

REPRESENTATIVENESS IN RANDOMISED CLINICAL TRIALS SUPPORTING ACUTE CORONARY SYNDROME GUIDELINES

BACKGROUND

Clinical practice guidelines (CPGs) guide the diagnosis, treatment, and prevention of acute coronary syndrome (ACS) and are largely based on evidence derived from randomized clinical trials (RCTs) [1]. Adequate representativeness of RCT populations is essential to ensure that guideline recommendations are generalizable to real-world clinical practice [2]. However, prior research has shown that ACS RCTs have historically under-represented women, elderly individuals, and non-white populations, while recruitment has been predominantly concentrated in North America and Europe [3]. Understanding the demographic, geographic, and clinical characteristics of trial populations underpinning current guidelines is therefore critical for evaluating the applicability and equity of ACS recommendations.

OBJECTIVE

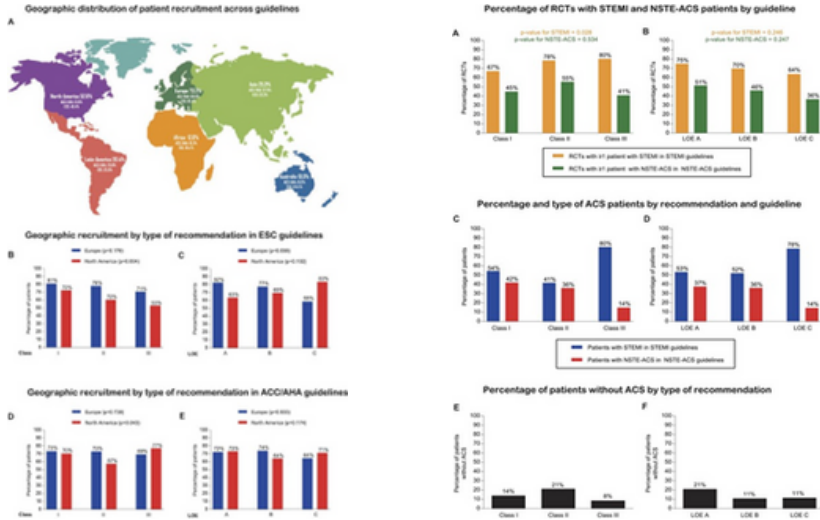
To evaluate the representativeness of RCTs cited in ACC/AHA and ESC ACS CPGs with respect to geography, patient characteristics, interventions, and outcomes.

MATERIAL & METHODS

Four CPGs (two ACC/AHA, two ESC) were screened for primary RCTs cited in recommendations. Data were collected at RCT- and patient-level, including geographic recruitment, ACS type, baseline characteristics, exclusion criteria, reperfusion/invasive therapy, and clinical outcomes. Recommendations were classified by class (I–III) and level of evidence (LOE A–C). Analyses used percentages, means, and χ^2 tests.

RESULTS

Out of 2,128 references, 407 (19.1%) were primary RCTs, enrolling 1,582,039 patients (728,605 control; 853,434 intervention). Most RCTs recruited patients in North America (52.6%) and Europe (73.2%), with under-representation from Asia (25.3%), Latin America (20.4%), Australia (19.9%), and Africa (12.8%) (Figure 2). Only 68.6% of RCTs enrolled ACS patients; 19.6% actively excluded ACS. Baseline characteristics in control arms: mean age 62.1 ± 6.3 years, women 29.9%, white 80.7% (Table 2). Percutaneous coronary intervention was performed in 42.7% of control patients, and STEMI patients more frequently received fibrinolysis than primary PCI (3.3-fold). All-cause mortality ranged from 4.7% (<72h) to 11.9% (1 month–1 year).



CONCLUSION

RCTs supporting ACS guidelines show geographic and demographic imbalances and lower representation of modern interventions. These findings underscore the importance of critical appraisal when applying guideline recommendations.