

DEVELOPMENT AND EVALUATION OF THE CHRONIC CONSTIPATION PRO RATING SCALE (CC-PRO)

Hypothesis / aims of study

Researching the Patient-Reported Outcome of Chronic Constipation questionnaire, which is in line with Chinese culture, reflecting the valid point of action of TCM and paying close attention to QOL.

Study design, materials and methods

Focusing on the patient, following the guideline of PRO of FDA^[1], establishing the synthetic index system combining symptom with syndrome under the guidance of TCM theory.

- Establishing theoretical mode of the questionnaire, including 4 domains: physiology (specific symptom of chronic constipation and effect index of syndrome), psychological, society and satisfaction.
- Through literature and interview, collecting typical feeling of patients of chronic constipation, which include 96 items. Establishing first draft of item pool.
- Screening the items for the first time through the first expert and patient questionnaire, remaining 63 items.
- Combining, deleting and revising the items according to the setting request of the questionnaire, optimizing the item pool.
- Establishing the item pool (45 items), including physiology domain (29 items), psychological domain (9 items), society domain (3 items) and satisfaction domain (4 items), and accomplishing quantification of the items.
- Modifying the presentation and quantification of the item through the second expert questionnaire, remaining 43 items.
- Accomplishing language adjusting and consummating the important element of the questionnaire, establishing the first draft of the questionnaire "CC-PRO V1.0".
- Carrying out the pre-investigation, screening the items for the second time on item distributing, dispersion degree, coefficient correlation, factor analysis, discriminant analysis and Cronbach α . Establishing the Patient-Reported Outcome of Chronic Constipation rating scale "CC-PRO V2.0".
- Determining scoring method of "CC-PRO V2.0".
- Examining the reliability, validity and responsibility of "CC-PRO V2.0".
- Determining the score meaning of the rating scale.

Results

- Establishing the Patient-Reported Outcome of Chronic Constipation rating scale "CC-PRO V2.0"
- Examining the reliability, validity and responsibility of "CC-PRO V2.0"
- Determining the score meaning of "CC-PRO V2.0"

Interpretation of results

● **Establishing the Patient-Reported Outcome of Chronic Constipation rating scale "CC-PRO V2.0"**

①Quality: Using for patients of chronic constipation, reflecting the health condition and QOL, the clinic outcome is reported by patient himself. ②Structure: The questionnaire includes 32 items, which is consist of 4 domains and 7 aspects. The 4 domains include: physiology domain (19 items), psychological domain (9 items), society domain (2 items) and satisfaction domain (2 items). Physiology domain contains specific symptom of chronic constipation and effect index of syndrome; psychological domain contains adjusting of disease and mental state; satisfaction domain contains self-evaluation of health and satisfaction of treatment.

● **Examining the reliability, validity and responsibility of "CC-PRO V2.0"**

①The receptance is 92.1%, the accomplishing rate is 97.4%,the accomplishing time is (12.14±7.79) min;②Internal reliability: Besides split-half reliability coefficient of satisfaction, the other domains and the total score of the questionnaire are all over 0.7;③Remeasure reliability: 4 domains and the total score of the questionnaire are all over 0.7;④Content validity: The coefficient correlation of domain and total score, item and total score, item and domain are all over 0.7; ⑤Construct validity: Accumulative offer rate of variance is 72.245% in factor analysis, the construction of the questionnaire is in line with the theory scheme; ⑥Responsibility: Statistical significance exists between patients of chronic constipation and normal on score of item, domain and general concept ($P < 0.05$).

● **Determining the score meaning of "CC-PRO V2.0"**

The questionnaire is used to evaluate the quality of life of patients of chronic constipation, the score meaning including: ① Normal: total score≤88; ② Slightly poor: 88<total score≤121; ③ Poor: 121<total score≤160; ④ Very poor: 160<total score≤199; ⑤ Quiet poor: total score > 199.

Concluding message

Focusing on patient, following the guideline of PRO of FDA, establishing the synthetic index system combining symptom with syndrome under the guidance of TCM theory, Patient-Reported Outcome of Chronic Constipation questionnaire(CC-PRO V2.0)

is quite suitable to evaluate the curative effect of chronic constipation on TCM with better reliability, validity and responsibility, which is worth spreading and applying.

References

1. 1 U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (Cder), Center for Biologics Evaluation and Research (Cber), et al. Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims, 2009.

Disclosures

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Helsinki: Yes **Informed Consent:** Yes