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Background

Kyphosis derives from the Greek “Kyphos,” meaning “hunchback,” and represents the natural curving of the thoracic spine. It refers to a deformity which can be caused by at least one vertebral compression fracture secondary to osteoporosis (OVCF). Kyphosis also results in well documented symptoms and has an impact on functioning and well-being.

There is an estimated prevalence of 2.5 million persons >50 years old with OVCF in Europe. The burden of OVCF is 246’000 quality-adjusted-life-years lost and an annual cost of €1.5 billion (France, Germany, Italy, Spain, and UK combined).

Current assessment of health outcomes of interventions to treat OVCF-related kyphosis concentrates on consequences of back pain, omitting relevant aspects of increased morbidity.

A three-part study led to the development of a conceptual measurement framework for comprehensive assessment of symptoms, impact, and treatment benefits in kyphosis.

Methods

A literature-based (PubMed, Medline) Disease Model (DM) was developed for selecting and developing kyphosis outcome measures, as recommended by regulatory agencies.

In-depth interviews were then conducted among physicians (n=10) and patients (n=10) to test the DM. Physician respondents were either primary care physicians (PCPs) or specialists treating patients with OVCF-related kyphosis. Patient respondents were >50 years old with an OVCF >= 90 days prior.

Results of these in-depth interviews were used to revise the DM and develop a Conceptual Framework to guide selection of endpoints for future studies.

Results: DM Changes

Summary of changes based on physician interviews

- Differentiate deformity associated with kyphosis in terms of changes to vertebrae from changes to shape of the spine overall [signs]
- Clarify “grade/severity” rather than “type” of fracture as an exacerbating factor [signs]
- Delete “neurological deficit” [signs]
- Add “neck pain/mobility” [symptoms]
- Delete “gender” [exacerbating factors]
- Delete “physical function” and “impaired coordination” (NOTE: latter confirmed in patient interviews) [impact – physical]
- Delete “sleep problems,” “anxiety,” and “loss of control” (NOTE: these were contradicted by patient data) [impact – emotional]

SAMPLE QUOTE ON CHANGED CONCEPT TO “GRADE/SEVERITY OF FRACTURE”:

“...grade or severity (change description)...rather than type because type of fracture, in my mind it’s a crushed vertebral fracture compared to a fracture of the posterior part of the vertebrae.” [P5]

Summary of changes based on patient interviews

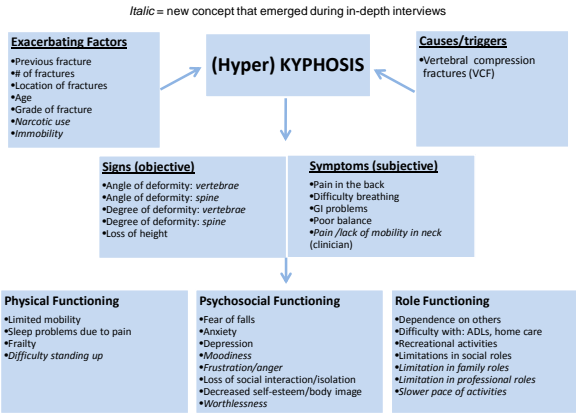
Note: Patients were not interviewed on Signs, Causes, or Exacerbating Factors. Comments already mentioned above are not repeated.

- Add “difficulty standing” [impact – physical]
- Add “slower pace of doing activities,” “limitations in family roles,” and “limitations in professional roles” [impact – role]
- Add “moodiness,” “frustration,” and “diminished self-worth” [impact – emotional]

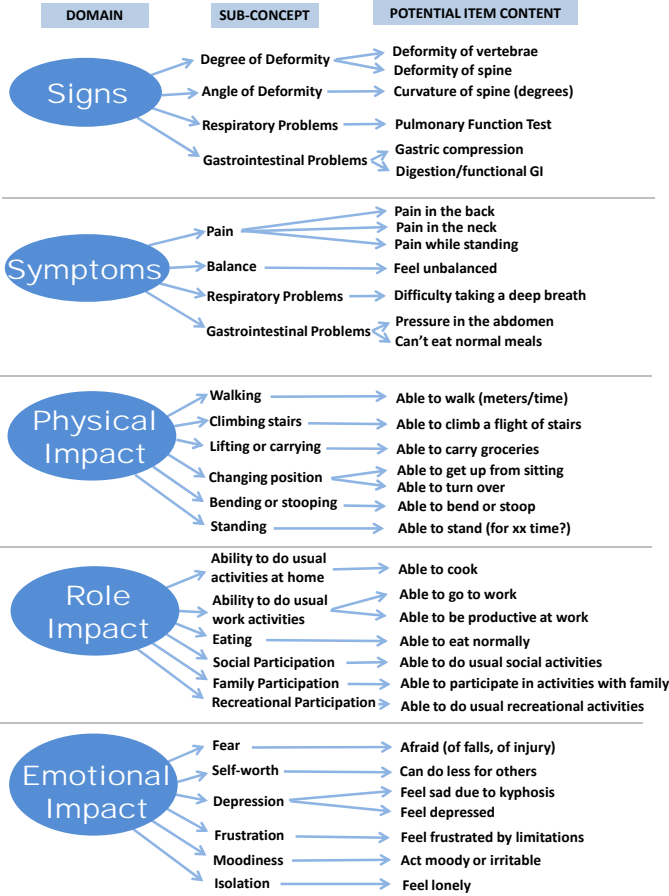
SAMPLE QUOTE ON EMERGING CONCEPT OF “FEELINGS OF WORTHLESSNESS”:

“...because I was always the type to help people and stuff like that I feel worthless right now because I can’t help people the way I used to.” [T1N]

Results: Final Disease Model



Results: Conceptual Model



Discussion

The DM included signs, symptoms, causes/triggers, exacerbations, and functional/well-being impact of kyphosis.

The DM content was largely confirmed by both physicians and patients. However, patients offered new concepts of emotional and functional impact, while physicians discounted psychosocial concepts (well-being and sleep impairment) and added clinical evaluations of spinal deformity.

Related to these findings, PRO instruments lacked adequate content validity or measurement properties for evaluating kyphosis outcomes. Close matches were the IOF Quality of Life questionnaire (Qualeffo-41) and the Osteoporosis Assessment Questionnaire (OPAQ), though neither includes gastrointestinal or respiratory symptoms.

Conclusions

This study confirms the need for more comprehensive assessment of health outcomes in kyphosis. Synthesizing patient and physician perspectives with published literature demonstrates that current approaches to evaluating kyphosis omits key concepts.

A comprehensive evaluation of the severity and impact of kyphosis requires clinical evaluation (ClinRO) of spinal deformity, respiratory, and GI problems; and patient evaluation (PRO) of symptoms – spinal, respiratory, GI – and functional impact.