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Evaluation The Role of Multislice Computed Tomography Imaging Versus Catheterization in The Diagnosis of Coronary Artery Diseases

Sheida Javadi[1]*; Valid Changizi[2]; Ali Mohammed Jouda[3]; Fatima Hassan Hussain[4]

[1]Assistant Professor of Radiology, Allied Medical Sciences, Radiology Technology TUMS, Iran.

[2]Department of Technology of Radiology and Radiotherapy, Allied Medical Sciences School, Tehran University of Medical Sciences, Iran.

[3]MSC Radiology Technology, Allied Medical Sciences School, Iran.

[4]Allied medical sciences. Radiology Technology TUMS, Iran.

***Corresponding Author(s): Sheida Javadi**

Assistant Professor of Radiology, Allied Medical Sciences School, Tehran University of Medical Sciences, Radiology Technology TUMS, Tehran, Iran.

Tel: 00989127796905; Email: Javadi_sheida@yahoo.com

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Abstract

Coronary Artery Disease (CAD) is a condition affecting the coronary arteries, which are vital for transporting oxygenated blood to the myocardium. It results from the presence of atherosclerotic plaques, leading to constriction of the arteries. The right and left coronary arteries supply blood to different parts of the heart. Atherosclerosis and reduced blood flow can damage the heart muscle's integrity, potentially leading to myocardial infarction and mortality. Cardiovascular Diseases (CVDs) are the primary cause of mortality, affecting 17.9 million people annually. Stroke and heart attacks account for over three-quarters of CVD-related fatalities, with one-third occurring prematurely in individuals under 70.

Coronary Computed Tomographic Angiography (CCTA) is a non-invasive diagnostic tool that uses Computed Tomography (CT) technology to create high-resolution images of coronary arteries. This allows healthcare professionals to visualize atherosclerotic plaques and assess the overall coronary anatomy. CCTA is particularly useful in cases where traditional invasive procedures are risky or not feasible. It is commonly used to evaluate patients with suspected Coronary Artery Disease (CAD), chest pain, or those at risk for cardiovascular diseases. Despite not providing real-time hemodynamic information, CCTA is an effective, radiation-controlled tool for initial assessment and can guide subsequent management decisions, such as the need for further interventions or medical therapy. The evolving technology of CCTA contributes to its increasing role in comprehensive evaluation of patients with suspected coronary artery disease.

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Cardiac catheterization is an invasive diagnostic method that involves inserting a catheter into the coronary arteries to visualize and assess blood flow within the heart. This allows healthcare professionals to obtain detailed information about coronary anatomy, identify atheromatous plaque, and assess the severity of coronary artery disease. It also allows the measurement of hemodynamic parameters like blood pressure and oxygen saturation, providing valuable insights into cardiovascular function. Despite being invasive, cardiac catheterization is the best way to diagnose Acute Coronary Syndrome (ACS) and plan subsequent treatments like Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Grafting (CABG) to improve blood flow and reduce the risk of adverse cardiac events.

Rationale and backgrounds

Coronary Artery Disease (CAD) is a pathological condition that affects the coronary arteries, which play a crucial role in the transportation of oxygenated blood to the myocardium. Coronary Artery Disease (CAD) refers to the constriction of the coronary arteries resulting from the presence of atherosclerotic plaques. The right coronary artery supplies blood to one side of the heart, whereas the left coronary artery supplies blood to the opposite side [1]. Every coronary artery terminates in a complex system of smaller arteries that transport oxygenated blood to various regions of the heart. Atherosclerosis and reduced blood flow via various arterial segments pose a significant risk to the integrity of the heart muscle, potentially leading to myocardial infarction and subsequent mortality [2].

Annually, Cardiovascular Diseases (CVDs) claim the lives of an estimated 17.9 million individuals worldwide, making them the primary cause of mortality. Stroke and heart attacks account for over three-quarters of Cardiovascular Disease (CVD)-related fatalities, with one-third of these incidents transpiring prematurely in individuals below the age of seventy [3].

Coronary Computed Tomographic Angiography (CCTA) has emerged as a non-invasive diagnostic tool that provides detailed imaging of the coronary arteries, aiding in the assessment of Coronary Artery Disease (CAD). This imaging technique utilizes Computed Tomography (CT) technology to generate high-resolution, three-dimensional images of the coronary arteries, allowing healthcare professionals to visualize the presence of atherosclerotic plaques and assess the overall coronary anatomy [4]. CCTA is particularly valuable in cases where traditional invasive procedures like cardiac catheterization may pose a higher risk or are not feasible. It is commonly employed in the evaluation of patients with suspected CAD, chest pain, or those at risk for cardiovascular diseases. The non-invasive nature of CCTA makes it an attractive option for both diagnostic purposes and risk stratification [5]. While it may not provide real-time hemodynamic information like invasive procedures, CCTA serves as an effective, radiation-controlled tool for initial assessment and can guide subsequent management decisions, such as the need for further invasive interventions or medical therapy. The evolving technology of CCTA contributes to its increasing role in the comprehensive evaluation of patients with suspected coronary artery disease [6].

Invasive diagnostic methods, notably cardiac catheterization, play a crucial role in the comprehensive assessment of individuals suspected of having Acute Coronary Syndrome (ACS). Cardiac catheterization is a medical procedure that involves the insertion of a catheter into the coronary arteries, typically through the femoral or radial artery, to visualize and assess the blood flow within the heart [7]. This procedure allows healthcare professionals to obtain detailed information about the coronary anatomy, identify the presence of atheromatous plaque, and assess the severity of coronary artery disease. Additionally, cardiac catheterization enables the measurement of various hemodynamic parameters, such as blood pressure and oxygen saturation, providing valuable insights into the overall cardiovascular function. Even though it is invasive, cardiac catheterization is still the best way to diagnose ACS and plan subsequent treatments like Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Grafting (CABG) to improve blood flow and lower the risk of bad cardiac events. The procedure's precision and ability to offer real-time information contribute significantly to the timely and accurate management of patients with acute coronary syndromes [8].

Review of Literature

In a review of literature, in 2015, Alaide Chieffo, MD, et al, said that the CTCA coupled to a cardiac CT scan appears to be a safe and effective routine, noninvasive diagnostic screening tool for Coronary Artery Disease (CAD) in patients undergoing Transcatheter Aortic Valve Replacement (TAVR) and severe Aortic Stenosis (AS). This method provides a comprehensive assessment of the aortic annulus, peripheral access sites, and coronary artery anatomy through a single test. Implementing CA exclusively in cases of absolute necessity may result in enhanced patient outcomes, decreased overall procedural expenses, and shorter hospital stays. Nonetheless, this hypothesis must be examined in prospective studies that are suitably designed [9].

In 2019, Young Bin Song, MD, et al, said that the CT coronary angiography utilizing 320-slice acquisition yields high accuracy in identifying patients with obstructive CAD by ICA at lower radiation exposure to patients. However, agreement between the modalities is lower when considering vessel- and segment-level analyses. Both CTA and ICA perform similarly for predicting clinically driven revascularization and for detecting myocardial ischemia by SPECT-MPI, suggesting that limitations by both CTA and ICA contribute to variability of stenosis quantification [10].

In same year (2019), Hyuk-Jae Chang, MD, et al, have been found that at one year of follow-up, it was discovered that a selective referral approach resulted in MACE rates that were comparable to those of a direct referral strategy in patients who were sent for guideline-directed ICA and who were suspected of having Coronary Artery Disease (CAD). In the context of gatekeeper operations, there is a growing body of information that suggests that noninvasive anatomic testing performed by CCTA alone may prove to be useful in terms of precisely and speedily selecting candidates for subsequent procedures. The present recommendations for the assessment of patients with stable ischemic heart disease need to be revised when these results and other findings from previous randomized trials that are equally relevant are taken into consideration [11].

In 2023 Aldo J. Vázquez Mézquita, et al. [12] said that Several modalities are available for clinical quantitative coronary artery stenosis and atherosclerosis imaging. CT is an accurate and reliable modality for stenosis assessment and quantification of total coronary plaque volume, making it most appropriate for directing treatment in patients with stable chest pain and an intermediate pre-test probability of CAD. Even though MRI is currently not widely used in the clinical setting and is mostly used at expert centers, it has the potential to become a reliable tool to assess stenosis and plaque morphology without exposing the patient to ionizing radiation, provided that further technical improvements can increase the robustness of images. PET has a role in the quantitative assessment of coronary plaque inflammation and is, therefore, the preferred modality for the monitoring and guiding of treatment. ICA is considered the reference standard for the evaluation of patients with stable chest pain and a high probability of coronary stenosis as well as for patients with ACS. IVUS and OCT are intravascular imaging modalities that have a relevant role in the estimation of coronary stenosis severity and in plaque characterization for treatment planning.

The clinical potential of these modalities can be substantially improved by technical advances. For CT, new technologies aimed at improving spatial and temporal resolution as well as at automating the quantification and coronary plaque characterization process will improve its clinical utility. The spatial resolution of MRI can be increased by reducing the voxel size and shortening acquisition times and better signal enhancement can be achieved with new contrast agents. The role of PET will expand with the translation of research findings into clinical practice and the development of new tracers for the detection of plaque vulnerability. Quantitative coronary angiography will help in the standardization of stenotic assessment by ICA, whereas RWS will provide insights into the deformation of the vessel wall caused by coronary plaques. Anatomical measurements by IVUS and OCT will facilitate the determination of coronary flow via the integration of FFR into the same catheters.

In 2020 Pei Ing Ngam et al. [13] said that there is no single quantitative coronary imaging modality is optimal for all groups of patients or disease types and not all are equally available with similar local expertise at all clinical centres. Using the Delphi method, we determined which imaging modalities are better suited for specific patient groups. In conclusion, this clinical Consensus Statement shows the current advantages, disadvantages and expected future development of different imaging modalities for clinical quantitative coronary artery stenosis and atherosclerosis imaging and will help clinicians to choose the most appropriate imaging modality on the basis of the specific clinical scenario, individual patient characteristics and availability of each modality.

In 2022 Pragya Ranjan et al. [14] said that Multisclice computed tomography of the heart has exhibited tremendous advances recently. Initially, its main clinical focus in cardiac imaging was coronary artery evaluation. This has expanded to several other areas such as evaluation of coronary stents, bypass grafts, and cardiac evaluation prior to procedures such as transcatheter aortic/mitral valve replacement and pulmonary vein isolation for atrial fibrillation ablation. Cardiovascular Magnetic Resonance has also been utilized in a broad set of applications, including myocardial viability, congenital heart disease evaluation, and aorta/caval/vascular evaluation. Both techniques can be utilized in combination in “no contrast” imaging for certain preprocedural planning.

Multislice Computed Tomography (MSCT) technology has advanced rapidly since its introduction 20 years ago. Currently, 64-MSCT and Dual-Source Computed Tomography (DSCT) are considered state-of-the-art for cardiac MSCT imaging with 320-slice systems also emerging in clinical practice. Initially, the main clinical focus of MSCT in cardiac imaging was coronary artery evaluation. This has expanded to several other areas such as evaluation of coronary stents, bypass grafts, and cardiac evaluation prior to procedures such as trans catheter aortic/mitral valve replacement and pulmonary vein isolation for atrial fibrillation ablation.

In 2022 Viktoria Wieske et al. [15] said that the results in our international cohort show CTA to have significantly higher diagnostic accuracy than the Agatston score in patients with stable chest pain, suspected CAD, and a clinical indication for ICA. Diagnostic performance of CTA is not affected by a higher Agatston score while an Agatston score of zero does not reliably exclude obstructive CAD.

Research objectives and goals

A. Main objective:

To diagnose coronary artery diseases using MSCT scans without surgical intervention.

B. **Specific objectives:**

To explain the advantages of using CT angiography and its role in diagnosis coronary artery diseases.

C. **Goals:**

The goal of this study is to develop and validate a non-invasive method for the possibility of diagnosing coronary artery diseases. This approach aims to eliminate the need for invasive methods in these cases and avoid catheterization by utilizing MSCT angiography.

Research questions and hypothesis

Research questions

1. What is the diagnostic accuracy of coronary CT angiography in detecting coronary artery disease compared to conventional catheterization?
2. What is the impact of coronary CT angiography on the rate of unnecessary invasive procedures compared to catheterization in the evaluation of coronary artery disease?

Hypothesis

1. Coronary CT angiography demonstrates comparable or superior diagnostic accuracy to catheterization in detecting coronary artery disease.
2. Coronary CT angiography results in a lower rate of unnecessary invasive procedures in the evaluation of coronary artery disease compared to catheterization.

Research design and methods

Study design

Subjects:

Patients will be classified into males and females, and according to age, coronary artery disease will be classified into invasive coronary angiography and coronary computerized tomography.

Inclusion criteria: will include patients with clinical indications for coronary evaluation, such as chest pain or other relevant symptoms.

Exclusion criteria: will include contraindications to either procedure, previous allergic reactions to contrast agents, or other specific medical conditions.

Sampling

The sample size will be 60 samples from patients who have clinical indications for coronary evaluation, such as chest pain or other relevant symptoms.

- **Recruitment plans**

The samples will be scanned by MSCT scan with contrast injection of the coronary arteries and compare with CA Catheterization test.

- **Patients**

This research will include a total number of (60) cases of patients with suspected Coronary Artery Diseases (CAD) in various age. The cases will collect After obtaining approval from TUMS committee. It will all taken from Cardiac surgery center in AL-Diwaniyah Teaching hospital.

The patients will undergo both of CCTA and ICA procedures. The study will done to assess the findings of the mentioned methods in patients with suspected any stenosis duo to a calcification, any other finding could make the diagnosis, or it will be normal.

In addition, various causes of CAD will take in account in a specific questionnaire designed by the investigators and their supervisor according to specific reference, with included demographic factors such as age, weight, family history, stress, lipids, clinical symptoms, etc.

The invasive coronary angiography

Patient preparation

- Ask the patient not to drink or eat anything since the night before the procedure.
- Check patient's renal functions test to rule out problems with renal insufficiency.
- Check the patient's risk factors of bleeding for giving the anticoagulant therapy (e.g., warfarin therapy) at the proper moment.
- Give the patient the instructions & explanation for the procedure to ensure that he or she is mentally prepared (well-informed patient will be less anxious and more cooperative). Then get the consent from the patient.
- Take the patient's information (name, age, weight, high, the possibility of any contrast allergies, patient's diseases like the diabetes mellitus, and clinical factors).

The technique of ICA

The staff in the ICA operations consists of a specialized cardiologist, radiographer, anesthetist and nurses. The equipment for the procedure are a digital angiography with C-arm device for continuous real X-ray imaging with variable doses and positions depending on the case, selective coronary artery catheters with appropriate diameter to inject the contrast medium, ECG device and pressure recording devices.

In invasive coronary angiography (or cardiac catheterization), a radiopaque catheter is inserted into a peripheral vein (the femoral vein or the radial vein) and passed under the fluoroscopic control into the right atrium, right ventricle, pulmonary trunk, and pulmonary arteries, respectively. Using this technique, intra-cardiac pressure can be recorded and blood samples may be removed. If a radiopaque contrast medium is injected, it can be followed through the heart and great vessels using serially exposed x-ray films; this technique permits study of the circulation through the functioning heart and are helpful in the study of congenital cardiac diseases.

In addition to the diagnostic role, the ICA may be therapeutic in many cases and treat the damaged (calcified) arteries.

Coronary CT angiography

Patient preparation

- Ask the patient to avoid the stimulate drinks especially for coffee (caffeine) since the night before the procedure.
- Check patient's renal functions test to rule out problems with renal insufficiency.
- The patient should take all the medications under the supervision of the cardiologist, and the assessment for the β-blockers (e.g., the Metoprolol & Concor) either orally, sublingually or intravenously should be done to control the heart rate within the acceptable range for CTA procedure (> 65 bpm).
- Give the patient the instructions & explanation for the procedure to ensure that he or she is mentally prepared (well-informed patient will be less anxious and more cooperative). Then get the consent from the patient.
- Take the patient's information (name, age, the possibility of any contrast allergies, and clinical factors).

The technique of CCTA

We have been used a Philip's CT device with 64 slices to obtain the images of our research. The device is supplemented with a proper ECG device for following up the condition of the heart and its rate, and as well as a dual syringe injector for giving the contrast medium through the radial vein. The patient is lying supine on the couch with feet first (closed to the gantry) and connect both injector and ECG to him.

The examination is performed through two stages with axial series of images; the first stage is for calcium scoring to detect the calcifications in the coronary arteries before the injection of the contrast medium. The second stage begins after we make sure that the Ca+2 is in normal ranges (> 400 for the total readout) we inject an amount of around 70-90 CC of a certain contrast medium (e.g., Omni paque) diluted with 40 CC of normal saline and take the axial images during the injection depending on the bolus-tracking which is placed on the ascending aorta.

Method of assignment to study groups

To obtain comprehensive images of the coronary arteries and measure blood flow, Coronary Computed Tomography Angiography (CCTA) follows a meticulous process. First, he checks for contraindications and explains the process. Intravenous line placement: A peripheral IV line is usually inserted to deliver contrast material during the examination with ECG monitoring to synchronize image capture with the heart cycle for the best image quality. Patients lie on their backs with their arms raised above their heads on a CT table. Initial non-contrast examination: This examination evaluates the basic structure of the chest and heart. A contrast agent (iodine-based contrast material) is given through an intravenous line to improve visibility of blood vessels during imaging. Tracking and scanning time is important. The dynamic bolus follows the contrast material through the blood vessels. The scan begins when the contrast reaches the coronary arteries, improving image quality. Helical or step-and-shoot acquisition: The CT scanner acquires images as it rotates around the subject. This method produces comprehensive cross-sections of the coronary artery. CCTA procedures may use multiphase imaging to measure coronary artery motion and increase diagnostic accuracy. The CT data is then reconstructed into CT images. Post-processing methods such as MPR and MIP are used to visualize the coronary arteries from different angles.

Image analysis: Radiologists and cardiologists examine reconstructed images for coronary artery disease, stenosis, and other anomalies. Finally, a detailed report is prepared that includes suggestions for future evaluation or treatment.

Data collection

We will collect samples after approval of the research proposal by: using different methods in this research, including:

- Data collection sheet, included
- Personal data
- Medical history
- Demographics
- MSCT scan records included
- MSCT images
- Medical files

Variables: outcomes, predictors, confounders

A certain number of patients who have clinical indicators of coronary artery disease, such as chest pain or other related symptoms, will be examined.

Measures/instruments

We will perform all MSCT studies by intravenous contrast injection, The patient will be in the supine position with his arms at his sides during imaging.

Procedures

We will use both techniques to compare the results By reading the reports by two doctors, one of whom is a radiologist and the second is a cardiologist, then we use statistical equations to determine the efficiency of the test compared to invasive diagnosis and determine the efficiency of the scanner in diagnosing infections and Evaluation Coronary artery, Number of CA Stenosis, Cause of CA Stenosis, type of CA Stenosis, Site of CA Stenosis, and lastly CT Predicative for determine CA lesions often depends on patient-specific factors, including clinical symptoms, risk factors, pre-test probability of CAD, and the presence of other medical conditions such as symptoms of a heart attack and for whom the initial diagnosis was made by echocardiography. Both techniques will be adopted to make an accurate diagnosis and compare the results. We will also prepare a consent form to participate in the examination, and we will encourage patients to be examined with the scanner by explaining the importance of the results of this examination in determining the location of the injury and seeing the location of the stenosis with image, in a free and quick way.

Intervention

No application

Statistical considerations

Sample size: This study is a prospective study and will consist of 60 cases that will be collected after obtaining official information from the university for patients who suffer from symptoms of chest pain and symptoms of stenosis. Sample size determined According to the method of the limited society, according to the formula Steven K. Thompson (Thompson, 2012) where N= 100.

$$n = N \times \frac{p(1-p)}{[[N-1 \times (d^2 \div z^2)] + p(1-p)]}$$

n= (100(0.5(1-0.5)))/ (((100-1) (0.002÷3.847)) +(0.5(1-0.5))) = 59.4

sample size was determining according to Thompson formula, has been determined to increase the accuracy of the results and ensure that the sample is represented population under study.

Where: N=population

n=sample size

p=probability 50%

d=error proportion 0.05

z=confidence level at 95% 1.96

Data analysis

The collected data will be analyzed using the Statistical Package for the Social Sciences (SPSS) version 25. It will be used to evaluate the role of CT scan in diagnosing coronary artery disease compared to the invasive method. In this study, we will use one of the methods used in scientific research (single sample test, independent test, and double test).

Estimated total time to complete the research (inmonths)

Research timeline table

Prepare a list of the activities planned for the research proposed. Mark with X the appropriate cells to reflect the time (each cell represents one month) and duration of each activity. An example of activities is provided in the first three rows.

Author Statements

Ethics: (Attach ethical consent form if applies)

This proposal will be submitted to Tehran University-School of public health research committee for discussion and approval and to Tehran University graduate studies committee approval. after approval of the research proposal.

Safety considerations

The device that will be used in this study is a Siemens 64 CT scan slice to determine the causes of blockages that affect the coronary arteries.

Limitations

Operators must receive special training to further enhance its development. Sometimes multiple CT scans are performed due to high blood urea levels or an irregular heartbeat.

Variables table

	Variable	Definition	Qualitative		Quantitative		Variable		Measurement Method	Scale
			Ordinal	Nominal	Discrete	Continuous	Independent	Dependent		
1	Age	Based on the age of the patient				*			Questionnaire	Ordinal
2	gender	Includes male and female patient		*					Questionnaire	Ordinal
3	Evaluation Coronary artery	Evaluation affected parts of the coronary arteries		*					Depend on CT measurement	Nominal
4	Number of CA Stenosis	Determine the number of blockages in the coronary arteries		*					Depend on CT Measurement	Nominal
5	Cause of CA Stenosis	Determine the Cause of blockages in the coronary arteries		*					Depend on CT Measurement	Nominal
6	Type of CA Stenosis	Determine the Type of blockages in the coronary arteries		*					Depend on the CT Measurement	Nominal
7	Site of CA Stenosis	Determine the Site of blockages in the coronary arteries		*					Depend on the CT Measurement	Nominal
	CT Predicative for determine CA lesions	Determine sensitivity, specificity, PPV, NPV and Accuracy of CT in diagnosis coronary arteries lesion compare with CA Catheterization		*					Depend on the CT Measurement	Nominal

	Activities	Duration of the activity																		
1	Example Activity 1	X	X	X	X	X	X	X	X											
2	Example Activity 2				X	X	X	X	X	X	X	X								
3	Example Activity 3						X	X	X	X	X	X	X	X	X	X	X	X	X	X

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