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Systematic review

Measurement properties of patient-reported outcome measures (PROMS) in Patellofemoral Pain Syndrome: A systematic review

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ABSTRACT

This systematic review investigated the measurement properties of disease-specific patient-reported outcome measures used in Patellofemoral Pain Syndrome. Two independent reviewers conducted a systematic search of key databases (MEDLINE, EMBASE, AMED, CINHAL+ and the Cochrane Library from inception to August 2013) to identify relevant studies. A third reviewer mediated in the event of disagreement. Methodological quality was evaluated using the validated COSMIN (Consensus-based Standards for the Selection of Health Measurement Instruments) tool. Data synthesis across studies determined the level of evidence for each patient-reported outcome measure. The search strategy returned 2177 citations. Following the eligibility review phase, seven studies, evaluating twelve different patient-reported outcome measures, met inclusion criteria. A 'moderate' level of evidence supported the structural validity of several measures: the Flandry Questionnaire, Anterior Knee Pain Scale, Modified Functional Index Questionnaire, Eng and Pierrynowski Questionnaire and Visual Analogue Scales for 'usual' and 'worst' pain. In addition, there was a 'Limited' level of evidence supporting the test–retest reliability and validity (cross-cultural, hypothesis testing) of the Persian version of the Anterior Knee Pain Scale. Other measurement properties were evaluated with poor methodological quality, and many properties were not evaluated in any of the included papers. Current disease-specific outcome measures for Patellofemoral Pain Syndrome require further investigation. Future studies should evaluate all important measurement properties, utilising an appropriate framework such as COSMIN to guide study design, to facilitate optimal methodological quality.

1. Introduction

Patellofemoral Pain Syndrome (PFPS) is a common knee disorder, with a typical pattern of symptoms characterised by anterior peripatella or retropatella knee pain (Heintjes et al., 2009; Collins et al., 2010; Hossain et al., 2011). Aggravating factors include activities or movements which either increase patellofemoral joint compression and/or produce mechanical forces in the surrounding soft tissue structures; for example: ascending/descending stairs, sitting with a flexed knee for prolonged periods, squatting, running, jumping or kneeling (Witvrouw et al., 2000; Crossley et al., 2002; Barton et al., 2008; Thijs et al., 2008; Tan et al., 2010). As many of these activities are an important part of daily life, PFPS may have a considerable impact on an individual's wellbeing (Collins et al., 2008; Tan et al., 2010). This impact may be especially debilitating as PFPS symptoms often reoccur, becoming chronic (Nimon et al., 1998; Stathopulu and Baildam, 2003; Collins et al., 2008; Boling et al., 2010).

Whilst the aetiology of PFPS is debated, there is some consensus that its development may be secondary to a functional or structural mal-alignment at the patellofemoral joint, or of the lower extremity as a whole (Powers, 2003; Barton et al., 2008; Heintjes et al., 2009; Carry et al., 2010; Hossain et al., 2011). There may be multiple interacting factors which cause mal-alignment, such as muscle strength or timing issues, altered tissue extensibility or bony morphology (Powers, 2003; Barton et al., 2008; Heintjes et al., 2009; Bennell et al., 2010).

Physiotherapy is the most common intervention in PFPS (Crossley et al., 2001; Heintjes et al., 2003), however, there is no clear consensus regarding the optimal components of a management programme. As a consequence, a wide variety of treatment techniques are employed by therapists including: quadriceps

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strengthening, vastus medialus obliques (VMO) muscle retraining, biofeedback, hip muscle strengthening, proximal strengthening, spinal manipulation, mobilisation, taping, knee supports, foot orthoses and stretching of the hamstrings, illiotial band, patella retinaculum or anterior hip (Crossley et al., 2002; Iverson et al., 2008; Heintjes et al., 2009; Earl and Hoch, 2011; Hossain et al., 2011; Callaghan and Selfe, 2012). In the absence of guidelines outlining the most favourable PFPS treatment options, physiotherapists should appraise their own management, utilising high quality, disease-specific, PFPS outcome measures to guide and evaluate patient care, so they may deliver efficacious treatment tailored to the individual (DoH, 2010; CSP, 2012; HCPC, 2013).

A number of patient-reported outcome measures (PROMs) have been developed to assess symptoms and function in patients with PFPS. These disease-specific measures are designed to be more sensitive to change in their target population than region-specific measures, which evaluate general knee disorders. When making the choice of which PROM to use in practice, it is important to examine their respective measurement properties, so that the optimal instrument can be confidently employed. These properties should at least satisfy existing minimum standards for PROMs, such as those presented by the International Society for Quality of Life research (Reeve et al., 2013). Previous systematic reviews that have evaluated the measurement properties of knee PROMs, have tended to focus on region-specific measures used in general knee conditions (Bellamy et al., 1997; Sun et al., 1997; Wang et al., 2010), or non-PFPS-specific musculoskeletal disorders (Smith et al., 2008; Howe et al., 2012), and not all reviews have used a validated tool to determine the quality of the included studies, for example, the COSMIN (Consensus-based Standards for the Selection of Health Measurement Instruments) tool (Mokkink et al., 2010a) or OMERACT (Outcome Measures in Rheumatology) filter (Boers et al., 1998). The purpose of this study was to evaluate the measurement properties of disease-specific PROMs for PFPS, using a validated measure of methodological quality.

2. Methodology

2.1. Design

A systematic review of outcomes was conducted according to a pre-defined protocol informed by the PRISMA guidelines (Liberati et al., 2009), the Cochrane Handbook of Systematic Review Interventions (Higgins and Green, 2011) and the COSMIN group (Mokkink et al., 2010b).

2.2. Search strategy

The MEDLINE, EMBASE, AMED, CINHAL+ and Cochrane Library electronic databases were searched from inception to August 2013 (the MEDLINE search strategy is presented in Appendix I). All records were downloaded into Endnote© version 15, and duplicates removed. Two authors (DK, CL) independently screened all citations by title/abstract, before retrieving potentially eligible full text articles for review. Disagreements were resolved through discussion, with a third reviewer on hand to mediate if required. The strength of agreement between investigators was established using Cohen's kappa statistic (Cohen, 1960) and interpreted using set criteria (Landis and Koch, 1977). Remaining articles were subjected to a citation search. Finally, a hand-search of all reference lists was conducted.

2.3. Identification of eligible studies

Full text original articles were included if they evaluated at least one PROM measurement property (reliability, validity, responsiveness or interpretability (Mokkink et al., 2010a)) in a cohort of PFPS patients. There are no universally agreed diagnostic criteria for PFPS, therefore, this review used criteria employed by several high-quality randomised controlled trials, each demonstrating treatment efficacy in a PFPS cohort (Collins et al., 2008; van Linschoten et al., 2009; Collins et al., 2010). Thus, studies had to include participants that presented with a main complaint of patellofemoral pain (defined as anterior peripatellar or retropatellar knee pain) with symptoms that were provoked by at least two of the following: prolonged sitting or kneeling, stair walking, running, squatting, hopping, a positive Clarke's sign or grind test, a positive patellar compression test and recognisable painful symptoms on palpation of the patellar facets (Collins et al., 2008; Syme et al., 2009; van Linschoten et al., 2009). Internationally agreed definitions for each measurement property Mokkink et al. (2010a) informed the eligibility review. Non-English language papers were excluded.

2.4. Data extraction

Two authors (AG, CL) independently extracted data regarding the following measurement properties: reliability, internal consistency, measurement error, validity (including content, construct, criterion and cross-cultural validity), responsiveness and interpretability (Mokkink et al., 2010a). Disagreements were resolved through discussion with the intervention of a third author (DK) if needed.

2.5. Measurement properties

Reliability examines the degree to which a measurement is free from error, and can be considered in three categories: test–retest reliability (the degree to which results can be replicated over time within a stable environment), this can be further divided into inter-rater reliability (between individuals) and intra-rater reliability (within the same individual); internal consistency (correlation between items that are interrelated); and measurement error (systematic and random error within a patient's outcome score that is not attributed to a true change) (Mokkink et al., 2010b). Validity encompasses: content validity (is the PROM an adequate reflection of the construct to be measured); construct validity (how a PROM performs against pre-defined hypotheses); criterion validity (how a PROM compares to a 'gold standard' if available); and cross-cultural validity (how well the translated PROM reflects the original version) (Mokkink et al., 2010b). Responsiveness is the ability of an outcome measure to detect a clinically meaningful change in a patient's condition over time (Mokkink et al., 2010b). In addition, a PROM must demonstrate adequate interpretability, to ensure that the meaning and significance of changes in score can be easily understood (Mokkink et al., 2010a).

2.6. Quality assessment and evidence synthesis

Methodological quality of the included studies was evaluated in order to determine their trustworthiness. Two investigators (AG, CL) independently assessed each study, rating the quality of methods employed to evaluate individual measurement properties, using the validated COSMIN framework (Mokkink et al., 2010a). Disagreements were resolved through discussion with a third author (DK). Papers were rated using a 4-point scale ('poor', 'fair', 'good', 'excellent') (Terwee et al., 2012). Synthesis across studies combined findings for each measure and measurement property, taking into account the quality of studies, to determine the level of evidence for each PROM (Schellingerhout et al., 2012). The overall level of evidence was rated as 'strong', 'moderate', 'limited' or

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