PMD15

AN UNBIASED METHOD OF PHARMACEUTICAL COST ANALYSIS

Nichol G, Wells G, Pham B
University of Ottawa, Ottawa, Canada

Pharmacoeconomic evaluation can assess costs by using controlled trials. Statistical analysis of costs follows a normal (N), lognormal (LN), or survival (S) model. Each model assumes different statistical properties that may introduce bias. If one pharmaceutical is less expensive and more effective than another, then no incremental cost-effectiveness ratio is calculated. Therefore, economically attractive pharmaceuticals may not be identified if a biased method of cost analysis is used.

OBJECTIVE: The purpose of this study was to (1) evaluate potential bias in methods of cost analysis and (2) demonstrate an unbiased method.

METHODS: Cost models were considered unbiased if they accounted for (1) independent variables, (2) disease-specific death, (3) unrelated death (4) dropouts, and (5) informative censoring. Potential differences in statistical significance were demonstrated by simulating 12-month cost data from the GUSTO study that compared use of streptokinase and tissue plasminogen activator (TPA). We simulated n = 10,000 from a gamma distribution for each therapy, and 5% incidences of death, unrelated death, or dropouts.

RESULTS: N and LN only account for independent variables. Kaplan-Meier (KM) does not account for independent variables, but competing risk (CR) accounts for all factors. For streptokinase and TPA, mean actual costs were $24,575 and $24,990; mean simulated costs were $24,575 and $24,990. Costs of streptokinase versus TPA were significantly different under N (mean difference [95% confidence interval] = $415 [277–554], $p < 0.001$), and under LN ($431 [289–547], $p < 0.001$) For S models, costs were not significantly different under KM (hazard ratio for costs [95% confidence interval] = 0.94 [0.89–1.01], $p = 0.08$), or CR (0.96 [0.91–1.01], $p = 0.09$). The robustness of results and goodness of fit depend upon the actual distribution of costs.

CONCLUSION: A competing risk model is an unbiased and comprehensive method of cost analysis. Further research is required to assess the clinical importance of alternate methods of cost analysis.

PMD16

IMPLICATION OF PREVENTING DISEASE ON LIFE YEARS GAINED (LYG)

Caro JJ, Klittich WS, for the WOSCOPS Economic Analysis Committee
Caro Research, Boston, MA, USA

While prevention of disease may lead to increased survival, appropriate estimation of LYG from shorter-term clinical trials has been controversial, with some arguing that only the gain actually observed during the trial is correct. The disagreement arises from a misunderstanding of the methods used.

OBJECTIVE: To examine this misunderstanding using the estimation of LYG by preventing cardiovascular disease (CVD) with pravastatin in hypercholesterolemic subjects without pre-existing disease, based on the West of Scotland Coronary Prevention Study.

METHODS: In WOSCOPS, there were 29 additional survivors among treated patients accumulating 71.05 years during the trial. But what happens at the end of the trial? Should one assume they all die immediately? A more reasonable presumption is that they attain their age and gender appropriate life expectancy. Although hypercholesterolemic, they have been successfully treated, and other trial selection criteria imply that they tend to be healthier than their peers. A more difficult issue concerns the non-fatal events prevented. Assigning no gain in life expectancy to the 76 additional survivors in the pravastatin group who remained free of cardiovascular disease (CVD) is tantamount to dismissing the impact of CVD on survival—a clinically untenable position. Instead, we estimated it using data from the Scottish Record Linkage System on 460,000 residents who had suffered a first CVD.

CONCLUSION: As LYG has become the predominant denominator in cost-effectiveness ratios, their proper estimation is crucial. Over- or under-estimation can lead to erroneous conclusions by decision makers about the economic efficiency of therapeutic interventions.

PMD17

SURVEILLANCE OF A NEW DRUG IN THE UNITED KINGDOM

Hartz SC[1], West S[2], Bunten E[1]
Medical Research International, [1]Burlington, MA, USA and [2]London, England, UK

Reports of adverse events often surface shortly after a new drug is introduced and in many cases provoke governmental regulatory action. Deaths pose a particular challenge, because drug takers may have excess mortality risk relative to nontakers for reasons unrelated to drug use. Aside from the implications for safety surveillance, a spurious association between drug use and mortality also can confound economic comparisons based on drug use.

OBJECTIVE: To investigate, at the request of the U.K. Medicines Control Agency, safety and health-care resource utilization related to use of a new drug.

METHODS: A postmarketing surveillance program was implemented at major medical schools in England and Scotland to monitor mortality, morbidity, and health-care resource utilization associated with use of a new drug for treating gastrointestinal conditions. The study employs a longitudinal design that identified 18,000 drug takers through automated pharmacy listings at 700+ general practitioner offices located within a one-hour drive from the medical schools. In addition to drug taking patterns and adverse event occurrences, use of ambula-