Quality of health economic evaluations for the ACC/AHA stable ischemic heart disease practice guideline: A systematic review

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Background The American College of Cardiology/American Heart Association (ACC/AHA) recently published a rigorous framework to guide integration of economic data into clinical guidelines. We assessed the quality of economic evaluations in a major ACC/AHA clinical guidance report.

Methods We systematically identified cost-effectiveness analyses (CEAs) of RCTs cited in the ACC/AHA 2012 Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease. We extracted: (1) study identifiers; (2) parent RCT information; (3) economic analysis characteristics; and (4) study quality using the Quality of Health Economic Studies instrument (QHES).

Results Quality scores were categorized as high (≥75 points) or low (<75 points). Of 1,266 citations in the guideline, 219 were RCTs associated with 77 CEAs. Mean quality score was 81 (out of 100) and improved over time, though 29.9% of studies were low-quality. Cost-per-QALY was the most commonly reported primary outcome (39.0%). Low-quality studies were less likely to report study perspective, use appropriate time horizons, or address statistical and clinical uncertainty. Funding was overwhelmingly private (83%). A detailed methodological assessment of high-quality studies revealed domains of additional methodological issues not identified by the QHES.

Conclusions Economic evaluations of RCTs in the 2012 ACC/AHA ischemic heart disease guideline largely had high QHES scores but methodological issues existed among "high-quality" studies. Because the ACC/AHA has generally been more systematic in its integration of scientific evidence compared to other professional societies, it is likely that most societies will need to proceed more cautiously in their integration of economic evidence. (Am Heart J 2018;204:17-33.)

Resource constraints, high costs of therapy, and rising national medical expenditures remain interlocked with clinical aspects of healthcare in the United States.[1,2] In this context, the American College of Cardiology and American Heart Association (ACC/AHA) recently published a rigorous framework to guide integration of economic data into clinical guidelines.[3] These guidelines significantly advance the frameworks that other professional societies have proposed to integrate economic evidence, but they also introduce new challenges. In particular, there is uncertainty about how to incorporate economic information into clinical guidelines, disseminate this guidance to clinicians and influence clinical practice, and determine which economic evidence is of sufficiently high quality to be worth integrating versus which is of lower quality. Regarding the third point, there is empirical cause for concern, because some disease-specific economic reviews report a high prevalence of low quality studies.[4]

In this study, we systematically reviewed the quality of economic evaluations/cost-effectiveness analyses (CEAs) pertaining to clinical trials cited in the 2012 ACC/AHA guideline for the diagnosis and management of patients with stable ischemic heart disease, a condition that affects over 15 million adults in the United States.[5,6] We chose this guideline for our analysis because it has substantial influence on clinical care. In our review, we focus on economic evaluations of randomized controlled trials (RCTs) because this study design represents the highest level of evidence for comparative health effectiveness and therefore should also represent the highest level of evidence for economic evaluations.[7,8]

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Methods

Identification of Randomized Comparison Studies

We reviewed all 1,266 citations in the "2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease."[5] Titles and abstracts of each citation were analyzed to determine whether they contained the word "random," as a flag for whether they were based on randomized controlled trial data. These studies were then selected for full-text review to confirm that they were RCTs. Meta-analyses of multiple randomized studies were excluded.

We then searched PubMed (which includes the MEDLINE database and other sources) and Scopus from inception until March 1, 2015 for English-language articles that were economic evaluations of the randomized controlled trials. As search terms, we used the first author, last author, and/or trial name of the randomized controlled trial, in combination with the Medical Subject Headings *cost* and *economics*. If no authors were listed, the study group conducting the trial was listed as the author. If the search yielded greater than 50 search results, the Medical Subject Heading *cardiovascular diseases* was added to the search terms. If no economic evaluations were found, a Scopus search was performed of all articles citing the referenced RCT containing the term "cost" or "economic" in the title.

Study Selection and Data Extraction

Two investigators (E.S. and D.F.), working independently, in duplicate, identified studies eligible for further review after screening titles or abstracts. Studies then underwent full-text retrieval and data extraction if authors reported using cost and efficacy data from the referenced RCT. Using a standardized protocol and reporting form, data were extracted by two investigators (E.S. and J.L) on the following characteristics: (1) identifying information (first author, journal, country, institution, publication year); (2) parent RCT information as reported in the cost-effectiveness analysis (population characteristics, intervention and control type); (3) economic evaluation characteristics (outcome type, intervention and control costs, outcome value, analysis perspective); and (4) study quality using the Quality of Health Economic Studies (QHES) instrument.[9] Disagreements between reviewers were resolved through discussion. All economic outcomes were converted to 2016 US dollars using historical exchange rates and CPI inflation rates.[10,11]

Quality Assessment of Economic Evaluations

Study quality was evaluated using the QHES instrument, a 16-item questionnaire with numerical points to tabulate a quantitative assessment of quality (Figure 1).[9] Studies were categorized as high (≥75 points) or low quality (<75 points) based on their score. This threshold was used in a prior study of the quality of economic evaluations.[9,12-17] In addition, we performed a detailed methodological assessment of a random subset of high-quality studies (limited to those with a score exceeding the mean QHES score) to identify methodological issues not addressed by the QHES.

Statistical Analysis

The primary outcome was study quality. We also examined the association between study quality and study characteristics. Parent RCT patient characteristics were summarized and descriptive data analysis was performed on study characteristics. Association between low quality scores and study characteristics was assessed using Fisher's exact t-test and Spearman's rank correlation coefficient. All analyses were performed using Stata (version 14, College Station, TX).

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Results

Literature Search

Of the 1,266 articles referenced in the 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guidelines, 219 were RCTs. Of these RCTs, we identified economic evaluations for 86, including 14 RCTs that were associated with two economic studies, for a total of 100 economic analyses. Of these analyses, 16 were excluded because they reported only cost data without a health outcome measure, and 7 were excluded because intervention cost and/or efficacy data were not attributable to a single RCT. Seventy-seven papers met inclusion criteria and were selected for data extraction (Figure 2). The economic evaluations included in this quality assessment and their parent RCTs are shown in Table I.

Reported Parent Clinical Trial Characteristics

The characteristics of these economic evaluations are summarized in Table II. Among studies that reported patient characteristics from the parent RCTs (n=69), the median population size of the parent clinical trials was 1,986 participants (min. 77, max. 33,357; interquartile range 641-5,238). The mean age was 61.3 years (min. 47.4 years, max. 83.6 years; median 62 years; interquartile range 60-63.7), with slightly more than half of the economic evaluations (n=42; 54.5%) reporting mean age of the parent clinical trial population. Males comprised 73.8% of the population (min. 34%, max.

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