Reviewer's report

Title: Reconsidering low dose aspirin therapy for cardiovascular disease: an integrative approach study protocol

Version: 3 Date: 14 February 2011

Reviewer: Catherine Barnes

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Major Compulsory Revisions:

This methods paper addresses the protocol for a randomized trial that will investigate how to change provider adherence behavior in light of revised clinical guidelines; specifically, guideline changes for low dose aspirin therapy for primary prevention of cardiovascular disease and for patients with high risk equivalents. The question posed is “how to change provider behavior to abide by new local guidelines related to prescribing (or not) low dose aspirin?” The patients and providers at the University of Colorado five primary care practices comprise the study population. There are a few issues/ flaws associated with this project.

1. Three intervention arms are outlined, but no control group is planned. It will be impossible to control for secular effects and thereby rule out the possibility that any possible association was caused by a third or outside factor. A 4th control arm that has no academic detailing, decision support, or patient activation would have provided this crucial dimension.

2. Three groups of participants are outlined: 1) on ASA with diagnosed CVD (a history of cardiac events/stroke), 2) on ASA not diagnosed with CVD, 3) not on ASA with diagnosed CVD. In each case, only ICD-9 codes for diagnosed CVD are used in the selection process; this excludes the undiagnosed high risk CV population for whom providers may feel ASA therapy is indicated.

   a. If ASA is prescribed, is the provider 1) non-adherent to local guidelines or 2) is he/she individualizing care for patients not clearly covered by prior RCT when evidence is conflicted? This is the primary objective of the study and there is no way to tease this information from these current groups. A provider questionnaire would help to assess this information.

3. It is difficult to change provider behavior. The proposed study will investigate whether combinations of academic detailing, a clinical decision support system, and patient activation that encourages patient-provider communication with make a difference. There are issues / limitations here:

   a. It is possible that provider behavior may be confused over conflicting local (University of Colorado) and national guidelines (National Cholesterol Education Program, American Diabetes Association, Canadian Diabetes Association,
American Heart Association, etc) than by the actual reluctance of providers to change.

b. Were the providers in this study part of the decision by the University of Colorado to change the clinical guidelines regarding low dose ASA? If not, many providers may disagree with the decision or even harbor ill feelings at not being involved. Either way, there may be disagreement between clinicians and guideline administrators and this may be a factor in noncompliance.

c. It is the belief of the members of the Clinical Decision Support group of University of Colorado that low dose ASA in non-CVD patients is not indicated, but, as the authors have pointed out, there is evidence both ways. Many providers may believe that since there is no evidence of major harm in prescribing ASA, why take the risk of discontinuing the ASA. Risks like GI bleeding may have less impact when compared with the benefits. Providers may feel able to “deal” with potentially treatable harms.

d. Although the patient activation form was not included with the manuscript, a form given to the patient before the provider visit asking them to “check with their provider concerning the use of ASA for primary prevention” poses more questions: e.g. What will provider’s reaction be to this?

In each of these cases, the addition of a provider questionnaire would give deeper insight into provider behavior.

Minor Essential Revisions:

4. There is conflicting evidence about the helpfulness of a clinical decision support system 1-3. The authors also indicated that members of the Clinical Decision Support group believe that removing ASA recommendations would have no impact on provider practice. It may also be that a longer time is needed for behavior extinction, hence the suggestion about adding a control group.

5. The authors offer the suggestion of conducting a qualitative investigation. To evaluate provider behavior, this seems to be an excellent first step to include. At the very least, include some anecdotal or qualitative measures (such as a post-visit provider questionnaires, post-visit interviews, etc).

Discretionary Revisions:

6. Inclusion of the patient activation form, with this manuscript, would be helpful.

Strengths

• It is excellent that the methodology, for this study, is monitoring to see that secondary prevention use of ASA is not lost.
• There is a robust array of interventions (however, the description for “detailing” is limited; a clearer definition would be helpful)
• This is a very important topic that needs to be addressed.
• Abstract is succinct and comprehensive.
• The manuscript introduction states what is known and unknown about the topic; interest is peaked.
• Manuscript title accurately reflects the purpose of the study.
• This is appropriate and interesting subject matter for this journal.
• The literature review for this manuscript is thorough and includes references that are either classics or current.

References


Level of interest: An article of outstanding merit and interest in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interest.