

## Original Article

# Adherence to American Heart Association and American College of Cardiology Standard Guidelines of Angiography in Shiraz, Iran

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## Abstract

**Background and Objectives:** Coronary angiography is the most accurate and standard method for investigating the anatomic status and blood supply to the heart tissue; however, this method has been overused during the past decade. The present study aimed to investigate the appropriateness of coronary angiography in the patients referred to the selected hospital clinics in Shiraz, Iran.

**Methods:** This study included 280 outpatients who were referred to seven selected hospitals of Shiraz for coronary angiography. In order to collect the data regarding the patients and the angiography use, a questionnaire and a checklist were utilized. All the analyses were performed in SPSS, version 15.

**Results:** Among 280 angiography cases, 206 (73.6%), 34 (12.2%), and 40 (14.3%) cases were considered as appropriate, uncertain, and inappropriate, respectively. Due to the 40 cases of inappropriate use of angiography, 19000 US dollars have been imposed on the insurance organizations as well as the patients.

**Conclusion:** Senior managers of healthcare centers are recommended to pay special attention to the performance of diagnostic as well as therapeutic procedures according to the reliable and standard guidelines. Besides, insurance organizations and other institutes which reimburse the expenses should consider the appropriateness of application of angiography as a basis for the imbursement.

**Keywords:** Angiography, ACC/AHA guidelines, coronary angiography, inappropriate angiography cost

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## Introduction

Although the increasing use of expensive, modern diagnostic services in the health system helps the physicians to diagnose the diseases timely and perform the necessary treatment measures for the patients, it has resulted in an increasing trend in the cost of medical imaging procedures during the recent two decades in a way that allocating the resources to this part in low- or middle-income countries leads to deprivation of other parts of resources. Furthermore, various investigations have shown that a large number of the healthcare services provided might be inappropriate or unnecessary.<sup>1,2,3</sup>

Analysis and understanding of the pattern of using diagnostic imaging technologies are of utmost importance for health planning systems particularly in low- or middle-income countries.<sup>4</sup>

Coronary angiography is one of the diagnostic services which has considerably increased during the recent years.<sup>5</sup>

During the past decade, coronary angiography has been quite effective in diagnosis and treatment of cardiac patients and consequently, improvement of the treatment outcomes as well as the

quality of life among patients. Nevertheless, although angiography is a gold standard in diagnosis of coronary artery disease (CAD),<sup>6</sup> cost-effectiveness analyses have shown that in case the probability of diagnosing CAD after performing an angiography procedure is less than 70%, this procedure will not be cost-effective. In this regard, effectiveness refers to the number of patients whose CAD has been confirmed after coronary angiography and, consequently, have undergone percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG). This improves the outcomes of the interventions as well as the treatment measures and increases the number of years the patients live a high-quality life.<sup>7,8</sup>

Evidence shows that coronary angiography has been overused during the past decade and although this procedure is an expensive and invasive one, its inappropriateness has been reported from 2% to 58% in different studies.<sup>9,10</sup> For instance, application of this procedure in the US is three times more than that in England and two times more than Canada.<sup>11,12</sup>

Overall, using noninvasive diagnostic tests is much more cost-effective for diagnosis and control of CAD.<sup>13,14</sup> However, in spite of recommendations of the world's reliable centers such as American Heart Association (AHA), American College of Cardiology (ACC), and European Society of Cardiology, a large number of patients directly get an angiography without performing initial diagnostic tests. This not only affects the quality of cardiovascular care services and the outcomes of the treatment interventions performed for the patients, but also increases the expenditures of the department of health as well as the patients.<sup>14,15</sup> On the other hand, mortality of coronary angiography is about 0.08% when its major complications are less than 2%, and poses the patients to the risk of complications such as allergy, infections, nephropathy, chole-

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terol emboli, local vascular injury, behavioral disturbances, death, myocardial infarction, cerebrovascular complications, dissection, and perforation of great vessels.<sup>16</sup>

Every year, governments spend a great amount of money for diagnosing CAD. According to statistics, 1.3 million cases of angiography performed in the US in 2005 had a 34% increase in comparison to 1970 and after five years, i.e., in 2010, the number of angiography cases reached three million. Thus, this procedure is the second mostly performed one in the US and the first procedure performed for the individuals above 65 years of age.<sup>7,17</sup>

According to what was mentioned above and considering the importance of the issue, the present study aimed to investigate the appropriateness of coronary angiography use in the outpatients referred to the selected hospitals of Shiraz, Iran.

## Materials and Methods

The present cross-sectional study was conducted in 2012 in order to investigate the appropriateness of coronary angiography use in selected university and private hospitals of Shiraz, Iran.

The research community of the study included the outpatients referred to the randomly selected hospitals including "N", "F", "A", "C", "D", "B", and "K" hospitals, for coronary angiography. At present, angiography is performed in nine hospitals of Shiraz, among which seven universities, private as well as semi-private, and charity hospitals were selected. In each hospital, we randomly selected different days of months and in each day, in the selected hospital, all patients of that day were selected and data were collected according to the study criteria.

Based on the appropriateness of coronary angiography performance in the studies conducted on the issue, considering  $P = 0.2^9$  and confidence interval (CI) = 0.95, and using the following equation, the required sample size of the study was determined as 246 subjects.

$$n = \frac{\left( Z_{1-\frac{\alpha}{2}} \right)^2}{d^2} \times pq$$

We considered 280 subjects in the present study. In addition, estimating the number of visits and coronary artery angiography cases in the centers under the study, the number of samples in each center was determined by proportion to size method through simple random sampling as follows: 40 samples in each of "N" and "F", 20 samples in each of "B" and "D", and "A", 30 samples in "C", and 110 samples in "K" hospitals, respectively.

In this study, a data collection form and a checklist were used in order to gather the data through the field method. This form consisted of two sections, the first of which including the patient's demographic information, name and type of the hospital, the patient's insurance status, and other information about the patient's identification. On the other hand, in the specialized section which was completed according to the patients' records and through interviewing the patients, the indications related to angiography and other necessary information were collected based on ACC/AHA guidelines for coronary angiography which have been developed to direct the performance of coronary angiography.

Moreover, the checklist used in this study, which was designed according to the indications of performance of coronary angiog-

raphy, included 114 questions and the information obtained from their analysis identified the type of appropriateness of angiography performance for the patients.

In ACC/AHA guidelines, indications of appropriateness for performance of coronary angiography are evaluated through 63 criteria in such a way that in case the patients have one or more of the 63 criteria during the angiography, their angiography has been appropriate. Indications of appropriateness are located in classes I and IIa. In addition, the indications introduced under the category of uncertain appropriateness are evaluated through 25 criteria of this guideline and are located in class IIb. In case the patients do not have the criteria of classes I and IIa and have one or more of the 25 criteria, their angiography is considered as uncertain. Finally, the indications located in class III of the guideline show the inappropriateness of the angiography use and are explained through 26 criteria. In case the patients do not have the indications of classes I, IIa, and IIb and have one or more of the 26 criteria, their angiography is considered as inappropriate.<sup>6</sup> Finally, we calculated financial burden of extra money paid by the patients or insurance companies for each procedure and then multiplying to total number of inappropriate angiographies. All the analyses were performed through the SPSS statistical software.

## Results

The results of the current study showed that among 280 patients under the study, 55.4% were males and the patients' age mostly ranged from 50 to 65 years. Besides, 97.1% of the patients were insured and 17% had supplemental insurance as well.

Moreover, 207 (73.9%) out of 280 study subjects suffered from typical cardiac pains and 260 patients (92.8%) had complete pre-clinical laboratory data before performing coronary angiography. The most common diagnostic test was exercise tolerance test (37.5%). On the other hand, 138 patients (49.2%) had no noninvasive diagnostic test before performance of coronary angiography.

The results showed that from 280 study subjects, 206 (73.6%), 34 (12.1%), and 40 (14.3%) cases were categorized as appropriate, uncertain, and inappropriate angiographies, respectively according to AHA/ACC guidelines. In addition, among the 206 patients with appropriate angiography use, 170 patients (82.5%) had the indications of class I of the guideline, while 36 (17.5%) had class IIa indications.

In this study, the highest frequency of inappropriateness of angiography use was related to "B" hospital with five out of 20 samples (25%), while the lowest rate was related to "K" hospital with 12 out of 110 samples (10.9%). Overall, 14.3% and 12.2% of the angiographies were inappropriate and uncertain, respectively and overall, in 26.4% of the cases, the performed angiographies were either inappropriate or their appropriateness or inappropriateness could not be determined.

Appropriate angiographies were done among 120 of 155 males (77.4%) and 86 of 125 females (68.8%).

Moreover, inappropriate angiographies had been performed in 10.7% of the patients with negative results in noninvasive diagnostic tests and 3.6% of those with positive results.

The study findings also demonstrated that the percentage of inappropriate angiography use ranged from 25% in B hospital to 10.9% in K hospital that shows inappropriateness was higher in private as well as social security hospitals ( $P = 0.044$ ).

In addition, inappropriate use was found in 5.7% of males and

**Table 1.** Frequency of coronary angiography use by hospital and appropriateness status.

Hospital	Appropriateness Frequency (%)			Total	P-value
	Appropriate	Uncertain	Inappropriate		
N	28 (70)	5 (12.5)	7 (17.5)	40	0.044
F	29 (72.5)	6 (15)	5 (12.5)	40	
A	14 (70)	3 (15)	3 (15)	20	
K	89 (80.9)	9 (8.2)	12 (10.9)	110	
B	12 (60)	3 (15)	5 (25)	20	
C	19 (63.3)	6 (20)	5 (16.7)	30	
D	15 (75)	2 (10)	3 (15)	20	
<b>Total</b>	<b>206 (73.6)</b>	<b>34 (12.1)</b>	<b>40 (14.3)</b>	<b>280</b>	

**Table 2.** Frequency of appropriateness of coronary angiography use by the results of diagnostic tests (positive or negative) before performing coronary angiography.

Result	Appropriateness			Total	P-value
	Appropriate	Uncertain	Inappropriate		
Negative	107 (38.2)	34 (12.1)	30 (10.7)	171 (61.1)	0.006
Positive	99 (35.4)	0 (0)	10 (3.6)	109 (38.9)	
<b>Total</b>	<b>206 (73.6)</b>	<b>34 (12.1)</b>	<b>40 (14.3)</b>	<b>280 (100)</b>	

8.6% of females ( $P = 0.05$ ).

As the data in Table 2 shows, there was a relationship between the appropriateness of the angiography use and the results of non-invasive diagnostic tests before performance of coronary angiography ( $P = 0.006$ ).

Considering the documents in the Department of Studies and Research affiliated to the Office of Medical Services Insurance Organization and the patients' accounting documents, the mean cost of performing each coronary angiography procedure was 480 US dollars, 90% of which is paid according to the insurance company's regulations. In addition, the patients with social security insurance who had done angiography in the centers related to this organization as well as those covered by banks' insurance did not have to pay the franchise fee and all the expenditures were paid by the insurance companies.

Calculation of the financial burden showed that inappropriate angiography which had been performed among 40 cases, costed 19000 US dollars, 92.5% of which was imposed on the insurance companies and the remaining 7.5% was paid by the patients.

## Discussion

Nowadays, the level of improvement in healthcare services is considered as one of the major indices of measuring the social as well as economic growth and development that affects the level of social welfare, and of course accounts for a large proportion of the countries' financial resources. Therefore, most countries face a lot of problems in supplying these resources and make attempts to limit the expenditures in this part. Lack of misusing healthcare services is considered as one of the ways to reduce the health expenditures without damaging the quality of the services. Evidence shows an increasing trend in using expensive diagnostic and treatment technologies, while a large number of them are inappropriate or unnecessary. Thus, different studies are needed to be conducted on the appropriateness of these services and estimation of the financial burden resulting from their inappropriateness. Therefore, the present study investigated the appropriateness of

performing the coronary angiography procedure.

The findings of the current study, as the first one in the field, conducted on the inappropriate use of coronary angiography in Iran showed that the average inappropriate performance of coronary angiography was equal to 14.3% and if this measure is added to the frequency of the uncertain performances, it will reach 26.4% which comprises one fourth of the patients and can have a great contribution to wasting the resources of the health system.

In this study, the rate of inappropriate coronary angiography use in the study hospitals ranged from 10.9% in "K" hospital to 25% in "B" hospital, which is in agreement with the findings reported in the studies conducted in other countries.<sup>10,18,19,20,21</sup>

Furthermore, in the study carried out by Sibai et al. in Lebanon in 2008, the sum of rates of inappropriate and uncertain angiography performances was reported as 45.3%.<sup>19</sup> Besides, Leung et al. investigated 6830 patients in Australia and reported the rate of inappropriate use of coronary angiography as 34.3%–36.2% which was equal to one third of the patients who had referred for angiography.<sup>21</sup>

Veloso et al. also conducted a study in Brazil in 2001 and revealed the sum of inappropriate and uncertain angiography performances as 65.6%.<sup>18</sup>

Our findings revealed a statistically significant relationship between the hospitals and the percentage of appropriateness of coronary angiography use. Since all the treatment expenditures of the patients in "B" hospital are paid by the social security insurance organization, the physicians readily recommend angiography to the patients in this center. According to the results, among the 20 patients investigated in this center, three and five had undergone uncertain and inappropriate angiographies, respectively. Also, 55% of the patients who had done angiography in this center had normal angiography results and this can confirm our claim as well.

On the other hand, the patients who more probably have the coronary problems and need specific interventions, such as PCI and CABG, as well as modern facilities are referred to the specialized hospitals, including "N" and "K" hospitals, which can reduce the number of inappropriate angiography performances in these centers. Of course, the presence of the faculty members of Shiraz

University of Medical Sciences and great management of these centers in optimal use of the facilities should not be neglected.

In spite of the recommendations of the world's reliable centers for doing noninvasive diagnostic tests before performance of angiography and performing this procedure in case at least 70% of the non-invasive diagnostic tests results are positive, the findings of the current study showed that among 280 patients under the study, 138 (49.3%), i.e., almost half of the patients, did not have the diagnostic tests. Besides, considering the significance level of 10% and probability of 90%, a significant relationship was found between the appropriateness of angiography use and the noninvasive diagnostic tests ( $P = 0.86$ ). Also, regarding the comparison of the appropriateness of angiography use and the results obtained from noninvasive diagnostic tests, Chi-square test showed a significant relationship between the appropriateness of angiography use and the results of noninvasive diagnostic tests ( $P = 0.006$ ). According to the results, the sum of inappropriate and uncertain angiography performances was 22.8% in the patients with negative diagnostic tests results and 3.6% in those with positive diagnostic tests results. These findings were in line with those of the study conducted by Sibai et al. in Lebanon in 2008<sup>19</sup> as well as the one carried out by Leung et al. in Australia in 2008.<sup>21</sup>

Our study showed more inappropriate angiographies among the female patients (8.6%), although the males outnumbered the females. In contrast to the results of the present study, the research performed by Sibai et al. in Lebanon in 2008 showed that the rate of appropriateness was higher among the males compared to the females.<sup>19</sup> It seems that women refer to the physicians more for examining their physical status, receiving diagnostic measures, and check-up. On the other hand, due to further concerns, men accept the diagnostic and treatment measures quite forcibly and late. Even if angiography is recommended for them, due to the fear from disability and the consequences of angiography, they do not give consent for angiography performance and are discharged and this might have resulted in the reduction of the number of inappropriate angiography cases in males compared to females.

According to the findings of this study, among 280 subjects, 272 (97.1%) were covered by insurance and only eight patients (2.9%) had their angiography without insurance. In addition, the results of the statistical test revealed no significant relationship between the appropriateness rate of coronary angiography use and the patients' insurance status ( $P = 0.321$ ). The findings of our study show that when making decision about performance of angiography, physicians take the patients' insurance status into account and perform the procedure more cautiously for the patients who are not covered by insurance.

According to the study results, 14.3% of the angiographies (40 patients) were inappropriate, and 92.5% of the financial burden resulting from inappropriate angiography use has been imposed on the insurance organizations.

Peleps investigated the increasing but noneffective costs of the field of health in the University of Rochester and, by taking various studies conducted on the issue into account, reported the unnecessary and inappropriate care services as 15%–30% and in some treatment methods as 40%.<sup>13</sup>

In spite of the recommendations of the world's reliable centers for observing the necessary indications for performance of coronary angiography and doing noninvasive diagnostic tests before it, the findings of the current study showed that among the 280 patients under the study, 138 (49.3%) did not have any non-in-

vasive diagnostic tests. Nevertheless, a significant relationship was observed between the results of non-invasive diagnostic tests and appropriateness of coronary angiography performance ( $P = 0.008$ ).

Investigation of the patients' records in this study showed that angiography was used as the first-line diagnostic procedure for the patients and even in some cases, angiography was performed due to the patients' insistence and their frequent visits.

Although coronary angiography is a highly expensive diagnostic procedure which imposes a great financial burden on the society as well as the patients, this research demonstrated that a large proportion of this financial burden is imposed on the insurance organizations, revealing the relative failure of the present insurance status in Iran.

Furthermore, based on the studies conducted on the issue, high capitulation of angiography apparatuses in Iran compared to other countries can be considered as one of the reasons that this diagnostic test is performed without taking the global criteria into account. Moreover, more than 200 requests for starting up medical imaging centers are annually sent to the Ministry of Health from different centers around the country. Health economic problems and low proportion of gross domestic product allocated to the department of health also cause this defective cycle to develop a more critical status due to lack of attention.<sup>22</sup>

Based on what was mentioned above, the increase in the costs of healthcare organizations is not only related to the level of expenditures, but it is mostly related to non-effectiveness and spending high expenses in this part which must be considered by the health policy makers and decision makers.

Overall, the following factors can affect the increase in inappropriateness of angiography use, so monitoring them can help us to solve the problem.

- Low level of awareness about more appropriate diagnostic methods for assessment of cardiovascular diseases particularly for the patients with comprehensive insurance support.
- High tariffs paid to the physicians for performing this procedure and lack of an appropriate paying system in a way that today the insurance systems, particularly the supplemental insurances, completely pay the diagnosis and treatment expenses back.
- Lack of an appropriate system in the country's health system for monitoring the physicians' performance and no need for the physicians to account for diagnostic and treatment processes except for special conditions such as complaints.

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