COMPARISON OF CORONARY PROGNOSTIC INDEX VS CLINICAL MARKERS OF REPERFUSION IN ACUTE CASES OF MYOCARDIAL INFARCTION

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ABSTRACT--*For the treatment of myocardial infarction with ST-segment elevation, primary angioplasty is considered superior to fibrinolysis for patients who are admitted to hospitals with angioplasty facilities. Whether this benefit is maintained for patients who require transportation from a community hospital to a centre where invasive treatment is available is uncertain so primary thrombolysis is frequently successful at restoring coronary artery blood flow in patients with acute ST-segment–elevation myocardial infarction.To evaluate prognostic index in patients of AMI, To evaluate clinical markers of reperfusion after thrombolysis.To correlate coronary prognostic index and clinical markers of reperfusion in AMI in relation to early morbidity & mortality.To evaluate prognostic index in patients of AMI To evaluate clinical markers of reperfusion after thrombolysis. To correlate coronary prognostic index and clinical markers of reperfusion in AMI in relation to early morbidity & mortality. To evaluate prognostic index in patients of AMI To evaluate clinical markers of reperfusion after thrombolysis. To correlate coronary prognostic index and clinical markers of reperfusion in AMI in relation to early morbidity & mortality.Clinical assessment every half hour for 2 hrs. will be done to assess:Reduction in chest pain in percentage on a subjective scale & to assess any change in Killip's class. Continuous ECG monitoring to observe occurrence of reperfusion arrhythmias. At the end of 2 hrs. of follow up patients will be evaluated for: Percentage reduction in chest pain on subjective scale A twelve lead ECG to detect any change in ST elevation.Repeat serial estimation of CKMB. Successful clinical reperfusion is defined as presence of two of the following criteria at 2 hrs. of starting treatment. Chest pain evolution: Pain intensity will be quantified by percentage reduction in chest pain on subjective basis. A succdssfull pain criterion is defined as 50% or more reduction in chest pain intensity at 2 hours after starting thrombolysis. ST segment elevation: A decreased 50% or more in summations of ST segment elevation is considered a positive electrocardiographic criteria. Enzyme evolution: A positive enzymatic criteria is define as, more than two times increase over upper normal limits or base line values. At the end of two hours of starting thrombolysis patients will be divided in to two groups based on SCR positive or negative. Successful reperfusion will be grouped into SCR positive group and without successful reperfusion SCR (negative) group.ResultsThe successful clinical reperfusion in the present study was 61% while 39% patients did not have successful clinical*

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reperfusion. It is come to an end that Killip's class at admission of ≥ 2 and absence of successful clinical reperfusion were predictors of mortality after thrombolysis. Mortality rate was more in patients without successful clinical reperfusion than in patients with successful clinical reperfusion. It is further advocated that all patients of acute myocardial infarction who receive thrombolysis should be examined at the end of 2 hours for these simple, non invasive clinical markers of reperfusion. Absence of successful clinical reperfusion group of patients with poorer prognosis after thrombolysis and in such patients alternative strategies of reperfusion should be considered.

Keywords-- *coronary prognostic index, myocardia infarction, clinical marker*

I.   INTRODUCTION

Ischemic Heart Disease is the cause of 25 to 30 % of death in most industrializes country. The WHO has highlight to the fact that coronary heart disease is our twenty-first-century "Epidemic".1

Ischemic heart disease is the commonest from of the heart disease > 40 years of age . With increase in life expectancy , coronary heart disease has become a predominant cause of mortality among men < 65 yrs of age.2 More than 50% of the patients with acute myocardial infarction die suddenly with or without pain before the patient reaches to the hospital.

One third to one half deaths from acute myocardial infarction occur in first 24 hours, about 70% of total deaths within first three days and 80-85% in first week 3

The outcome of an attack of acute myocardial infarction in any given individual person is unpredictable. There is a constant threat of sudden unexpected death even for the persons convalescing favorably. In acute myocardial infarction the most serious complications having highest mortality occur in the first few days.

To access the outcome in acute myocardial infarction a strong need to introduce some criteria was felt.

The coronary prognostic index (C.P.I.) was thus developed. This index was developed on bedside clinical findings. It should be simple and easy to calculate. The index should guide to identify seriously ill patient so that these patients could be carefully observed in intensive care unit during the period of greatest danger. It is on the ground of unpredictability of outcomes of acute myocardial infarction, that there have been many attempts by many workers to identify the prognostic factors.

They evaluated significance of prognostic factors as far as prognosis in any given individual with acute myocardial infraction was concerned.

This resulted into development of coronary prognostic index in acute myocardial infarction by different methods in recent years with varying conclusions.4 Coronary prognostic index is an index that is calculated by summation of individual score.

The individual score is allotted to particular variable that is known to affect the outcome of patient of acute myocardial infarction. Coronary prognostic index generally reflects the "probability of survival" trend of a patient of acute myocardial infarction. It helps at initial stages to separate groups of patients requiring intensive care from those who can very well be kept in intermediate coronary care unit or the general ward.

Especially in developing countries, this can minimize expenses involved in running coronary care unit. Most of the coronary prognostic indices (CPI) are based on retrospective evaluation of hospital records. These records are usually imperfectly mentioned. There was a strong need for its reconstruction.

The wide spectrum of the severity of myocardial infarction is well recognized and therefore, it was felt that a numerical system based on a "prospective study" might be devised. This system would express the severity of myocardial infarction concurrently and provide a prognostic score.5

Various authors have formulated CPI by giving different weights for different factors which involved complex calculation and therefore difficult to remember. There is a linear correlation of mortality with coronary prognostic index in acute myocardial infarction.

Introduction of thrombolysis in the management of acute myocardial infarction was turning point in the management of acute myocardial infarction as it has changed the results after acute myocardial infarction. It has been persuasive that early opening of infarct related artery is associated with the limitation of the infarct size, preservation of cardiac function and better clinical results .6-14.

Because angiography is not available rural setup, there is an increasing interest in simple noninvasive tests of patency assessment 7. Furthermore; clinical signs after thrombolysis may have a better correlation with functional reperfusion than the isolated image of angiographic patency.8

It was reported earlier, clinical features are poor markers of reperfusion & no single finding or findings are reliable markers of reperfusion.8 However, recent studies have shown association between clinical markers of reperfusion & patency of IRA, preservation of cardiac function, decrease morbidity rates & improved short & long time survival. 8, 9

Chest pain depletion after thrombolysis indicates reperfusion of ischemic myocardium surrounding the zone of infarction.10 the amount of chest pain reduction after thrombolysis has been shown to correlate with angiographically assessed patency of infarct related artery with a fair specificity and sensitivity and can be used as clinical marker of reperfusion.11

ECG is one of the simplest ways to assess reperfusion. It was found that dynamic ST changes in the ECG after thrombolysis in AMI are uniquely sensitive to changes in coronary artery patency. Time and rate of ST resolution after AMI are significantly influenced by coronary artery patency and gaining of early ST resolution is both sensitive and specific marker of reperfusion .12, 13 ,14.

Plasma level of CKMB is used to diagnose AMI, to extent of its size, and to predict patient's prognosis. Peak levels of CKMB are often higher and are reached earlier after infarction in patients, who have either spontaneous or iatrogenic thrombolysis leading to reperfusion of an area of infarction. Early raise of CKMB occurs after successful thrombolysis. Patients who reach peak levels rapidly are more likely to have better outcome in left ventricular function. This reflects washout of CKMB that is released from injured myocytes after restoration of coronary artery patency. Hence early raising of CKMB after thrombolysis is successful reperfusion marker. 15, 16, 17 Understanding of this concept thus further strengthens the need to evaluate markers of functional myocardial reperfusion. Better the functional recovery of myocardium better will be the clinical outcome after thrombolysis.

Presence of functional reperfusion assessed by noninvasive markers of reperfusion will indirectly indicate successful anatomic reperfusion. Understanding of this concept thus further strengthens the need to evaluate markers of functional myocardial reperfusion. Better the functional recovery of myocardium better will be the clinical outcome after thrombolysis.

In view of amplifying indications for thrombolysis in patients with AMI , it becomes necessary to have new & earlier prognostic indicators, which can be predict the clinical outcome after thrombolysis & will help to decide whether the patient should undergo coronary angioplasty.

This present study is therefore undertaken to compare clinical prognostic index Vs outcome of reperfusion using noninvasive clinical criteria of reperfusion & evaluate patency of IRA, preservation of cardiac function, morbidity rates and survival. 8, 9

II. OBJECTIVES

1) To evaluate prognostic index in patients of AMI

2) To evaluate clinical markers of reperfusion after thrombolysis.

3) To correlate coronary prognostic index and clinical markers of reperfusion in AMI in relation to early morbidity & mortality.

III. METHODS

Study design:

This is a observational study. Patients of acute myocardial infarction, being admitted in the ICU & who satisfying the inclusion criteria of the study will be enrolled in the study. After thrombolysis patients will be divided into two category based on success of thrombolysis ascertained using noninvasive criteria. Success of thrombolysis will be decided if 2 out of 3 clinical markers comes positive. Those with successful reperfusion (SCR) (as per criteria's of reperfusion)19, 17 patients will be grouped into SCR positive group & those without successful reperfusion will be grouped into SCR negative group. Both the groups will be followed for next 7 days & comparison will be done at the end, between prognostic index Vs clinical markers of reperfusion in terms of occurrence of post infarct angina, recurrence of MI, congestive cardiac failure, left ventricular function assessed by echocardiography & mortality

Setting: The study will be carried out by department of medicine in Acharya Vinoba Bhave Hospital, Sawangi (Meghe), a tertiary care teaching hospital, situated in rural area of central India.The present study will be carried out on all patients of acute myocardial infarction, who will satisfy the selection criteria of the study, admitted in the M.I.C.U. of Acharya Vinoba Bhave Rural Hospital of Jawaharlal Nehru Medical College, Sawangi, Wardha during the period of Aug 2018 to Aug 2020. The duration of the study will be from AUGUST 2018 to MAY 2020

Participants: Sample size will be calculated using Manual for calculation of Sample Size in epidemiological studies, by Lawangaand Lemeshaw, a WHO publication. 20

Inclusion criteria:

1) The present study will include all cases of AMI undergone thrombolysis being admitted in MICU.

2) Twelve lead ECG done within 6 hours of onset of chest pain Suggestive of AMI in the form of ST elevation of at least 2 mm in contiguous precordial leads and 1 mm in two adjacent limb leads persisted more than 10 minutes after administration of nitrates.

3) Willingness to participate in the study.

Exclusion Criteria:

1) Those with the duration of chest pain more than six hours.

2) Those with LBBB in the ECG before thrombolysis.

3) Those with the contraindication to thrombolysis as per guidelines given by American College Of Cardiology18

All the patients of AMI presenting within first six hours of onset of chest pain have been evaluated. Detailed history of chest pain was taken in terms of duration from onset of chest pain in minutes, the site, the character & radiation. History of associated complaints like palpitations, giddiness, syncope, breathlessness will be recorded to assess occurrence of any complications of AMI. An attempt will be made to assess evidence of risk factors for AMI in the form of past history of HTN, IHD, DM in the patients & history of these conditions in first degree relatives of the patients. Behavioral risk factors for AMI like smoking, tobacco & alcohol consumption were also recorded.

General examination of the patients will be include height, weight, BMI, pulse rate, BP & signs of CCF at admission. Detailed systemic examination of cardiovascular, respiratory, abdominal & nervous system will be carried out in all patients and Killip's class will be assessed as per criteria given by Killip and Kimbal (1967).19 All these patients in the study will be then investigated for baseline parameters.. Serum CKMB estimation will be done by using optimized UV method / immunoinhibition method , Values of CKMB less than 25 IU/L were taken as normal . ECG will be taken using 12 lead machine.

All the patients will be thrombolysed using 1.5 million IU of streptokinase in 100 ml normal saline over 60 mins.

Clinical assessment every half hour for 2 hrs. will be done to assess:

1. Reduction in chest pain in percentage on a subjective scale & to assess any change in Killip's class.

2. Continuous ECG monitoring to observe occurrence of reperfusion arrhythmias.

At the end of 2 hrs. of follow up patients will be evaluated for:

a. Percentage reduction in chest pain on subjective scale

b. A twelve lead ECG to detect any change in sum of ST elevation

c. Repeat estimation of CK-MB.

Successful clinical reperfusion is defined by presence of at least two of the following criteria at 2 hrs.of starting treatment.

1.Chest pain evolution: Pain intensity will be quantified by percentage reduction in chest pain on subjective basis. A positive pain criterion is defined as 50% or more reduction in chest pain intensity 2 hours after starting thrombolysis.

2.ST segment elevation: A reduction 50% or more in sum of ST segment elevation is considered a positive electrocardiographic criteria.

3. Enzyme evolution: A positive enzymatic criteria is define as, more than two fold increase over upper normal or base line values.

At the end of two hours of starting thrombolysis patients will be grouped into two groups based on presence or absence of SCR. Those with successful reperfusion will be grouped into SCR (positive) group and those without successful reperfusion grouped into SCR (negative) group.

FOLLOWUP

Patients from both groups will be followed at 24 hr after thrombolysis and then on 7th day. This included noting down patients symptoms, a detailed clinical examination and recording 12 lead ECG. A pre discharge trans-thoracic 2-D echocardiography will be done to assess LV function and occurrence of regional wall motion abnormality (R.W.M.A.). Coronary angiography will be carried out in patient whenever possible as aim of study is to compare prognostic index Vs clinical markers of reperfusion rather than angiographic validation of success of reperfusion.

IV.   STATISTICAL ANALYSIS

By univariate analysis (chi square test), the association of mortality rate with various clinical variable will be analyzed. The comparison of base line variables will be made by students unpaired t test , chi square test for continuous & categorical variables respectively. A 'p' value of less than 0.05 will be considered statistically significant.

V.   ETHICAL ISSUES

Proposal of the study will be subjected to the ethical committee of our institute for approval.

SAMPLE SIZE   100

Bias: Describe any efforts to address potential sources of bias.

Study size: Explain how the study size was arrived at.

Quantitative variables: Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why.

Statistical methods: Describe all statistical methods, including those used to control for confounding. Describe any methods used to examine subgroups and interactions. Explain how missing data were addressed. If applicable, describe analytical methods taking account of sampling strategy. Describe any sensitivity analyses.

VI.   EXPECTED OUTCOMES/RESULTS

Data will be analyzed to evaluate prognostic index in patients of AMI, To evaluate clinical markers of reperfusion after thrombolysis and to correlate coronary prognostic index and clinical markers of reperfusion in AMI in relation to early morbidity & mortality.

VII.   DISCUSSION

Relevant related studies in this region were explored for additional information related to geographic context (21-45). Few studies related to other related non-communicable entities(46-68) and sociocultural aspects (69-78) were reviewed. The results of this study will be compared with relevant.

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