Use of the GRACE Checklist for Rating the Quality of Observational Comparative Effectiveness Research

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Objectives:

To determine the best algorithm for using the Good ReseArch for Comparative Effectiveness (GRACE) checklist to rate the quality of individual observational comparative effectiveness research (CER) studies
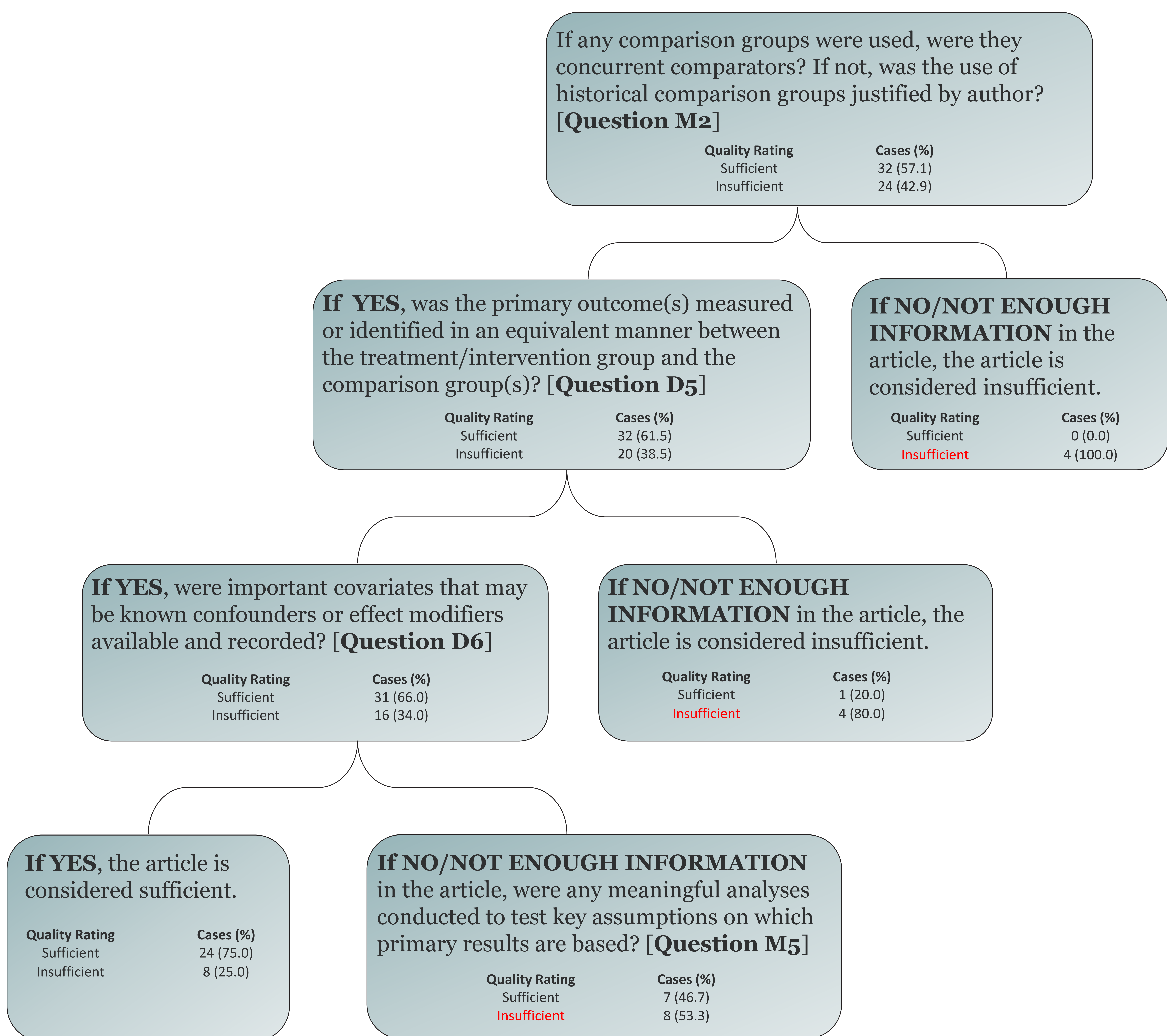
Methods:

- An 11-item checklist about data (6 questions) and methods (5 questions) was developed through literature review and consultation with experts. Development and validation of the checklist has been described previously.[†]

- Classification and Regression Tree (CART) analysis was conducted on data collected from 22 volunteer rater's assessment of 28 CER articles compared to an expert's quality assessment of the article.

- Multivariate regression analysis was conducted as a sensitivity analysis to assess the robustness of the checklist questions most predictive of quality as identified in the CART analysis.

Results:

- The CART analysis identified 4 checklist questions in the optimal decision tree.
  - Use of concurrent comparators [M2]
  - Primary outcome(s) measured equivalently [D5]
  - Important covariates available and recorded [D6]
  - Meaningful analyses to test key assumptions [M5]

- CART tree statistics
  - ROC Learn=0.7891
  - ROC Test=0.6842
  - Sensitivity=78.1%
  - Specificity=58.3%
  - Positive Predictive Value=71.4%
  - Negative Predictive Value=66.7%

- The multivariate model identified three questions in common [M2, D5, D6] with CART plus question D4 (Were primary outcomes validated, adjudicated or otherwise known to be valid in a similar population?), though only D5 was statistically significant.

GRACE Checklist
Classification and Regression Tree (CART)

If any comparison groups were used, were they concurrent comparators? If not, was the use of historical comparison groups justified by author? [Question M2]

Quality Rating	Cases (%)
Sufficient	32 (57.1)
Insufficient	24 (42.9)

If YES, was the primary outcome(s) measured or identified in an equivalent manner between the treatment/intervention group and the comparison group(s)? [**Question D5**]

Quality Rating	Cases (%)
Sufficient	32 (61.5)
Insufficient	20 (38.5)

If NO/NOT ENOUGH INFORMATION in the article, the article is considered insufficient.

Quality Rating	Cases (%)
Sufficient	0 (0.0)
Insufficient	4 (100.0)

If YES, were important covariates that may be known confounders or effect modifiers available and recorded? [**Question D6**]

Quality Rating	Cases (%)
Sufficient	31 (66.0)
Insufficient	16 (34.0)

If NO/NOT ENOUGH INFORMATION in the article, the article is considered insufficient.

Quality Rating	Cases (%)
Sufficient	1 (20.0)
Insufficient	4 (80.0)

If YES, the article is considered sufficient.

Quality Rating	Cases (%)
Sufficient	24 (75.0)
Insufficient	8 (25.0)

If NO/NOT ENOUGH INFORMATION in the article, were any meaningful analyses conducted to test key assumptions on which primary results are based? [**Question M5**]

Quality Rating	Cases (%)
Sufficient	7 (46.7)
Insufficient	8 (53.3)

Conclusions:

Four GRACE checklist questions were selected in the optimal CART tree. Characteristics around the comparison groups, including whether concurrent comparators were used and outcomes were measured equivalently across groups, were identified as the most important predictors of article quality. Availability of covariates that may be confounders or effect modifiers was selected as an important indicator of article quality. Sensitivity analyses were identified as particularly important when in doubt about the covariates. The moderately high sensitivity and positive predictive value of the tree indicate the selected questions are most useful to select articles of sufficient quality for decision support. Further evaluation of the predictive ability of the checklist questions would be strengthened from a larger sample of article assessments.

[†]Dreyer NA, Velentgas P, Westrich K, Dubois R. The GRACE Checklist for Rating the Quality of Observational Studies of Comparative Effectiveness: A Tale of Hope and Caution. J Manag Care Pharm. 2014; 20(3):301-8.