Validation of a quality assessment checklist for case series studies

Bing Guo[1], Don Schopflocher[2], Christa Harstall[1], Carmen Moga[1]
[1]Institute of Health Economics, Edmonton, Canada
[2]University of Alberta, Edmonton, Canada

Background

- Case series (CS) studies, although often considered the lowest level of evidence due to the lack of a control group but the only evidence source, have been increasingly used in health technology assessments (HTA) and systematic reviews.
- Currently there is no consensus on how to assess the methodological quality of CS studies, and no single validated tool has been widely accepted.
- Through a collaborative effort by researchers from the IHE and two other HTA agencies, a 20-item checklist was developed.
- Face and content validity of the tool were evaluated via a Delphi process where a panel of experts judged the relevance and representativeness of the items.

Objective

To evaluate the construct validity (defined as the degree to which an operational measure correlates with the theoretical concept investigated) of the IHE quality assessment checklist for CS studies.

Method

- Two HTA researchers randomly selected 105 CS studies of various topics from a broad literature search.
- Six HTA researchers from Canada, Australia, and Spain participated. Researchers were paired to overlap and assess seven studies in common and each researcher assessed 35 studies in total.
- An independent biostatistician conducted a factor analysis to inform further refinements of the item pool of the checklist.

Figure 1: Scoring the case series checklist

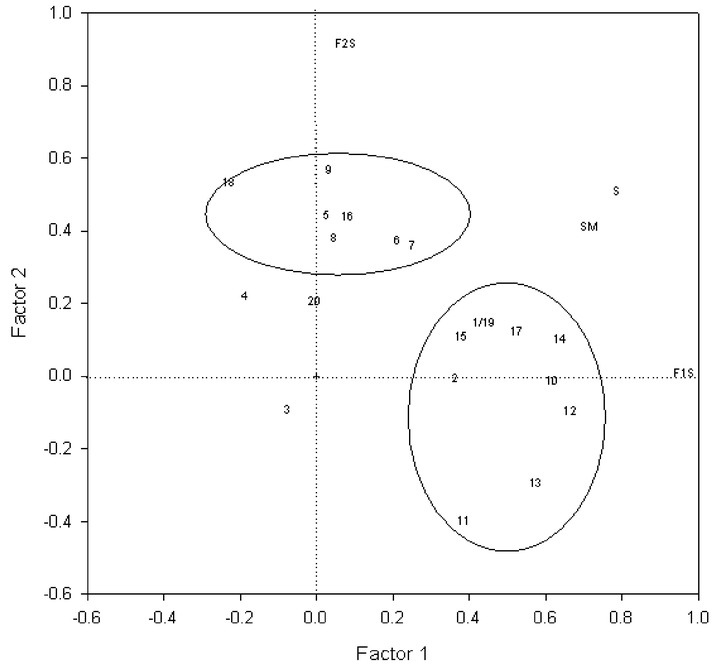

Table 1: Preliminary results of the factor analysis

Component 1	Component 2	Other
1. Hypothesis/aim/objective	5. Characteristics described	3. multi-center study,
2. Study conducted prospectively	6. Inclusion/exclusion criteria	4. consecutive recruitment,
10. Outcome measures established a priori	7. Similar disease points of entry in study	20. reporting of competing interest and sources of support)
11. Outcomes measured blinded	8. Intervention clearly described	
12. Outcomes measured appropriately	9. Co-interventions reported	
13. Outcomes measured before-after	16. Loss to follow-up reported	
14. Statistical tests appropriate	18. Adverse events reported	
15. Length of follow-up reported		
17. Estimates of random variability in data analysis of relevant outcomes		
19. Conclusions supported by results		

Results

- Preliminary results of the factor analysis revealed a trend of a separation of the 20 items into two components (Figure 1 and Table 1):
  - Component 1 (Factor 1): Ten items on the presence of the traditional features of the execution of a statistical hypothesis-testing paradigm.
  - Component 2 (Factor 2): Seven items on the descriptions of the subjects' characteristics that might feature in the experimental design, particularly in judgments about the likelihood of confounding. This component provides the richness of information.
  - The other three items do not correlate very highly with either of these two components.
- No item(s) can be eliminated on the bases of the preliminary analysis.

Discussion

- Exploratory factor analysis empirically examines the interrelationships among the items and helps to identify clusters of items that share sufficient variation to justify their inclusion as a factor or construct to be measured by the checklist.
- The set of items for hypothesis testing may be more critical for some conditions where causal relationship between the intervention and efficacy/effectiveness outcomes can be established from a before-after case series study.
- The set of items describing study/intervention characteristics may be more important when assessing clinical outcomes such as long-term adverse effects.

Conclusion

The checklist should be tailored to meet the specific objectives of the HTA or systematic review, taking into account the relevant importance of hypothesis-testing versus description of subject/intervention characteristics of the CS studies.

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CONFLICT OF INTEREST

All authors declared no conflict of interest.

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