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Quality of Care and Outcomes Assessment

NONCARDIOVASCULAR MORTALITY IN CARDIOVASCULAR CLINICAL TRIALS

Poster Contributions
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Background: Cardiovascular clinical trials routinely present data on cardiac, noncardiac (nonCV), and total mortality. In primary prevention studies, up to 72% of deaths may be nonCV. Several studies have reported statistically significant changes in nonCV mortality with the intervention studied. There is, however, little information on how our interventions affect nonCV mortality when viewed in the aggregate.

Methods: A systematic review was performed of major general medical and cardiovascular journals to find reports of studies which presented nonCV mortality in the results. Multiple analyses were performed to assess whether the interventions affect nonCV mortality,including meta-analysis based on the intervention provided; funnel plot analysis, Markov simulation techniques, and assessment of changes over time.

Results: There are 411 studies included in this analysis. Eighteen studies had statistically significant changes in nonCV mortality with intervention, with 8 studies demonstrating a statistically significant improvement in nonCV mortality and 10 studies with worsened noncardiac mortality. Funnel plot analysis shows that all statistically significant studies fall on the equipoise curve. Meta-analysis demonstrated that while overall there was no change in nonCV mortality, studies of vitamins and non-statin cholesterol lowering agents had statistically significant increases in nonCV mortality, while diuretic based therapies had a significant decrease in nonCV mortality. Markov analysis of the funnel plot demonstrates an appropriate distribution of hazard ratios with 20% of studies with hazard ratio of <0.8 and 25% with hazard ratio >1.2. Analyses according to year of publication show no change in nonCV mortality over time in either placebo or treatment arms regardless of the underlying disease state.

Conclusions: Overall, nonCV mortality is not affected by the interventions studied in these trials. While large differences in nonCV mortality may occur in individual trials, this is due to low numbers of events in the individual trials and not the intervention. Care must be exercised in interpreting differences in nonCV mortality in individual clinical trials.