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Applying appropriate-use criteria to cardiac revascularisation in India

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ABSTRACT

Objectives: The high prevalence of coronary heart disease and dramatic growth of cardiac interventions in India motivate an evaluation of the appropriateness of coronary revascularisation procedures in India. Although, appropriate-use criteria (AUC) have been used to analyse the appropriateness of cardiovascular care in the USA, they are yet to be applied to care in India. In our study, we apply AUC to cardiac care in Karnataka, India, compare our results to international applications of AUC, and suggest ways to improve the appropriateness of care in India.

Setting: Data were collected from the Vajpayee Arogyashree Scheme, a government-sponsored health insurance scheme in Karnataka, India. These data were collected as part of the preauthorisation process for cardiac procedures.

Participants: The final data included a random sample of 600 patients from 28 hospitals in Karnataka, who obtained coronary artery bypass grafting or percutaneous coronary intervention between 1 October 2014 and 31 December 2014.

Primary and secondary outcome measures: We obtained our primary baseline results using a random imputation simulation to fill in missing data. Our secondary outcome measure was a best case–worst case scenario where missing data were filled to give the lowest or highest number of appropriate cases.

Results: Of the cases, 86.7% (CI 0.837% to 0.892%) were deemed appropriate, 3.65% (CI 0.023% to 0.055%) were inappropriate and 9.63% (CI 0.074% to 0.123%) were uncertain.

Conclusions: The vast majority of cardiac revascularisation procedures performed on beneficiaries of a government-sponsored insurance programme in India were found to be appropriate. These results meet or exceed levels of appropriate use of cardiac care in the USA.

Strengths and limitations of this study

- Our study is the first to apply appropriate-use criteria to cardiac care in India.
- Our data are missing stress test results but we account for this by utilising a random imputation and best case–worst case simulations.
- Our results may not be generalisable to situations without preauthorisation for cardiac revascularisation.
- Our results depend on the veracity of reported angina symptoms and medication use.

INTRODUCTION

Cardiovascular diseases such as coronary heart disease (CHD) and stroke are the leading causes of death in developing countries, including India.[1] The prevalence of CHD in India in 2003 was estimated to be 3–4% in rural areas and 8–10% in urban areas.[2] CHD affects a younger population in India, with disease onset being almost 10 years earlier on average in India compared with the developed world.[2 3] The burden of CHD is expected to rise rapidly in India, and it has been projected that roughly 60% of the world's patients with heart disease currently live in India.[1 4] There has also been remarkable growth in the number of percutaneous coronary interventions (PCIs) performed in India. Based on data from a national registry, roughly 22 000 PCIs were performed in 2002.[5] The number of interventions increased more than sevenfold in a decade and about 150 000 PCIs were performed in India in 2011.[6] Further, there have been media reports of high levels of unnecessary stenting.[7 8] The high prevalence of CHD and dramatic growth of cardiac interventions in India along with reports of unnecessary use motivate an evaluation of the appropriateness of coronary revascularisation procedures in India. Such a review is especially important in India, where resources for healthcare are limited, and access to secondary care and follow-up procedures might also be limited.

Appropriate-use criteria (AUC) for coronary revascularisation have been used in the USA to assess appropriateness of coronary artery bypass graft (CABG) surgeries and PCI. PCI, also known as percutaneous transluminal coronary angioplasty or PTCA, is a non-surgical stenting procedure. The criteria determine whether the procedure is appropriate for a given clinical scenario. The procedure is determined appropriate for a given

clinical scenario when the benefits of performing the procedure outweigh the risks by a sufficient margin, inappropriate if the risk outweighs the benefits by a sufficient margin, or uncertain if the benefit-to-risk ratio is equivocal. In addition to periprocedure/operative complications, risks to patients of PCI and CABG include bleeding secondary to use of long-term anticoagulation. AUC help physicians select an optimal intervention that balances risks versus benefits based on the patient's specific clinical presentation. The goal of AUC is to simultaneously improve outcomes and reduce costs by reducing the amount of inappropriate use of coronary revascularisation and increase its appropriate use. In this study, we assess the state of cardiac care in Karnataka, India, using AUC. To the best of our knowledge, this is the first time AUC have been applied to examine the value of cardiac care in India.

BACKGROUND

Development of AUC

AUC were developed by the American College of Cardiology Foundation in collaboration with the Society for Cardiovascular Angiography and Interventions, the Society of Thoracic Surgeons, the American Association for Thoracic Surgery and other societies initially in 2009, and were recently, in 2012, updated.[9] Relevant literature was reviewed and synthesised into an annotated summary of the evidence for the effectiveness and risks of PCI and CABG for each of the indications for revascularisation. Next, a set of clinical scenarios were derived that encompassed both appropriate and inappropriate care that would likely arise in clinical practice. For example, a scenario could be class III–IV chronic stable angina in a patient who has been treated with maximal medical therapy and who has three-vessel coronary artery disease. These scenarios or indications were grouped into symptom complexes called chapters, such as 'chronic stable angina'. A single chapter thus had many indications, each representing a unique combination of essential factors. A technical panel of internationally distinguished cardiologists then rated the appropriateness of each indication through a two-step modified Delphi exercise.[i] Panellists were first asked individually, and then collectively, to assess the benefits and risks of a test or procedure in the context of the potential benefits to patients' outcomes, and an implicit understanding of the associated resource use and costs. After the rating process, the final appropriate-use ratings were summarised using an established rigorous methodology. The major variables for determining appropriateness include severity of angina, extent of medical therapy, extent of ischaemia and extent of anatomic disease. A list and description of these variables can be found in table 1. Since AUC was developed based on the best available evidence from international medical literature at the time, it is applicable to many countries and settings. In the USA, studies of AUC and other appropriateness criteria applied to PCI and CABG demonstrate, on average, that 85–90% of procedures/surgeries were appropriate, 7–10% were uncertain and 3–5% were inappropriate.[10 11] The prevalence of inappropriate use of care was minimal for patients presenting for care with acute indications.

Study context

This analysis is part of study of a government-sponsored social health insurance scheme in Karnataka that was initially introduced in the northern part of the state in February 2010 and then rolled out to the rest of the state in 2012. The design and features of this health insurance programme are similar to those of other state-sponsored insurance programmes in India. The scheme, called Vajpayee Arogyashree Scheme (VAS), entitles recipients to free tertiary care, including cardiac, oncological, neurological, burn and trauma care at both public and private hospitals empanelled in the scheme, and is financed through taxes. The majority of people participating in VAS are poor and live in rural areas. Because the eligible population is mostly rural and many of the empanelled hospitals are located in the urban south of Karnataka, hospitals are required to conduct local health camps to screen patients and then transport the eligible patient to the tertiary centres. These health camps are staffed with a cardiologist and are the standard way screening occurs in VAS as opposed to rural health clinics, which typically have no specialist on their staff. Authorisation was carried out by the independent cardiologist who was employed through VAS. Procedures covered under the scheme are cashless transactions—patients obtain treatment without any payments to the hospital. For cardiac procedures, eligible patients were authorised CABG or PCI if they had at least a 70% block of any cardiac vessel. Hospitals were reimbursed for their services in a fixed bundled payment based on a schedule for more than 400 tertiary care service packages.

DATA COLLECTION AND METHODS

We used data from the Payer-Provider Healthcare Data Exchange Platform maintained by VAS to access the medical records for 600 cases (300 CABG and 300 PCI) for the period 1 October 2014 to 31 December 2014. These were randomly selected from over 2000 PTCA procedures and about 1500 CABG procedures performed during this period. These data were collected as part of the VAS preauthorisation process. An initial pilot study found largely inconsistent data on angina symptoms, stress testing and outpatient medications. Based

[i]In the Delphi method, experts in a field anonymously respond to questionnaires. After responses are obtained, each expert receives statistics on the responses of the entire group, after which the process is repeated. The aim of a Delphi exercise is to arrive at a consensus with little variation in responses.

Table 1 Variables that determine appropriateness

Variable	Description
Severity of angina	Asymptomatic, CCS class I, II, III or IV
Extent of medical therapy	Maximum antianginal Rx: use of at least two classes of drugs to reduce angina symptoms
Extent of ischaemia	Based on non-invasive stress testing and assessment of ischaemic risk (low, intermediate, high)
Extent of anatomic disease	One-vessel, two-vessel, three-vessel disease, with or without proximal LAD or left main coronary artery

CCS, Canadian Cardiovascular Society; proximal LAD, proximal left anterior descending coronary artery.

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-authorisation for all empanelled hospitals from 1 September 2014. Our study period began on 1 October 2014, from which time we collected data on cardiac cases that came up for preauthorisation approval. The data collection period extended from 1 October 2014 to 31 December 2014, during which time a random sample of 600 medical records were studied.

Empanelled hospitals uploaded PDF documents to an online portal. The PDF documents contained detailed medical records and the SCIS for each patient being considered for CABG or PCI. Information from these PDF documents was entered into an Excel spreadsheet, de-identifying the patient. The key data elements noted on the spreadsheet are outlined in table 1. Only those patient records approved for the procedure by the insurance programme were taken into consideration. The final data included a random sample of 600 patients from 28 hospitals in Karnataka, evenly divided between CABG and PCI. The majority of the hospitals were located in Bangalore. Some of the hospitals included in our study are large national chain hospitals with locations in several other states, while others are large academic medical centres. The distribution of hospital locations can be found in online supplementary appendix table 1. The average age of patients included in the study was 55 years and 77% of the patients were male. All the patients included in our study were below the poverty line. Our data had complete coronary anatomy information from angiogram reports with missing information for only two cases, standardised information on angina symptoms with missing information for only 49 cases and complete information on outpatient antianginal medication therapy with missing information for only six cases. However, our data 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 reported that a stress test was not performed. Table 2 reports summary statistics on angiogram findings, angina symptoms and antianginal medications relevant for AUC. We provide a detailed description of antianginal medication that patients were taking on arrival and were prescribed on discharge in online supplementary appendix tables 2 and 3.

Table 2 Summary results from chart abstraction tool

AUC category and variable	Per cent
Procedure, N=600	
PCI	50
CABG	50
Angiogram findings, N=598	
CTO of 1 vessel (non-LAD)	5
1–2 vessel (not prox LAD)	12
1-vessel disease of prox LAD	31
2-vessel disease including prox LAD	27
3-vessel disease (not left main artery)	19
Medical therapy, N=594	
No or minimal medication	37
Maximal medication	63
CCS class, N=551	
Asymptomatic	0
Class I	2
Class II	12
Class III	56
Class IV	25

CCS class, Canadian Cardiovascular Society grading of angina pectoris; CTO, chronic total occlusion; LAD, left anterior descending coronary artery; prox, proximal.

In order to perform AUC scoring and account for these missing data, we performed two simulation analyses: a random imputation and a best case–worst case scenario. Both analyses were programmed in STATA. In the random imputation, we fill in missing data randomly. For example, if a case had missing medication information, it would be randomly filled in with either minimal medication or maximal medication with both categories having a one in two chance of selection for imputation. We followed a similar procedure for each missing data element (Stress Test, CCS, Rx, or angiogram). After missing data were imputed, we calculated the proportion of patients that fell into each respective appropriateness classification. We repeated the process 500 times and took the average.

In the best (worst) case analysis we assigned the least (most) severe level for each category to the missing data. Thus, the 'best case' is the highest possible proportion of appropriate cardiac interventions and the 'worst case' is the least possible proportion of appropriate cardiac interventions. The best case–worst case scenario gives a sense of how vital missing data are to accurately inferring appropriateness.

RESULTS

We found that, at baseline, 86.7% (CI 0.837% to 0.892%) of cases were deemed appropriate, 3.65% (CI 0.023% to 0.055%) were inappropriate and 9.63% (CI

0.074% to 0.123%) of cases were uncertain. Our results are displayed in figure 1. Our best case–worst case scenario gives us the range of possible outcomes. We found that in the best case: 92.2% (CI 0.897% to 0.940%) of revascularisations were appropriate, 2% (CI 0.011% to 0.035%) were inappropriate and 5.8% (CI 0.042% to 0.080%) were uncertain. In the worst case scenario, we found that: 76.7% (CI 0.73% to 0.799%) of cases were appropriate, 7.5% (CI 0.056% to 0.099%) were inappropriate and 15.8% (CI 0.131% to 0.190%) were uncertain. Our results for the best case–worst case analysis are presented graphically in figure 2. We looked at the best case–worst case scenario by hospital for the five hospitals with more than 30 observations. In the worst case, the per cent of appropriate cases ranged from 60.9% (CI 0.462% to 0.755%) to 91.7% (CI 0.873% to 0.961%), the per cent of inappropriate cases ranged from 3.2% (CI 0.004% to 0.059%) to 13% (CI 0.029% to 0.232%) and the per cent of uncertain cases ranged from 5.1% (CI 0.016% to 0.086%) to 26% (CI 0.129% to 0.393%). In the best case scenario, the per cent of appropriate cases ranged from 81.5% (CI 0.734% to 0.896%) to 98.3% (CI 0.947% to 1.000%), the per cent of inappropriate cases ranged from 0% (CI 0.000% to 0.063%) to 6.52% (CI 0.014% to 0.117%) and the per cent of uncertain cases ranged from 1.8% (CI 0.000% to 0.053%) to 15.22% (CI 0.044% to 0.260%).

We also compared our results running our analysis on only PCI cases and then only CABG cases. For PCI, we found that 80.9% (CI 0.761% to 0.852%) of cases were deemed appropriate, 5.6% (CI 0.033% to 0.089%) were deemed inappropriate and 13.4% (CI 0.097% to 0.177%) were deemed uncertain. In the best case–worst case scenario for PCI, we found that appropriate cases ranged from 72% (CI 0.666% to 0.770%) in the worst case to 86% (CI 0.816% to 0.897%), inappropriate cases ranged from 2.7% (CI 0.011% to 0.051%) to 11.3% (CI 0.079% to 0.155%) and uncertain cases ranged from 11.3% (CI 0.079% to 0.155%) to 16.7% (CI 0.126% to 0.213%). Restricting to only CABG cases, we found a slightly higher level of appropriateness. In the baseline analysis, 92.6%

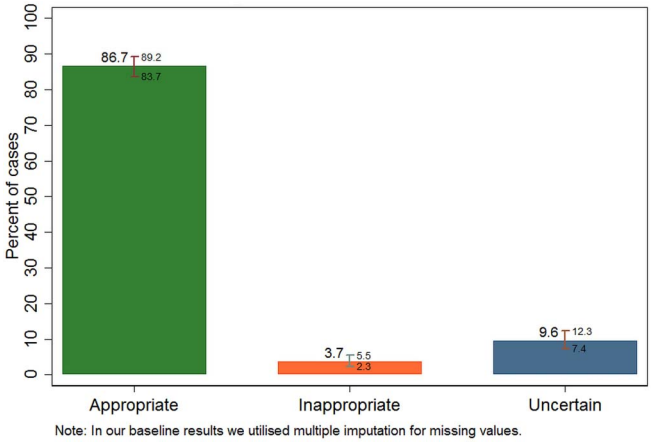

Figure 1 Baseline results.

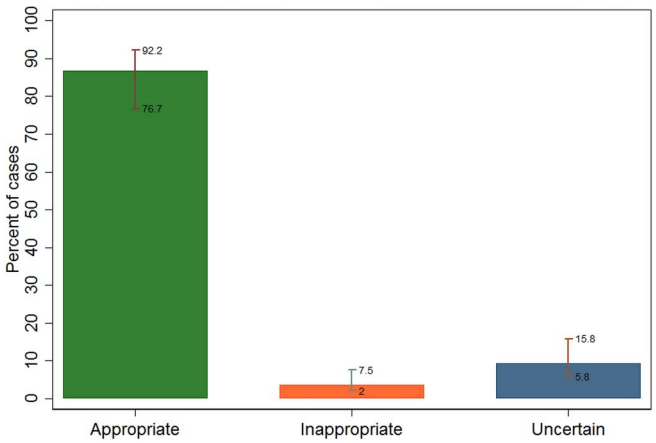

Figure 2 Best case–worst case simulation results.

(CI 0.891% to 0.953%) were deemed appropriate, 1.7% (CI 0.005% to 0.038%) were deemed inappropriate and 5.7% (CI 0.033% to 0.089%) were deemed uncertain. The best case–worst case for CABG cases gives a range of 81.3% (CI 0.765% to 0.856%) to 98.3% (CI 0.962% to 0.995%) for appropriate cases, 1.3% (CI 0.003% to 0.034%) to 3.7% (CI 0.018% to 0.065%) for inappropriate cases and 0.3% (CI 0.000% to 0.018%) to 15% (CI 0.112% to 0.196%) for uncertain cases.

DISCUSSION AND RECOMMENDATIONS

The results of our analysis indicate that the appropriateness of cardiac care among beneficiaries of a government-sponsored insurance programme in Karnataka, India, meets or exceeds international norms.[10–14] This is an important finding given that this is the first application of AUC to cardiovascular care in India. Even though our results are encouraging, there are still about 13% of procedures being deemed as inappropriate or of uncertain value. Owing to the large and growing number of cardiac revascularisations performed in India, even a slight reduction in the proportion of inappropriate cases could have a huge impact on health outcomes. Moreover, given that rural households in low-income countries often lack access to medical care and medications, the consequences of inappropriate cardiac procedures might be more severe in these countries. For example, patients might have a higher risk of restenosis due to lack of access to medications for secondary prevention, challenges with long-term adherence to anticoagulation and lack of standard follow-up care. Although our study is the only application of AUC in India, expansions of government-sponsored health insurance programmes both at the state and national level could make it more feasible for AUC to be utilised for prior authorisation of cardiac procedures in India.

The findings of this study should be viewed in light of its limitations. First, our results may not be generalisable to situations without preauthorisation; although preauthorisation for patients in our data set did not use AUC it is possible that contexts lacking preauthorisation

have a higher rate of inappropriate cardiac procedures. Second, our study is limited by the availability of information. We lacked stress test information for all patients in our data set, which is a key factor for determining appropriate use. Thus, our study cannot provide exact estimates of the fraction of patients receiving appropriate or inappropriate care. However, as shown in our best case–worst case scenario, our study can provide assessments of the range of possible estimates. For example, our estimates imply that the fraction of patients receiving inappropriate care ranged between 2% and 7.5%. We believe this information is valuable for practitioners and policymakers. The credibility of our results also depends on the veracity of the data on angina symptoms and medication use, these are based on physician reports and we could not verify this information independently. Our study is also comprised of individuals who previously lacked health insurance. It is possible that people who needed to be treated in the years prior did not seek out treatment due to costs, thus the highest marginal benefit cases are inflating the number of appropriate cases in our sample. Finally, we used international appropriate-use criteria rather than those designed specifically for the local population.

Going forward, we recommend strengthening AUC analysis by auditing AUC information through both patient interviews for angina symptoms and outpatient medications, and medical reviews for angiogram results. We also suggest that a survey be established to follow patients who received cardiac procedures, to gather information on long-term patient outcomes that can be used to develop a more localised AUC. AUC was created in the developed world and more localised AUC could address challenges specific to this population, such as lower access to follow-up care and medicine for prevention. In addition to more careful monitoring of appropriate-use criteria, we also recommend wider use of AUC for preauthorisation of cardiac revascularisation procedures. Even though our results are similar to what has been found internationally, there are still about 13% of cases that have been deemed inappropriate or uncertain. Procedures that have been deemed inappropriate under AUC should not be authorised and procedures deemed uncertain should undergo additional medical screening to determine whether the revascularisation should occur on a case-by-case basis. Finally, we were completely missing data on stress testing. We suspect that this may be due to a lack of reimbursement for such tests. We recommend encouraging non-invasive stress testing, or Treadmill Stress Test (TMT). Encouraging these tests will help to avoid angiograms in cases where stress test results indicate mild or no disease. In addition to this, it is more difficult to alter the results of these tests, so having stress test information will improve the accuracy of AUC determination. Incorporating these recommendations will improve AUC identification in the future, and also improve the quality and efficiency of cardiac care in India.

Contributors NS conceived the idea for the study, developed the study design, analysed the data, and drafted and revised the paper. KB analysed the data, and drafted and revised the paper. APU collected the data and developed the study design. AM developed the study design, and drafted and revised the paper.

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Ethics approval Institutional Review Board (IRB) at University of Southern California (USC) and Indian Institute of Management, Bangalore.

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