Content validity of patient-reported outcome measures (PROMs) used in women with childbirth perineal trauma : A systematic review (#573)

Billy Cho[1], Isabelle Legood[1], Stergios K Doumouchtsis[1,2,3,4,5]

[1] St George's University of London, Crammer Terrace, London, SW17 0RE, United Kingdom, [2] Department of Obstetrics and Gynaecology, Epsom & St Helier University Hospitals NHS Trust, London, KT18 7EG, United Kingdom, [3] Laboratory of Experimental Surgery and Surgical Research N.S. Christeas, Athens University Medical School, Athens, Greece, [4] American University of the Caribbean, School of Medicine, [5] Ross University, School of Medicine

Abstract

Hypothesis : There is inconsistency in the use of patient-reported outcome measures (PROMs) in clinical trials. This leads to research waste. The objective of this study was to assess the content validity of commonly used PROMs in women with childbirth perineal trauma.

Methods : A systematic review of clinical trials using PROMs in women with childbirth perineal trauma. EMBASE, Medline, PsychInfo and Google Scholar databases were searched. The COSMIN criteria were applied.

Results : Three development studies were retrieved (Cleveland Incontinence Clinic Scale, McGill Pain Questionnaire, Fecal Incontinence Quality of Life Scale). No content validity studies on PROMs were found.

Conclusion : There is limited evidence surrounding the content validity of PROMs used in women with childbirth perineal trauma.

Introduction

Childbirth perineal trauma affects approximately 80% of women worldwide[1] and can be associated with significant long-term morbidity. PROMs aim to assess patient-reported outcomes (PROs) however, reporting of PROMs and PROs has been inconsistent in clinical trials so far.

The Consensus-based Standards for the Selection of Health Measurement INstruments (COSMIN) taxonomy underlines three domains in the validation process of PROMs : validity, reliability and responsiveness. Each domain is further subdivided. Content validity is considered the most important parameter[2].

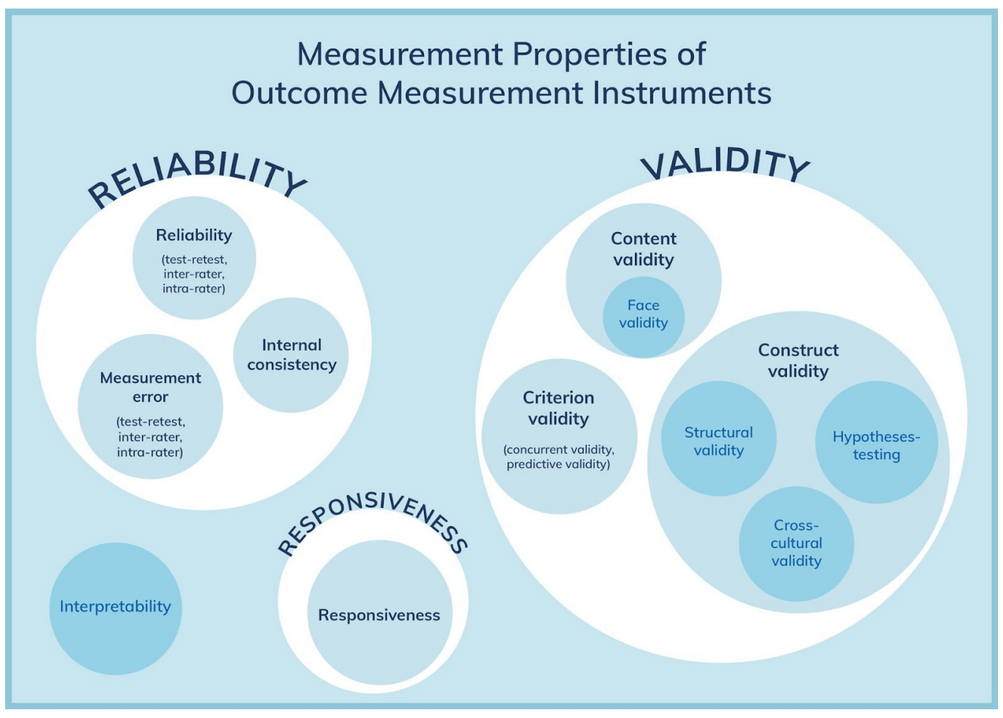
We aimed to systematically review based on the COSMIN methodology and examine the content validity of commonly used PROMs in trials on women with childbirth perineal trauma[4,5].

This study is part of a wider research programme led by CHORUS, an International Collaboration for Harmonising Outcomes in Research, and Standards in Urogynaecology and Women's Health aiming to develop core outcome sets and core outcome measures sets in various areas of pelvic floor disorders including childbirth perineal trauma.

Methods and Materials

- Adapted MeSH terms[2] and Terwee filters[3]
- Five most commonly used PROMs[3]
  - Visual Analogue Scale 0-10
  - Visual Analogue Scale 0-100mm
  - Cleveland Incontinence Clinic Score
  - McGill Pain Questionnaire
  - Fecal Incontinence Quality of Life Scale
- Databases : EMBASE, MEDLINE, PsychInfo, Google Scholar (from inception to January 2022)
- Selection criteria : perineal trauma of any degree acquired during childbirth, availability of the full text of the original paper, English language, studies concerned with the cross-cultural adaptation of a PROM
- COSMIN criteria
- No patient involvement

Table 1. COSMIN taxonomy of measurement properties[2]



Results

A total of 10,827 papers were identified across three databases (EMBASE, MEDLINE, PsychoInfo). After applying additional limits, 10,464 papers were excluded. A further 61 papers were excluded after deduplication. This was further narrowed down to 302 papers. The titles were screened and checked against the inclusion criteria, but none were eligible. A hand-search on Google Scholar was performed for potential eligible papers.

The development studies for three of the five most used PROMs were retrieved (Cleveland Incontinence Clinic Scale, McGill Pain Questionnaire, Fecal Incontinence Quality of Life Scale). No content validity studies on PROMs were located.

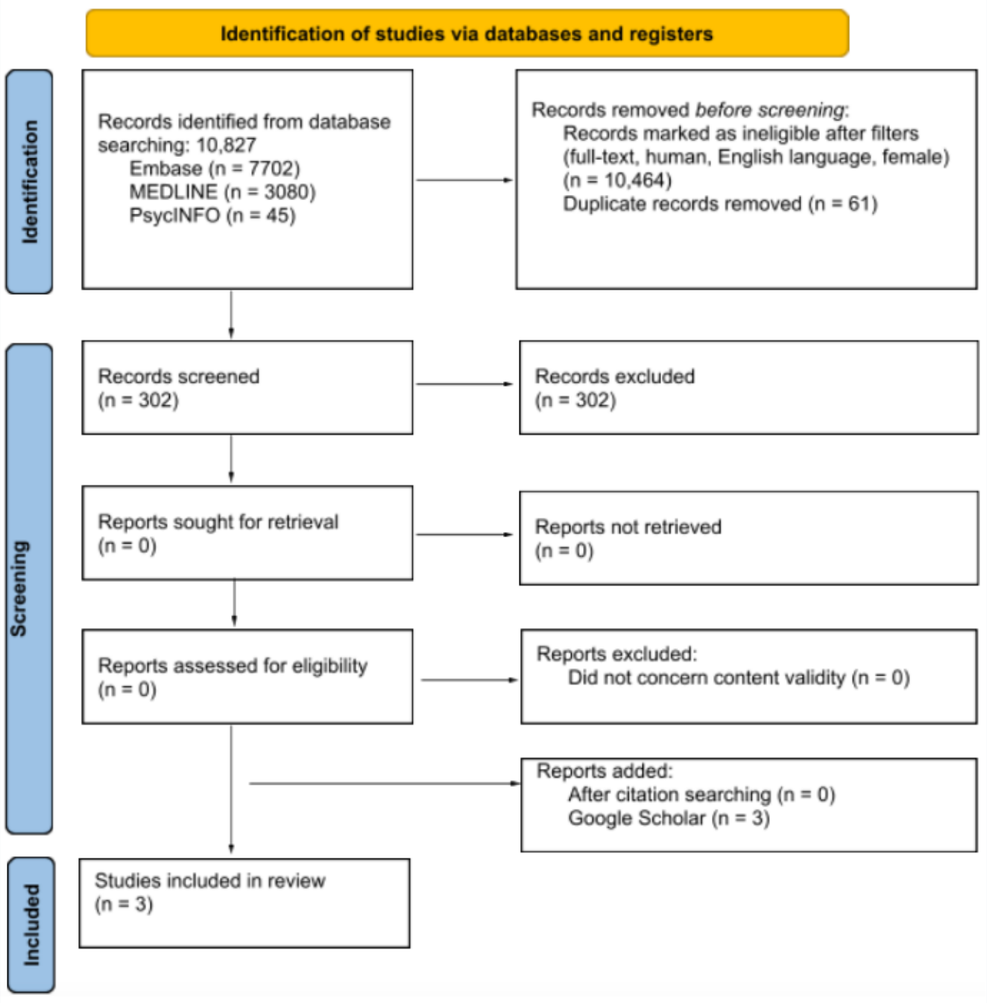


Chart 1. A PRISMA flow diagram showing the final set of eligible papers

Discussion

We applied criteria based on the COSMIN guidelines to assess the development studies of PROMs. Only one PROM development study (Fecal Incontinence Quality of Life Scale) presented a clear but broad description of the target population for which it was developed. Pilot studies were performed in the development stage of only two PROMs (McGill Pain Questionnaire, Fecal Incontinence Quality of Life Scale). All PROM development studies lacked patient participation and did not report on cognitive interviews. It is unclear whether the items included in the PROMs are of relevance and whether saturation was reached when developing these instruments. The overall quality of the development studies of the PROMs was inadequate. No content validity studies on PROMs were identified.

The quality of evidence of all PROMs were given a 'very low' score. Therefore, based on the available evidence it is difficult to establish which PROM has the best content validity and when they should be selected for use.

Conclusions

The limitations identified in quality assessment of the PROM development studies are concerning.

Researchers and clinicians should exercise caution while using PROMs and interpreting results.

There is a need for more research in the field of PROM development and validation aiming to enhance quality and standards in both clinical practice and research to reduce resource waste.

References

[1] Ellen Samuelsson, Lars Ladfors, Britta G Lindblom, Henrik Hagberg. A prospective observational study on tears during vaginal delivery: occurrences and risk factors. Acta Obstet Gynecol Scand. 2002 Jan. 81(1): 44-49.

[2] Caroline B Terwee, Cecilia AC Prinsen, Alessandro Chiarotto, Henrica CW de Vet, Lex M Bouter Jordi Alonso, Marjan J Westerman, Donald L Patrick Lidwine B Mokkink. (2018). Available at: https://cosmin.nl/wp-content/uploads/COSMIN-methodology-for-content-validity-user-manual-v1.pdf *COSMIN methodology for assessing the content validity of PROMs.*

[3] Stergios K. Doumouchtsis, Jemina Loganathan, John Fahmy, Gabriele Falconi, Maria Rada, Abdullatif Elfituri, Jorge Milhem Haddad, Vasilios Pergialiotis, Cornelia Betschart. Patient-reported outcomes and outcome measures in childbirth perineal trauma research: a systematic review. International Urogynecology Journal. 2021 Jun 18. 32: 1695-1706.

[4] Sylvia Pellekooren, Raymond Ostelo, Annelies Pool, Maurits van Tulder, Elise Jansma, Allessandro Chiarotto. Content validity of patient-reported outcome measures of satisfaction with primary care for musculoskeletal complaints: a systematic review. J Orthop Sports Phys Ther. 2020 Nov 12. 51(3): 94-102.

[5] Alessandro Chiarotto, Raymond W Ostelo, Maarten Boers, Caroline B Terwee. A systematic review highlights the need to investigate the content validity of patient-reported outcome measures for physical functioning in patients with low back pain. JCE. 2018 Mar 1. 95: 73-93.

[6] Carline B Terwee, Elise P Jansma, Ingrid I Riphagen, Henrica C W de Vet. Development of a methodological PubMed search filter for finding studies on measurement properties of measurement instruments. Qual Life Res. 2009 August 27; 18(8): 1115-1123.