Reviewer's report

Title: Coronary artery bypass grafting and sensorineural hearing loss, a cohort study.

Version: 2 Date: 18 August 2005

Reviewer: Roger Davis

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This paper describes a proposed cohort study to evaluate whether CABG surgery is a risk factor for sudden hearing loss. The study will compare patients undergoing CABG to those undergoing surgery for head and neck tumors not having otologic, brain stem or VII or VIII cranial nerve complex involvement.

1. The study proposed is actually a matched cohort study, rather than a standard cohort study.
2. In section 7, the use of the terms ‘cases’ and ‘controls’ is inappropriate. Cases and controls are defined for case-control studies where groups are defined by whether or not they have the disease under investigation (in this case, hearing loss). The groups under study in a cohort study are defined in terms of their exposure (in this case, whether they have CABG). I would suggest replacing ‘case’ with ‘exposed’ and ‘control’ with ‘unexposed’.
3. An important part of designing a study such as this is conducting an analysis to determine how large a sample size is required. This has not been done. The outcome of interest appears to be a binary outcome (hearing loss versus no hearing loss). The author cites two widely varying estimates of the rate of hearing loss (0.1% and 13.2%). If the rate is anywhere near the lower estimate, the required sample size would be tens of thousands per group, a number that strikes me as too large to be feasible.
4. The standard method of analyzing a cohort study with a binary outcome is with logistic regression. This allows for adjustment for other factors (e.g., age and sex).
5. The author should consider alternate means of defining the outcome of hearing loss. If change in hearing acuity were measured on a continuous scale, the study would probably have better power to detect differences between the CABG and unexposed groups.