

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Applying Appropriate Use Criteria to Cardiac Revascularization in India
AUTHORS	Sood, Neeraj; Ugargol, Allen; Barnes, Kayleigh; Mahajan, Anish

VERSION 1 - REVIEW

REVIEWER	Dennis Ko Institute for Clinical Evaluative Sciences
REVIEW RETURNED	16-Nov-2015

GENERAL COMMENTS	<p>The authors examined the proportion of AUC in Karnataka, India, which is an area that has government sponsored health insurance. The authors examined a random sample of 600 patients (50% PCI and 50% CABG) and found that 86.7% of procedures are deemed appropriate, 3.65% deemed inappropriate, 9.63% deemed uncertain. The authors concluded that these levels of care met or exceeded the levels of cardiac care in the United States.</p> <p>The paper is well written and interesting that it applied the AUC in an area of India. The study is descriptive and focused on reporting rates of appropriate, inappropriate, uncertain coronary revascularization. The biggest limitation is the lack of information on stress testing. Whether it related to the fact that stress tests were not performed or missing is uncertain. This limitation is critical because categorization of AUC is based on symptoms, anatomy, medication use and stress test. When no stress test was performed, these patients will actually be classified into the missing group, rather than arbitrarily assigning them a score. The best/worst case assigning of stress test is not adequate because it is possible that the majority of patients did not actually get a stress test.</p> <p>Additional detail should be provided such as:</p> <ul style="list-style-type: none">a) Characteristics of PCI vs. CABGb) What medications were prescribed, at what timeframec) Demographic characteristicsd) Why a random selection of patients was performed?e) Information on the city that the study was performed. Was the regional practice representative of the practice in India?f) Is this a typical cohort of stable CAD? It is unusual to see 81% had class III to IV angina.
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REVIEWER	Jeremy Barofsky Brookings Institution, USA.
REVIEW RETURNED	28-Nov-2015

GENERAL COMMENTS	Summary: The authors analyze whether cardiac interventions in the Indian state of Karnataka were performed appropriately for patients
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in a given clinical scenario. Specifically, they examine patients who obtained either coronary artery bypass grafting (CABG) or percutaneous coronary interventions (PCI) through the Vajpayee Arogyashree Scheme (VAS), a government sponsored health insurance program. This program entitles recipients to free tertiary care, but requires pre-authorization for these cardiac procedures. Given that most recipients live in rural areas and participating hospitals are in the state's urban south, local health camps were conducted to pre-authorize patients and organize their transportation to the hospital. The authors collect data on 600 patients from 28 hospitals in Karnataka in late 2014, 300 obtained CABG and 300 PCI. To measure the appropriate use of these cardiac procedures, the authors used patient data from a VAS-maintained data exchange supplemented by additional cardiac information. Appropriate use criteria (AUC) identify patients for whom the benefits of performing the procedure outweigh the costs by a sufficient margin (appropriate) versus those where the benefits do not outweigh costs (inappropriate) or where the balance of risk is unclear (uncertain). To deal with missing data, they use random imputation and a best (worst) case scenario where the best (worst) level for each category is assigned to the missing data. When applying AUC, they find that 86.7% [83.7%-89.2%] of cases are deemed appropriate, 3.65% [2.3%-5.5%] inappropriate, and 9.63% [7.4%-12.3%] of cases uncertain. After implementing the best (worst) case analysis to deal with missingness, they find broadly similar high levels of appropriate use as with random imputation.

Main Comments: Given the recent expansion in health insurance coverage in India, throughout the developing world, and growing efforts to extend universal health coverage, this analysis is an important investigation of whether fighting coronary heart disease is effective in lower income settings. Since 150,000 PCIs were performed in India in 2011 and has undoubtedly grown considerably since, the scope for better understanding appropriate care use in this context is substantial. Although expanding health insurance coverage is an important first step toward financial risk protection and improved health outcomes, there are many steps in the process from coverage to health outcomes that could break down, including inappropriate use of care. It is possible that because of the recent expansion in coverage, the highest marginal benefit cases are being treated here and that over time appropriate use would decline. Also, it would be helpful in future research to connect AUC to health outcomes to verify that this measure, created in the developed world, applies in a lower-resourced setting and correlates to improved health outcomes. Nevertheless, this analysis represents an important contribution to our understanding of how extending coverage affects care quality. More specific comments are below.

1) Motivation and Background

- a. CHD should be written out in words in the abstract.
- b. Is there reason to believe that cardiac care / procedures aren't being used effectively? For example, if there aren't examples from the developing world, what is the range of appropriate use in the U.S.
- c. As the authors note, AUC were created in the developed world. The authors could include additional discussion of how AUC in India would vary from that used here, for example with greater emphasis on health status post-procedure, given

	<p>the lower level of access to medication for secondary prevention and follow-up care among this lower income, rural patient population.</p> <p>d. P. 5 Delphi exercise should be defined in a footnote / endnote.</p> <p>2) Data:</p> <p>a. P. 7. PTCA is mentioned without defining it and PTCA's relationship to PCI should also be clarified there, as well.</p> <p>b. Representativeness: Discussion should be added on the representativeness of these data of Karnataka's overall population. Where were the rural villages drawn from?</p> <p>c. It is possible also that since health insurance was recently extended to this population, these patients represent the highest marginal value ones. If so, this would suggest that over time, cases presenting would be less clear and appropriateness would decline. This possibility should be added to the limitations.</p> <p>d. In addition, the health camp itself represents another difference from the standard way in which patients access the health system. Those that went to a health camp might not be the same that would present in a rural health clinic because of lower transaction costs or perceptions of higher quality care. A brief discussion of changes in access from the health camp versus access to rural health centers, should be included. Will the health camps continue to be organized?</p> <p>e. Table 2 – the acronyms such as CTO, non-LAD, Prox LAD, and CCS class should be defined in table notes since they not otherwise defined in the text.</p> <p>f. P.9 Sentence reads: "For example, if a case has missing stress test information..." Since it is stated that all stress test information is missing, another example should be used.</p> <p>g. There should a short discussion added as to the importance of the stress test information for differentiating cases in AUC. Given the best (worst) case scenario simulation, and the fact that the results do not vary substantially, this suggests that having stress test information does not provide sensitive case differentiation, but this should mentioned.</p> <p>3) Results:</p> <p>a. It would be interesting to tell us whether the AUC results differ by procedure type or if they are consistent between the two. Would we expect AUC to more accurately apply to patients indicated for CABG or PCI or not expect any difference?</p> <p>b. The pre-authorization may be the reason for such a high level of appropriate use (determining this is of course not possible using these data), but to better understand the likelihood of the effectiveness of pre-authorization, were those that authorized procedures in the health camps also those that benefited by that authorization? That is, were the hospitals performing the authorization or another entity? Knowing this would help others design their</p>
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	pre-authorization program effectively.
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dennis Ko
Institute for Clinical Evaluative Sciences

Comments to authors

The authors examined the proportion of AUC in Karnataka, India, which is an area that has government sponsored health insurance. The authors examined a random sample of 600 patients (50% PCI and 50% CABG) and found that 86.7% of procedures are deemed appropriate, 3.65% deemed inappropriate, 9.63% deemed uncertain. The authors concluded that these levels of care met or exceeded the levels of cardiac care in the United States.

The paper is well written and interesting that it applied the AUC in an area of India. The study is descriptive and focused on reporting rates of appropriate, inappropriate, uncertain coronary revascularization.

Response: Thank you for the careful review of the paper and for agreeing that the paper is well written and interesting.

The biggest limitation is the lack information on stress testing. Whether it related to the fact that stress tests were not performed or missing is uncertain. This limitation is critical because categorization of AUC is based on symptoms, anatomy, medication use and stress test. When no stress test was performed, these patients will actually be classified into the missing group, rather than arbitrary assigning them a score. The best/worst case assigning of stress test is not adequate because it is possible that the majority of patients did not actually get a stress test.

Response: We conducted a pilot study and found that information on stress testing, angina symptoms and medications was missing from the preauthorization records. Based on these findings, a Supplemental Cardiac Information Sheet (SCIS) was developed to capture more consistent information on these data elements. This SCIS was included in the mandatory documents checklist for pre-authorization for all empaneled hospitals from September 1, 2014. Our study period began from October 1, 2014 from which time we collected data on cardiac cases which came up for preauthorization approval. The SCIS data had more or less complete information on coronary anatomy from angiogram reports, standardized information on angina symptoms, and information on outpatient anti-anginal medication therapy. However, it had no information on stress test results. The SCIS did ask whether a stress test was performed and in 100% of the cases the doctor at the treating hospital reported that a stress test was not performed. However, we cannot be sure if the stress test was performed at an earlier time in an outpatient setting and the doctor at the treating hospital simply did not have the information.

We agree that lack of information on stress test is a limitation. To address this limitation we conducted best-case – worst-cases scenario. While the best-case worst-case scenario is not ideal, it does give upper and lower bounds for appropriate and inappropriate. Thus, although without stress test information we cannot provide exact estimates of inappropriate care we can provide a range of estimates. For example, our estimates imply that the fraction of patients receiving inappropriate care ranged between 2% and 7.5%. We believe that this information on the range of outcomes is valuable. In the revised paper, we now clearly note in the limitations section that missing stress test information is limitation of this study and we note our approach of dealing with this limitation. In addition, in the discussion section we again highlight the missing stress test information and note the importance of encouraging stress tests and collecting systematic information on the results of the tests.

Additional detail should be provided such as:

a) Characteristics of PCI vs. CABG

Response: Thank you for this excellent suggestion. We have updated our paper now provide separate estimates of appropriate, uncertain and inappropriate care by PCI and CABG. We find higher rates of appropriate care for CABG patients.

b) What medications were prescribed, at what timeframe

Response: We have included tables in the appendix with information about the drugs that were prescribed to patients upon discharge and the drugs patients were taking prior to being admitted. We do not have information on how long patients had been taking anti-anginal medication prior to being admitted. We find that a larger percentage of patients who had CABG surgery were taking aspirin, nitrates, beta blockers, and calcium channel blockers than those who had PCI. Aspirin was the most common drug already being taken upon arrival, followed by beta blockers and a majority of patients were also taking "other cardiac medication" prior to being admitted. Virtually all patients were prescribed some type of aspirin upon discharge. A large percentage were also prescribed beta blockers and dyslipidaemic agents.

c) Demographic characteristics

Response: Age, gender and location demographics were already included in the Data section of our paper. All of the people in our study are below the poverty line. We do not have demographic data beyond age, sex, and location of the hospital at which the patient was treated.

d) Why a random selection of patients was performed?

Response: A random selection of cases was performed due to budgetary constraints. We could not have reviewed all of the cases given the budget for this research project.

e) Information on the city that the study was performed. Was the regional practice representative of the practice in India?

Response: We have revised the paper to note that the majority of the cases were performed in Bangalore – a major urban center and the capital of the state. Some of the hospitals in our study are large national chain hospitals with locations not only in Karnataka but also in several other states in India. While others are academic research centers.

f) Is this a typical cohort of stable CAD? It is unusual to see 81% had class III to IV angina.

Response: We mention in the Discussion section that our data is limited by the veracity of the physicians' reporting. The high level of class III and IV angina could be due in part to physician over reporting. Another consideration is that the people included in the study previously did not have health insurance. These people could have been requiring cardiac care for long before they received the insurance to be able to do so thus causing our cohort to include a high number of people who have been sicker for longer. We have revised the limitations section of the paper to highlight this information.

Review of "Appropriate use criteria for coronary artery disease in India"

Summary: The authors analyze whether cardiac interventions in the Indian state of Karnataka were performed appropriately for patients in a given clinical scenario. Specifically, they examine patients who obtained either coronary artery bypass grafting (CABG) or percutaneous coronary interventions (PCI) through the Vajpayee Arogyashree Scheme (VAS), a government sponsored health insurance program. This program entitles recipients to free tertiary care, but requires pre-authorization for these cardiac procedures. Given that most recipients live in rural areas and participating hospitals are in the state's urban south, local health camps were conducted to pre-authorize patients and organize their transportation to the hospital. The authors collect data on 600 patients from 28 hospitals in Karnataka in late 2014, 300 obtained CABG and 300 PCI. To measure the appropriate use of these cardiac procedures, the authors used patient data from a VAS-maintained data exchange supplemented by additional cardiac information. Appropriate use criteria (AUC) identify patients for whom the benefits of performing the procedure outweigh the costs by a sufficient margin (appropriate) versus those where the benefits do not outweigh costs (inappropriate) or where the balance of risk is unclear (uncertain). To deal with missing data, they use random

imputation and a best (worst) case scenario where the best (worst) level for each category is assigned to the missing data. When applying AUC, they find that 86.7% [83.7%-89.2%] of cases are deemed appropriate, 3.65% [2.3%-5.5%] inappropriate, and 9.63% [7.4%- 12.3%] of cases uncertain. After implementing the best (worst) case analysis to deal with missingness, they find broadly similar high levels of appropriate use as with random imputation.

Main Comments: Given the recent expansion in health insurance coverage in India, throughout the developing world, and growing efforts to extend universal health coverage, this analysis is an important investigation of whether fighting coronary heart disease is effective in lower income settings. Since 150,000 PCIs were performed in India in 2011 and has undoubtedly grown considerably since, the scope for better understanding appropriate care use in this context is substantial. Although expanding health insurance coverage is an important first step toward financial risk protection and improved health outcomes, there are many steps in the process from coverage to health outcomes that could break down, including inappropriate use of care. It is possible that because of the recent expansion in coverage, the highest marginal benefit cases are being treated here and that over time appropriate use would decline. Also, it would be helpful in future research to connect AUC to health outcomes to verify that this measure, created in the developed world, applies in a lower-resourced setting and correlates to improved health outcomes. Nevertheless, this analysis represents an important contribution to our understanding of how extending coverage affects care quality. More specific comments are below.

Response: Thank you for a careful review of the paper and for noting that it makes an important contribution.

1) Motivation and Background

a. CHD should be written out in words in the abstract.

Response: We have revised the paper to address this.

b. Is there reason to believe that cardiac care / procedures aren't being used effectively? For example, if there aren't examples from the developing world, what is the range of appropriate use in the U.S.

Response: We discuss the range of appropriateness in the US in both the background and discussion sections. In addition, we have cited media sources that discuss worries of unnecessary stenting and cardiac care in India.

c. As the authors note, AUC were created in the developed world. The authors could include additional discussion of how AUC in India would vary from that used here, for example with greater emphasis on health status post-procedure, given the lower level of access to medication for secondary prevention and follow-up care among this lower income, rural patient population.

Response: We address the need for more localized AUC in our discussion section and we have expanded upon reasons necessitating more localized criteria.

d. P. 5 Delphi exercise should be defined in a footnote / endnote.

Response: We have revised the paper to address this.

2) Data:

a. P. 7. PTCA is mentioned without defining it and PTCA's relationship to PCI should also be clarified there, as well.

Response: We have clarified the relationship between PTCA and PCI in and its relationship with CABG in the introduction.

b. Representativeness: Discussion should be added on the representativeness of these data of Karnataka's overall population. Where were the rural villages drawn from?

Response: All of the patients in our study were below the poverty line and enrolled in VAS. According to the Reserve Bank of India the poverty rate in Karnataka is 20.91%, thus our study is considerably poorer than the general population of Karnataka. We did not have data on which villages patients came from as this was considered to be protected information. However, we do know the cities in Karnataka where the procedures were performed. The majority of the procedures were performed in Bangalore. We have included a table in the appendix that shows the distribution of procedures across

cities in Karnataka.

c. It is possible also that since health insurance was recently extended to this population, these patients represent the highest marginal value ones. If so, this would suggest that over time, cases presenting would be less clear and appropriateness would decline. This possibility should be added to the limitations.

Response: We addressed the possibility of the highest marginal benefit cases being treated in the Discussion section. That was a great point that we hadn't considered.

d. In addition, the health camp itself represents another difference from the standard way in which patients access the health system. Those that went to a health camp might not be the same that would present in a rural health clinic because of lower transaction costs or perceptions of higher quality care. A brief discussion of changes in access from the health camp versus access to rural health centers, should be included. Will the health camps continue to be organized?

Response: Health camps were organized by the hospitals and included a cardiologist, this is the standard way screening occurs. These health camps differ from rural health clinics which typically do not have a specialist. To the best of our knowledge health camps will continue to be organized. We have revised the paper to note the differences between health camps and rural clinics.

e. Table 2 – the acronyms such as CTO, non-LAD, Prox LAD, and CCS class should be defined in table notes since they not otherwise defined in the text.

Response: We have revised the paper to address this.

f. P.9 Sentence reads: "For example, if a case has missing stress test information..." Since it is stated that all stress test information is missing, another example should be used.

Response: We have revised the paper to address this.

g. There should a short discussion added as to the importance of the stress test information for differentiating cases in AUC. Given the best (worst) case scenario simulation, and the fact that the results do not vary substantially, this suggests that having stress test information does not provide sensitive case differentiation, but this should mentioned.

Response: We discuss how our results vary in best case – worst case scenario in the discussion section and have expanded on how that variation reflects the importance of stress testing.

3) Results:

a. It would be interesting to tell us whether the AUC results differ by procedure type or if they are consistent between the two. Would we expect AUC to more accurately apply to patients indicated for CABG or PCI or not expect any difference?

Response: We have conducted the analysis separately and have found that PCI tends to have less appropriate cases than CABG by about 10% of cases. This is expected as CABG or bypass surgery is more invasive procedure.

b. The pre-authorization may be the reason for such a high level of appropriate use (determining this is of course not possible using these data), but to better understand the likelihood of the effectiveness of pre-authorization, were those that authorized procedures in the health camps also those that benefited by that authorization? That is, were the hospitals performing the authorization or another entity? Knowing this would help others design their pre-authorization program effectively.

Response: The authorization was done by an independent cardiologist employed through VAS, the health insurance scheme. Although the health camps were organized by the hospital the assessment and authorization was done by an independent entity. We have now addressed this in the Study Context section.

VERSION 2 – REVIEW

REVIEWER	Jeremy Barofsky Brookings Institution, USA
REVIEW RETURNED	29-Feb-2016

GENERAL COMMENTS	The changes made and clarifications provided by the authors appropriately address the questions and comments made during the paper's review.
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