ISSN: 2693-4965
DOI: 10.33552/OJCRR.2022.06.000635
Online Journal of Cardiology Research & Reports
Iris Publishers

Research Protocol

Diagnostic Value of Multidetector Computer Tomography Coronary Angiography in Detection of Coronary Artery Stenosis

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Received Date: December 07, 2021

Published Date: January 24, 2022

Introduction

Invasive coronary angiography (ICA) is the accepted reference standard for the assessment of coronary artery stenosis because of its unprecedented temporal and spatial resolution and ability to perform therapeutic interventions in the same session [1]. The inconvenience for the patient and economic deliberations have strengthened the search for a non-invasive alternative, current multi-slice computed tomography (MSCT) scanners provide promising results in the assessment coronary artery disease (CAD), but some segments are not evaluative because of motion artifacts or sever vessel wall calcification [2]. To become a clinically accepted tool for the examination of patients with suspected CAD, the main requisite for CT coronary angiography includes the complete visualization of all therapeutic relevant coronary arteries without excluding segments [3]. The recently developed 64 slice CT scanner generation of provide 0.4 mm nearly isotropic voxels in a rotation time of 0.37 sec, thus increasing temporal and spatial resolution when compared with previews CT scanner types [5, 6].

This suggests a certain improvement regarding diagnostic accuracy and an important future role of CT coronary angiography for reliably excluding residual significant, stenosis in patients with an equivocal clinical presentation thus being more convenient and saving these risky patients from undergoing another cost extensive and invasive coronary angiography procedure [7-9].

Aim of the Work

The aim of our study is to investigate the accuracy of dual source multi-slice 64 detector row computed tomography for assessing coronary artery stenosis in native coronaries. Using coronary angiography as the reference standard.

Patient and Method

The study will include patients who will be referred for suspected coronary artery disease.

Exclusion criteria

The following patients will be excluded from the current study:

1. Patients with irregular heart rates, for example atrial fibrillation.
2. Renal insufficiency (creatinine more than 1.5 mg %).
3. Known allergy to iodinated contrast material.
4. In ability to breath hold.
5. Heart failure.

Patient preparation

History taken will be done (with special emphasis) on presence or absence of cardiovascular risk factors, history of bronchial asthma (which will be contraindicate the administration of beta blockers) or history of dye allergy. Full clinical examination will be carried out. The heart rate and blood pressure will be recorded. Chest examination will be done to rule outpatients with reactive airways. Routine cardiac examination will be carried outpatients with decompensate heart failure or patients who cannot lie flat will be excluded from the test. Also, patients who cannot breath hold

will be excluded from the test. The patient's lab investigations will be reviewed. Patients with serum creatinine levels above 1.5 mg/dL will be excluded from the test. All patients will be instructed to remain fasting for about 4 hours before doing the scan. Patients will be instructed to avoid coffee and tea, 2 hours before the study to minimize their effects on patient's heart rate [10-12].

Type of Study

Study design

It is comparative, monocentric and randomized study.

Sample Size

The sample size will be calculated according to the following formula:

N = Za2 PQ/D2

Where

N = Number of subjects for the study.

Za = The value of standard normal distribution for type I error probability for the sided test and equals 1.96.

P = Prevalence of coronary AD in Egypt which is 40% [4].

Q = The completion of the prevalence so that the summation of both equals 1 (Q = 1 – P).

D = The difference between the prevalence and the results of the study; it equals (Z x 1/10 P) as only 10% bias is accepted.

N = (1.96)2 x 0.4 x 0.2 / (1.96 x 0.04)2 = 50.

For economic reason 30 patients will be collected.

Plan for Statistical Analysis

The following statistical analysis methods will be used for analyzing results obtained from this study:

Descriptive statistics

1) Arithmetic mean that will be used as a measure of central tendency.

2) Standard error of deviation will be used as a measure of dispersion.

Comparative methods

A. t-est: in order to compare the mean of the studied groups. The most appropriate test of significance is found to the student's t-test. The level of significance will be considered at probability level ($P<0.05$).

B. Chi-square test: to compare frequencies between the studied groups.

Ethical Considerations

During the course of this study the following ethical considerations will be implemented into action:

1. This proposal will be approved by the Ethical committee of the Department and Hospital.

2. All participants of the study will be given explanation about the nature of the study.

3. Informed written consent will be taken from all patients who will involve in the study.

4. Professional care in doing multislides computed tomography and angiographic views.

5. Privacy and confidentiality of the obtained data will be insured for all participants.

6. Results may be given to all tested members after consulting with the cardiologist.

7. All results will be used for research purposes only.

8. All the data and the samples obtained will be saved in the cardiology department and only the researcher will have access to it and at the end of the research all the samples will be discarded.

9. No stored samples will be shipped out of the country.

Acknowledgement

None.

Conflict of Interest

No conflict of interest.

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