qualities in people with osteoarthritis, with several different studies reporting various descriptors of pain [7,79-81], pain quality has not been assessed in population based studies of arthritis. This study will use stand-alone measures of pain, the SF-MPQ and painDETECT, to assess the sensory, affective and neuropathic qualities of pain. Dimensions other than intensity, severity and quality will also be explored. Previous studies have identified constant and intermittent pain, [15] the impact of beliefs on pain [82] and coping strategies, impact and severity perceptions) [7]. This study will use measures to assess pain onset and frequency, course or variability, fatigue, catastrophizing, sleep, social relations and the role of emotion. Multiple dimensions of pain are to be explored and analyzed, and these dimensions will be taken into consideration to group women to define "profiles" of pain. Recent work has investigated the psychological profiles in persons with knee osteoarthritis and found homogenous profiles with unique sets of characteristics [83]. Women with arthritis may also group into unique profiles based on their multidimensional experience of pain. This would be the first time.

Conclusion

This study will investigate the multi-dimensional nature of the experience of pain in arthritis using a sub study survey of a large cohort of older, community based women in Australia. With no core set of measures for the evaluation of arthritis pain, this survey was created from an amalgamation of measures of health, arthritis and pain to capture multiple dimensions of pain. It will allow generation of profiles of pain in community dwelling older women, and comparisons will be made between women with and without arthritis. Findings from this study will assist in defining the disease state of arthritis and may lead to further research in evidence-based treatment options for people with arthritis.

Abbreviations

ALSWH: Australian Longitudinal Study on Womens Health survey; AUSCAN: Australian/Canadian Osteoarthritis Hand; BPI: Brief pain inventory; FSS: Fatigue severity scale; GCP-PCS: Graded chronic pain-primary care scale; HAQ: Health Assessment Questionnaire; OARSI: Osteoarthritis Research Society International; OMERACT: Outcome measures in rheumatology; PCS: Pain catastrophizing scale; SF-36: Medical Outcomes Study: 36 Item

Short Form Survey; WOMAC: Western Ontario and MacMaster Universities Arthritis Index.

Competing interests

The authors declare that they have no competing interests.

Authors' contribution

KD, LP and JB contributed to the conception of the project, design of the study and drafted the manuscript. All authors read and approved the final manuscript.

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