Study Protocol of Death Anxiety, Perceived Stress, Sleep Quality, Cardiac Illness Denial and Subjective Well-being among Stable Patients with Acute Myocardial Infarction

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Abstract

Background: It has been seen that negative affective states (e.g., depression, anxiety, anger), social isolation, and social insecurity are specific psychosocial determinants that adversely influence ischemic heart diseases, and these patients experience higher levels of death anxiety. Hence, studying death anxiety, perceived stress, sleep quality, and illness acceptance among myocardial infarction (MI) patients will give insight into their psychosocial management.

Method: The study will be conducted on patients (18–60 years) with a diagnosis of acute MI hospitalized in the cardiology unit of King George's Medical University (KGMU) and clinically stable at the time of assessment. The participants will be assessed via semi-structured proforma for sociodemographic and clinical details, the scale of death anxiety (SDA), perceived stress scale, single item sleep quality index, cardiac denial of impact scale and WHO well-being index-5.

Result: This study will measure death anxiety, perceived stress, sleep quality, cardiac denial of impact scale and subjective well-being among stable patients with acute MI, to study their associations among each other and their change with time during follow up (10–12 weeks after the initial event).

Conclusion: It is expected that death anxiety and perceived stress will be high among patients with acute MI, affecting their sleep quality and subjective well-being.

INTRODUCTION

Cardiovascular disorders are a leading cause of mortality globally. Ischemic heart diseases are the most common cause of cardiovascular mortality globally and in all regions of the world.¹ Over the past 25 years, there has been a decline in cardiovascular mortality with the increase in a sociodemographic index (SDI);¹ however, India, a developing country with a huge population, still has high cardiovascular mortality.² In India, the age-standardized death rate...
due to cardiovascular disorders is 272 per hundred thousand population versus 235 per hundred thousand population globally. Over a period of 20 years (1990–2010), there is an increase by 59% in premature mortality due to cardiovascular disorders in India. Evidence supports that negative emotional states (e.g., sadness, anxiety, anger), social isolation, and social insecurity are psychosocial determinants that adversely influence ischemic heart diseases.

Death anxiety refers to the fear of and anxiety related to the anticipation and awareness of dying, death, and nonexistence. Death anxiety leads to significant emotional and behavioral outcomes and is a universal human phenomenon. Studies have seen that life-threatening illnesses are associated with greater death anxiety. The MI being a critical event may presumably be associated with heightened death anxiety. It has been seen that patients with cardiovascular disorders experience higher levels of death anxiety.

The ability to appraise the impact and severity of negative life events differs from one individual to another and perceived stress reflects the thoughts and feelings of an individual in response to stressful events and their ability to handle them. There is an established association between perceived stress and incidence of coronary heart disease. Research suggests that people with MI with moderate to high-stress levels are at increased risk of mortality than those with lower levels of stress. Between males and females, perceived stress was found to be higher among females following MI. It was also seen that there is a decline in the level of perceived stress with time following the acute event of MI and the initial high level of distress at the hospital following MI is a predictor of adverse outcome and poor quality of life. Additionally, it has been seen that patients with a higher perception of controlling the situation are likely to experience less stress than those who perceive that the situation is going out of their control.

Another psychological disturbance often seen in patients with acute MI is poor sleep quality and studies have shown that it is a factor that may adversely impact outcomes in these patients. Previous research in this field has shown a connection between cardiovascular diseases and patients exhibiting a preoccupation with the feelings of inner emptiness, a lack of interest in living, poor sleep and complicated grief.

Higher stress levels and poor sleep quality can unquestionably lead to poorer subjective well-being or self-reported well-being. The adequate addressal of these psychological factors can improve an individual’s overall well-being and reduce risk of cardiovascular events as studies suggest that individuals who are satisfied and experience more positive emotions have reduced risk for coronary heart disease.

Indian population constitutes unique socio-cultural and psychological characteristics and contributes to a significant proportion of cardiovascular mortality globally. Hence, studying death anxiety, perceived stress, sleep quality and illness acceptance among patients of MI in this particular region will give insight into their psychosocial management.

The study hypothesize that patients with a higher level of death anxiety are likely to experience higher perceived stress levels and are expected to have poor quality of sleep, poor subjective well-being, and possibly poorer outcomes. This study aimed to measure death anxiety, perceived stress, sleep quality, cardiac illness denial and subjective well-being among stable patients with acute MI and to examine the change of these variables with time during 3 months follow-up.

**Material And Methods**

- **Study design:** It is a prospective observational non-interventional study.
- **Study population:** Stable patients with Acute MI
- **Sampling technique:** Purposive sampling
- **Source of sample:** Stable patients with Acute MI as mentioned in the selection criteria

**Sample Size**

Sample size is calculated through Priori analysis using “G*Power: Statistical Power analyses 3.1.9.7” application.

T tests - Correlation: Point bi-normal model Analysis: A priori: Compute required sample size Input:
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Tail(s) = two Effect size |\(\rho| = 0.3\) \(\alpha\) err prob = 0.05 Power (1-\(\beta\) err prob) = 0.95 Output Non-centrality parameter \(\delta = 3.6404323\) Critical \(t = 1.9780988\) df = 132 Total sample size = 134 Actual power = 0.9509217 Considering a drop-out rate of about 20%, the expected number of initial participants is 161.

Selection Criteria

Inclusion Criteria
- Patient who are willing and cooperative for assessment (informed consent)
- Age 18–60 years
- Patients with a diagnosis of acute MI and clinically stable* at the time of assessment irrespective of interventions
  *definition of clinically stable: patients not having cardiogenic shock, absence of vasopressor therapy for more than 24 hours, refractory angina, refractory heart failure, hemodynamically unstable arrhythmias.
- Patient was diagnosed with acute MI within one week of assessment

Exclusion Criteria
- Medical/psychiatric co-morbidities interfering with assessment

Drop-out Criteria
- Patients who cannot be traced for follow up
- Patients unwilling to give consent for follow up
- Patients who have developed some serious medical or surgical illness during the period between the two assessments
- Patients who have another episode of Acute MI before the next assessment
- Patients who have died before the follow-up assessment

Diagnosis of MI

According to the third universal definition of MI, implemented by a joint task force from the European Society of Cardiology (ESC), American College of Cardiology (ACC) Foundation, American Heart Association (AHA), and the World Heart Federation (WHF), MI is diagnosed when either of the following two criteria are met.20

- Detection of an increase or decrease in cardiac biomarker values (preferably using cardiac troponin [cTn]) with at least one value above the 99th percentile of the upper reference limit (URL) and with at least one of the following findings:
  - Symptoms of ischemia
  - New or presumed new significant ST-segment-T wave (ST-T) changes or new left bundle branch block (LBBB)
  - Development of pathologic Q waves on the ECG
  - Imaging evidence of new loss of viable myocardium or a new regional wall motion abnormality
  - Identification of an intracoronary thrombus by angiography or autopsy
- Cardiac death with symptoms suggestive of myocardial ischemia and presumed new ischemic changes or injury or new BBB on ECG, but death occurred before cardiac biomarker levels were obtained, or before cardiac biomarker values would be increased.

Tools

Semi-structured Proforma

The proforma will be used to collect the sociodemographic and clinical details of the included patients after obtaining their consent. The proforma will also include the details regarding the lifestyle, especially the patient’s physical activity, and a rating based on the Kubler Ross model of grief to know the level of acceptance of the patient regarding the illness.

Scale of Death Anxiety (SDA)

It is a 17-item SDA which is a reliable and valid questionnaire to assess death anxiety based on an individual’s somatic, cognitive, emotional, and behavioral reactions. It helps to understand the individual differences in and perceptions of death anxiety. It has components under the four major aspects of death anxiety-dysphoria, death intrusion, fear of death, and avoidance of death.20

Perceived Stress Scale (PSS)

It is the most widely used psychological instrument for measuring the perception of stress. It is a measure of the degree to which situations in one’s life are appraised as stressful. It consists of 10
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questions regarding feelings and thoughts of the individual for the past one month.21

**Single Item Sleep Quality Index**

The single item sleep quality scale (SQS) was developed as a simple and practical sleep quality assessment and psychometrically evaluated tool. It is a single questionnaire tool and measures the quality of sleep for the majority of the nights for the past 7 days only. It categorizes sleep into terrible, poor, fair, good and excellent.22

**WHO Well-being index- 5 Items Version**

This inventory was developed by the WHO, regional office for South-East Asia. It consists of 5 questions related to subjective well-being.23

**Cardiac Denial of Impact Scale**

The CDIS is composed of 8 items, rated on a 5-point Likert scale from not present to very high, leading to an overall score ranging from 8 to 40.24

**Procedure**

The study got ethical approval from the institutional ethics committee (ref. code: PGTSC-IIA/P39). Patients diagnosed with Acute MI and hospitalized in the Cardiology department of King Georges’ Medical University, will be screened on selection criteria. Those meeting the selection criteria will be assessed for the study variables by using above mentioned tools after obtaining informed consent. The initial assessment would be conducted within the first week after being diagnosed with Acute MI and would be conducted in offline mode. The 2nd assessment will be conducted between 10–12 weeks after the initial event, via online/offline mode (Figure 1). Patients with significant psychological distress will be referred to adult psychiatry OPD for appropriate treatment and will be explained about non-pharmacological therapy for impairment. Drop-outs will be eliminated from the study as per the drop-out criteria. The consultants from the department of cardiology, who are co-supervisors in this project, will help recruit the patients and confirm the patient’s diagnosis. The primary investigator will assess the patient as per the study protocol as per the study protocol under the supervision of co-supervisors from the department of psychiatry.

**Data Analysis Plan**

Data obtained will be analysed by using computerised software SPSS version 16.0. Descriptive data obtained will be presented in the form of percentages, proportions, ranges and mean. Categorical variables will be compared by using Chi-square test/Fisher Exact test. Averages will be compared among various study groups by applying t-test/ANOVA. The association of various study variables with each other will be analysed using correlational analysis.

**Implications And Conclusion**

Understanding the soft psychological domains like death anxiety, perceived stress, and sleep quality among patients with acute MI is important as these variables significantly affect subjective well-being. Assessing and addressing these variables in the initial days following the acute MI diagnosis is expected to improve the subjective well-being and subsequently reduce future cardiovascular events.

A life-threatening illness, such as MI, is a traumatic experience that can have significant effects on a patient’s health. Even though we have thoughts about death at almost every stage of life, having a death-related illness can urge us to think about death more than ever. It is well known that anxiety, and stress are important predictors of quality of life and predictors of survivability in patients with MI. Hence, there is a need to understand the level of death anxiety and perceived stress among survivors of acute MI. Adequate addressal of death anxiety

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**Figure 1:** Assessment schema of the patients
and perceived stress may normalize sleep quality, subjective well-being and is also likely to reduce.

REFERENCES