Author’s response to reviews

Title: The Effect of a Regional Care Model on Cardiac Catheterization Rates in Patients with Acute Coronary Syndromes

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Author’s response to reviews: see over
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Dear Dr. Morrey

Re: Manuscript Submission –“The Effect of a Regional Care Model on Cardiac Catheterization Rates in Patients with Acute Coronary Syndromes” Corresponding author: Michelle M. Graham, MD

Please consider the enclosed revised manuscript for publication in BMC Health Services Research. Reviewer comments have been addressed and appropriate changes made in the revised manuscript (highlighted in red for convenience). In addition please see the attached document for a detailed description of changes including page and line numbers.

All authors have read and approved the submission of the manuscript. The manuscript has not been published and is not being considered for publication in whole or part in any language except as an abstract. All authors had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Drs Curran, Graham and Hubacek participated in study design, analysis, and manuscript revision. Drs Knudtson, Ghali and Ms. Galbraith participated in study design and manuscript revision. Ms. Southern participated in analysis and manuscript revision.

We thank the reviewers for their comments and feel that the manuscript has improved. Thank you very much for your further consideration. Please advise us if additional information is required.

Sincerely Yours,

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We thank the reviewers for their comments.

**Reviewer 1**

1) Whilst guidelines indicate an early invasive strategy some selection based on comorbidities and procedural risk and benefit forms part of the guideline recommendation eg AHA. The introduction should be rephrased.

We agree with this point and therefore the introduction has been modified as per this suggestion (page 4, line 66-69) ‘In patients with non-ST elevation myocardial infarction (NSTEMI), an early invasive strategy, in patients without contraindications or prohibitive comorbidities, is superior to a selective invasive strategy in reducing re-hospitalization and myocardial infarction (MI)’.

2) How do the authors explain that patients admitted to the interventional center underwent catheterization sooner than those admitted to community centers (2.6 vs. 4 days, p<0.001). BUT In the interventional group, 9.8% underwent catheterization within 24 hours of admission compared to 16.7% in the community group. Within 48 hours from admission, 32.5% and 54.3% of the interventional and community patients underwent catheterization and within 72 hours, 48% and 68.3% had undergone the procedure (p<0.0001). Does a very skewed distribution account or this? If so the median time to catherisation may be better reported.

Please note that data regarding time to catheterization was inappropriately reversed in the interventional and community columns in Table 1. This accounts for the discrepancy in findings mentioned above. We apologize for this oversight. Table 1 data has been corrected (pages 22-23) as shown below and supports the finding that patients admitted to the interventional center underwent catheterization sooner than those admitted to community centers.

<table>
<thead>
<tr>
<th></th>
<th>Interventional</th>
<th>Community</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheterization not received</td>
<td>1730 (48.6%)</td>
<td>1834 (32.2%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Catheterization received</td>
<td>11832 (51.4%)</td>
<td>1759 (67.8%)</td>
<td></td>
</tr>
<tr>
<td>Within 24 hours of admission</td>
<td>594 (16.7%)</td>
<td>255 (9.8%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Within 48 hours of admission</td>
<td>995 (54.3%)</td>
<td>571 (32.5%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Within 72 hours of admission</td>
<td>1260 (68.8%)</td>
<td>844 (48%)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

3) The paper should reference existing published NSTEMI regional models and discuss eg Chen et al Heart Lung and Circulation 2013. The HPP study in Australia also compares access to revascularization in interventional versus non interventional centers. Med J Aust 188(4): 218-223. This and a number of other studies had very different findings (better access and outcomes at interventional centers) please discuss.
Thank you for the suggestion. Numerous NSTEMI regional models exist and although it would be difficult to include all in our discussion, the HPP project in particular is certainly an important initiative worthy of discussion, and we thank the reviewer for pointing this out. It is now included to illustrate the importance of audit and feedback (page 10, lines 191-196) ‘The Heart Protection Partnership (HPP) project was an Australian initiative developed to audit compliance with evidence-based treatments in patients with acute coronary syndromes treated at interventional and non-interventional centers across the country. The program identified treatment gaps, particularly in non-interventional centers, and provided feedback to individual centers with the purpose of improving compliance with benchmark standards of care’.

Other investigators have demonstrated better access to cardiac catheterization when admitted to an interventional center. An additional study demonstrating this was added to the discussion (page 11, lines 217-220) ‘Data from the New Zealand Cardiac Society Audit Group demonstrated that patients with ACS admitted to non-interventional centers were less likely to be referred and had longer time delays to access cardiac catheterization compared to those admitted to interventional centers’.

4) As an observational study selection biases may have a significant impact on the patient outcomes and therefore it difficult for the authors to generalise their findings. This is supported by the very different baseline characteristics of the two groups. The discussion should be revised to reflect this issue.

We agree that even with the clinically rich dataset used in our study, there may be residual confounders at play. We have therefore revised the discussion (page 11, lines 230-233) ‘Due to the observational nature of this study, selection bias may influence outcomes and partially account for baseline differences in patients chosen for cardiac catheterization. This may limit generalization of our findings to different populations’.

5) One deficiency of the registry is it does not audit against benchmark KPIs. Is data available about performance against guideline based care eg ECG within 10 minutes of arrival, prescription of guideline based medical therapy? How do the authors explain the relative lack of investigation and intervention at interventional centers? Can they benchmark with other registries that have been published.

A limitation of this study and of APPROACH is the absence of auditing against some benchmark KPIs. Data regarding treatment timelines (ie time to ECG, time to reperfusion) are available, however only for STEMI patients, which are not the focus of the current study. APPROACH does not have access to data outlining ongoing use of evidence based medical therapies at proven doses. The limitations section of the study was therefore revised to reflect this (page 13, lines 64-66) ‘Additionally, our registry does not audit against key performance indicators or provide detailed information regarding guideline based medical therapies’.

The rates of use of invasive investigation at the interventional centre are consistent with or higher than other reported rates in the literature. As with any tertiary care academic centre there will always be some patients who are not candidates for these tests.
6) The tables lack units and abbreviation legends.

We apologize for this oversight. Units have been added to Tables 1 and 2 (page 22-25) and abbreviation legends are included in the footnote below each table.

7) Why are the hazard ratios for interventional centers all 1.0 with no confidence intervals? Is this better presented in another way?

The interventional group undergoing catheterization was used as the reference group and therefore the hazard ratios were presented as 1.0. Table 3 has been revised (page 26) so that hazard ratios of 1.0 were replaced with the term ‘reference’ for clarity.

Reviewer 2

1) Typing error on page 4 -- delete "surgery" after CABG.

We thank the reviewer for pointing this out. The word surgery was deleted (line 74, page 4).

2) Please carefully review/edit the references

The entire reference section has been revised (page 15-20). One reference was deleted and three were added. Subsequently the order of the references was updated.

3) Table 1 and 2 "Coronary anatomy" should be removed from the title since there is no information regarding coronary anatomy.

The words “coronary anatomy” were deleted from Tables 1 and 2 (page 22-25).

4) Please list all abbreviations (such as BP, ECG) used in the footnote.

The footnote of Tables 1 and 2 have been revised to include all abbreviations (page 22-25).

5) The sentence "* Values are for ...." is irrelevant and should be removed

The sentence “Values are for N=4,739 patients who had coronary angiography” has been deleted from the footnote of Table 1 (page 22).

6) The footnote says "Values are median .....". Should it be "Values are expressed as mean (SD) and number (%)"?

The footnotes of Tables 1 and 2 were revised (page 22-25) to read ‘Values are expressed as mean ± SD and number (%)’.
7) Please add the title of table 3 and give an interpretation in the manuscript

The title of Table 3 was added (page 26) ‘Hazard ratios for 30-day and 1-year mortality’. An interpretation is included in the manuscript (page 12, lines 237-245) ‘In this study, there were no differences in 30-day or 1-year risk adjusted mortality between patients admitted to interventional and community hospitals, despite the differences noted in cardiac catheterization and revascularization rates. Differences in adherence to acute and long-term, guideline based medical therapies, in addition to numerous other patient care factors not evaluated in this study, could account for these findings. Similar findings were noted in a study evaluating outcomes of NSTEMI patients treated in academic and non-academic centers in the United States. Despite higher utilization of guideline based medications, cardiac catheterization and revascularization in academic centers, there were no differences in 1-year mortality compared to non-academic center patients’.

Requested formatting changes

1) Please rename your introduction section to background.

The introduction sections in the abstract (page 3, line 41) and the manuscript (page 4, line 64) have been renamed to background

2) Include purpose of the study in background section of the abstract.

The purpose of the study was included in the background section (page 3, lines 43-45) and (page 24-5, lines 83-86) ‘The purpose of this study was to evaluate process of care within a regional care model by comparing cardiac catheterization and revascularization rates and outcomes in ACS patients presenting to community and interventional hospitals’.

3) Please provide details of consent in the methods section.
The methods section has been modified to include the following statement (page 5, lines 101-104) ‘The APPROACH registry has an approved privacy impact assessment. The University of Calgary and University of Alberta Research Ethics Boards have approved APPROACH registry data collection and linkages with secondary sources’.