



Quality of Care and Outcomes Assessment

CLINICAL TRIAL PARTICIPATION AFTER ACUTE CORONARY SYNDROME AND ASSOCIATED OUTCOMES: INSIGHT FROM THE ACTION REGISTRY-GWTG

ACC Moderated Poster Contributions
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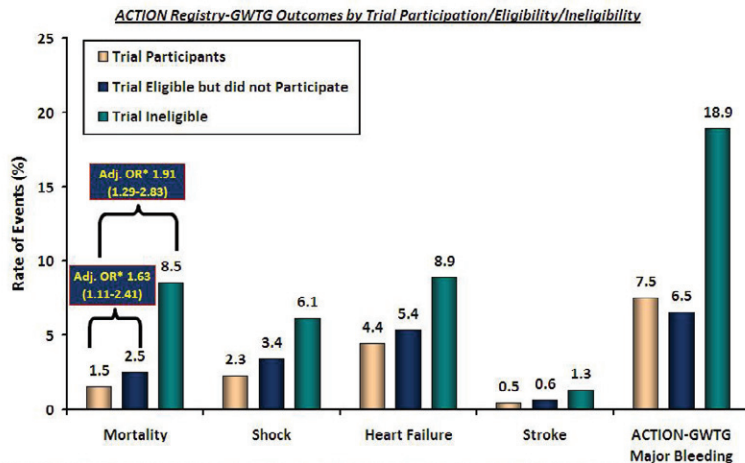
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Background: ACTION-GWTG (ARG) provides a unique opportunity to evaluate whether patients (pts) in CV trials are representative of the broader US ACS population.

Methods: 289,322 ACS pts participated in ARG from 2007-2011. From ACS trials during the study period, generalized trial ineligibility criteria were derived: age <18 yrs, major bleeding, uncontrolled HTN, CKD, shock, INR >1.5, Hb <10 and fibrinolysis on arrival. After excluding pts with missing data for ineligibility or trial participation, a remaining 190,004 pts were divided into 3 categories: participated; eligible but did not participate; ineligible. Multivariable regression with generalized estimating equation modeling derived OR and 95%CI for mortality + CV events.

Results: 4,008 (3%) participated, 93,274 (66%) were eligible but did not participate and 43,853 (31%) were ineligible for a clinical trial. Trial participants more often were younger, male, had less CV history, received early therapy, angiography, discharge therapy and rehab. In-hospital outcomes also differed: risk of death was lower in pts who participated (1.5%) compared with those who were eligible (2.5%; adj. OR 1.6, 95%CI 1.1-2.4; p=0.01) or ineligible (8.5%; adj. OR 1.9, 95%CI 1.3-2.8; p<0.01; figure).

Conclusion: Within this voluntary registry, 2 out of 3 ACS pts were eligible for but did not participate in a clinical trial. Trial participation is infrequent and may be associated with significant differences in presenting factors, hospital care and outcomes.



*Adjusted for: Age, initial serum creatinine, SBP, Baseline Troponin ratio to U/LI, HF only on admission, Shock only or HF with Shock on admission, none (ref), STEMI, ST-segment changes & no ST-segment changes (ref), HR (linear spline with knot at 70), Prior PAD, Female (vs. Male), Caucasian (vs. Non-Caucasian), Weight, initial Hgb, Medicare, Medicaid, Self/none, Other insurance vs. HMO/private (ref), Hypertension, Diabetes Mellitus, Current/recent smoker, Dyslipidemia, Prior MI, Prior PCI, Prior CABG, Prior C/IF, Prior Stroke