Evaluation of Changes in Health Related Quality of Life (HRQoL) before and after Coronary Artery Bypass Grafting (CABG)

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ABSTRACT

Coronary Artery Disease (CAD) is a major cause of morbidity and mortality in developing countries. Coronary Artery Bypass Grafting (CABG) has become the most frequently used treatment for CAD. Measuring and understanding the current status of Health Related Quality of Life (HRQoL) of patients before and after CABG is essential to manage the disease more effectively. We conducted 6 months Prospective, observational study at Narayana Hrudyalaya Hospital (tertiary care) with 98 CAD patients to evaluate the changes in HRQoL before and 3-months after CABG using SF-36 questionnaire. Demographics of patients including clinical parameters such as medical history, diagnosis of CAD and disease severity were collected. All the 8 domains of SF-36 (Physical Functioning, Role Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Emotional, Mental Health) improved significantly (P<0.05) from before to 3-months after CABG. The results of the study quantify the benefits of CABG on HRQoL of patients. This study also revealed the desired prognosis of our patients.

Keywords: Coronary artery disease, Coronary artery bypass grafting, Health-related quality of life, SF-36 questionnaire

INTRODUCTION

Coronary artery disease (CAD)

Coronary Artery Disease (CAD) is also called Coronary Heart Disease (CHD) or Ischemic Heart Disease (IHD). It is defined as a lack of oxygen and decreased or no blood flow to the myocardium resulting from coronary artery narrowing or obstruction. CAD may present as an Acute Coronary Syndrome (ACS, which includes unstable angina and non–ST-segment elevation or ST-segment elevation myocardial infarction [MI]), chronic stable exertional angina, ischemia without symptoms, or ischemia due to coronary artery vasospasm (Variant or Prinzmetal angina) [1].

Epidemiology
The huge burden of Cardiovascular Disease (CVD) in the Indian subcontinent is the consequence of the large population and high prevalence of CVD risk factors [2]. The annual number of deaths from CVD in India is projected to rise from 2.26 million (1990) to 4.77 million (2020) [3]. Coronary Artery Disease (CAD) is the largest contributor to CVD burden in India. Coronary Artery Disease prevalence rates in India have been estimated over the past several decades and have ranged from 1.6% to 7.4% in rural populations and from 1% to 13.2% in urban populations [4]. CAD affects Indians with greater frequency and at a younger age than counterparts in developed countries, as well as many other developing countries. Age-standardized CAD death rates in people 30-69 years old are 180 per 100,000 in Britain, 280 per 100,000 in China, and 405 per 100,000 in India [2]. Driving this steep rise in CVD risk factor burden is the rapid increase in the proportion of urban inhabitants (currently at 30% with a projected rise to 43% in 2021). Urbanization is characterized by a marked increase in the intake of energy-dense foods, a decrease in physical activity, and a heightened level of psychosocial stress, all of which promote the development of dysglycaemia, hypertension, and dyslipidaemia [5].

Risk factors of cad
Risk factors that can be altered include smoking, hypertension, hyperlipidemia, obesity, sedentary lifestyle, psychosocial factors such as stress and type A behavior patterns.

Cigarette smoking is common. The Centers for Disease Control and Prevention estimates that 45.1 million people are current smokers (23.9% men; 18.1% women) in America, and the risk for CHD is increased by about 1.8 in active smokers and by about 1.3 for passive or environmental smoke exposure. From 1997 to 2001 437,902 Americans died from smoking-related illnesses and 34.7% of deaths were attributable to CVD [8]. Risk because of smoking is related to the number of cigarettes smoked per day and the duration of smoking. Passive smoking in angina pectoris patients decreases exercise time. The direct effects of cigarette smoke that are detrimental to patients with angina include (a) elevated heart rate and blood pressure from nicotine, which increases MVO2, and impaired myocardial oxygen delivery due to carboxyhemoglobin generation from carbon monoxide inhalation in smoke; (b) the negative inotropic effect of carboxyhemoglobin; (c) increased platelet adhesiveness and promotion of aggregation resulting in thrombotic tendencies because of nicotine and carboxyhemoglobin; (d) lowered threshold for ventricular fibrillation during ischemia as a consequence of carboxyhemoglobin; and (e) impaired endothelial function owing to smoking. Smoking also accelerates the risk for myocardial infarction, sudden death, cerebrovascular disease, peripheral vascular disease, and hypertension, and it reduces high-density lipoprotein concentrations. Clearly, primary prevention is needed for this risk factor and much of the education effort to discourage initiation of smoking should be targeted for teenagers. Cessation of smoking reduces the incidence of coronary events to approximately 15% to 25% of that associated with continued smoking and these benefits are noted within 2 years of cessation. Hypertension, whether labile or fixed, borderline or definite, casual or basal, systolic or diastolic, at any age regardless of gender, is the most common and a powerful contributor to atherosclerotic coronary vascular disease.

Morbidity and mortality increase progressively with the degree of blood pressure elevation of either systolic or diastolic pressure or pulse pressure, and no discernible critical value exists. Numerous trials have documented the reduction in risk associated with blood pressure lowering; however, most of these studies show that mortality and morbidity reduction is a result of fewer strokes and less renal failure and heart failure. The reduction in coronary heart disease end points is significant but not as dramatic. The reasons for this are unclear but perhaps relate to the multi-factorial etiology of IHD. Recent guideline changes from the AHA recommend goal blood pressure of <130/80 mm Hg for patients with stable angina, unstable angina, non-ST-segment myocardial infarction, ST segment myocardial infarction and <120/80 mm Hg in patients with left ventricular dysfunction.

Hypercholesterolemia is a significant cardiovascular risk factor, and risk is directly related to the degree of cholesterol elevation. As with hypertension, there is no critical value that defines risk, but rather, risk is incrementally related to the degree of elevation and the presence of other risk factors. A fasting lipoprotein panel should be obtained in all patients with known CAD. Reductions in LDL-
cholesterol for primary prevention and secondary intervention have been shown to reduce total and CAD mortality and stroke as well as the need for interventions such as PTCA and CABG. Supplemental vitamin E or other antioxidants reduce the susceptibility of LDL-cholesterol to oxidation, but clinical trial data fail to show any benefit with supplementation.

The prevalence of overweight and obesity, defined as a body mass index (weight in kilograms divided by height in meters squared) of ≥ 25 kg/m² and ≥ 30 kg/m², respectively, are estimated to occur in 66.3% and 32.2% of the U.S. population. Body mass index is associated with an increased mortality ratio compared with individuals of normal body weight, and the objective for patients with IHD is to maintain or reduce to a normal body weight [6-13]. This may be accomplished through dietary modification, exercise, pharmacologic therapy or surgical therapy.

Frequently associated with obesity is a sedentary lifestyle, and inactivity may contribute to higher blood pressure, elevated blood lipid levels, and insulin resistance associated with glucose intolerance in diabetics (insulin resistance or metabolic syndrome). Exercise to the level of about 300 kcal three times a week is useful in improving maximal oxygen uptake, improving cardiorespiratory efficiency, promoting collateral artery formation, and promoting Potential alterations in the risk of ventricular fibrillation, coronary thrombosis, and improved tolerance to stress. Epidemiologic studies have found that mortality is directly related to resting heart rate and a low heart rate difference between resting and maximal exercise heart rate, and inversely related to exercise heart rate. A regular exercise program has been shown to reduce all-cause and cardiac mortality [14].

Competitiveness, intense striving for achievement, easily provoked hostility, a sense of urgency about doing things quickly and being punctual, impatience, abrupt and rapid speech and gestures, and concentration on self-selected goals to the point of not perceiving and attending to other aspects of the environment are traits that characterize the behavioral pattern known as the type A or coronary prone personality. Although the issue is somewhat controversial, type A individuals may have increased cardiovascular risk with risk ratios ranging from insignificant to three times that of a matched population. Psychological stress and type D personality have been associated with adverse cardiac prognosis, but little is known about their relative effect on the pathogenesis of CHD. “Type D” refers to the tendency to experience negative emotions and to inhibit the expression of these emotions in social interactions. The mechanism by which personality affects the cardiovascular system is not understood, but may reflect the activity of the sympathetic system and enhanced responsiveness of other stress hormones when compared with non-type personalities. Alcohol ingestion in small to moderate amounts (<40 g/day of pure ethanol) reduces the risk of coronary heart disease; however, consumption of large amounts (>50 g/day) or binge drinking of alcohol is associated with increased mortality from stroke, cancer, vehicular accidents, and cirrhosis [15,16].

There appears to be a differential effect depending on race with an inverse relationship between ethanol consumption in whites but a direct relationship in Blacks between consumption and CAD risk. The mechanisms for the presumed protective effects of alcohol are not known but the effects may be related to increased high-density lipoprotein levels, impaired platelet function, or associations between the amount of alcohol ingested and personality type.

Whatever the relationship, it is well to remember that alcohol drinking is implicated in more than 40% of all fatal automobile accidents and consumption of alcohol predisposes to hepatic cirrhosis, the sixth to seventh most common cause of death in middle age adults in the United States. With this in mind, it seems illogical to suggest alcohol ingestion as a prophylactic measure for coronary disease but rather to advise moderation of alcohol consumption, if it is the preference of the individual [17].

**Classification of CAD**

Coronary Artery disease is classified into two groups:

1. Angina
2. Myocardial Infarction

**Angina**

Angina pectoris is the result of myocardial ischemia caused by an imbalance between myocardial blood supply and oxygen demand. It
is a common presenting symptom (typically, chest pain) among patients with coronary artery disease (CAD).

**Clinical classification of angina**

**Stable angina**

It is the most common kind of angina. It is diagnosed when the chest pain has remained unchanged in severity, frequency and duration over several weeks or month. It is usually provoked by unusual physical exertion or emotional stress and is relieved by rest. Variant angina of Prinzmetal: It refers to the Vasospasm of the coronary arteries.

Unstable angina: Angina occurring at rest or with minimal exertion. ECG shows elevated or depressed ST segment and characteristic inversion of T waves (Figure 1) [18].

**Clinical presentation of angina**

**General**

Many episodes of ischemia do not cause symptoms of angina (silent ischemia). Patients often have a reproducible pattern of pain or other symptoms which appear after specific amount of exertion. Increased frequency, severity, duration, or symptoms at rest suggest an unstable angina pattern and the patient should seek help immediately (Figure 2).

**Symptoms**

Sensation of pressure or burning over the sternum or near it, often but not always radiating to the left jaw, shoulder and arm; also chest tightness, shortness of breath. Pain usually lasts from 0.5 to 30 minutes, often with a visceral quality (deep location). Precipitating factors include exercise, cold environment, walking after a meal, emotional upset, fright and anger. Relief occurs with rest and nitroglycerin.

**Signs**

Abnormal precordial (over the heart) systolic bulge.

Abnormal heart sounds.
Laboratory tests
Typically, no laboratory tests are abnormal; however, if the patient has intermediate to high-risk features for unstable angina, electrocardiographic changes and serum troponin, or creatine kinase may become abnormal. Patients are likely to have laboratory test abnormalities for the risk factors for CAD such as elevated total and low-density lipoprotein cholesterol, low high-density lipoprotein cholesterol, impaired fasting glucose or elevated glucose, high blood pressure, elevated C-reactive protein, and abnormal renal function. Hemoglobin should be checked to make sure the patient is not anemic [19].

Myocardial infarction
Myocardial infarction (MI or AMI for acute myocardial infarction), also known as a heart attack, occurs when the blood supply to part of the heart is interrupted (Figure 3). This is most commonly due to occlusion (blockage) of a coronary artery following the rupture of a vulnerable atherosclerotic plaque, which is an unstable collection of lipids (like cholesterol) and white blood cells (especially macrophages) in the wall of an artery. The resulting ischemia (restriction in blood supply) and oxygen shortage, if left untreated for a sufficient period, can cause damage and/or death (infarction) of heart muscle tissue (myocardium).

Clinical presentation of myocardial infarction
General
The patient typically is in acute distress and may develop or present with cardiogenic shock.

Symptoms
The classic symptom is midline anterior chest discomfort. Accompanying symptoms may include arm, back or jaw pain, nausea, vomiting, or SOB. Patients less likely to present with classic symptoms include elderly patients, diabetic patients, and women.

Signs
No signs are classic for MI. Patients with MI may present with signs of acute heart failure, including jugular venous distension, rales, and S3 sound on auscultation. Patients may present with arrhythmias and therefore may have tachycardia, bradycardia, or heart block.

Laboratory tests
Troponin I or T and CK MB are measured. Blood chemistry tests are performed with particular attention to potassium and magnesium, which may affect heart rhythm, and glucose, which when elevated places the patient at higher risk for morbidity and mortality. Serum creatinine level is measured to identify patients who may need dosing adjustments for some pharmacotherapy and...
patients who are at high risk for morbidity and mortality. Baseline complete blood count and coagulation tests (aPTT and INR) should be obtained because most patients will receive antithrombotic therapy, which increases the risk for bleeding. Fasting lipid panel should be obtained [20].

Coronary artery bypass grafting (CABG)
Coronary artery bypass grafting (CABG) is defined as “open-heart surgery in which a section of a blood vessel is grafted from the aorta to the coronary artery to bypass the blocked section of the coronary artery and improve the blood supply to the heart” [21].

Coronary artery bypass surgery (CABG) involves creating new arteries to provide blood to the heart by use of other blood vessels as conduits to bypass the obstructions in the patient’s coronary arteries. In most cases, the surgeon constructs at least one of the bypasses by using an artery called the internal mammary artery that is located behind the breastbone or sternum.

Other bypasses may be constructed by using a vein from the leg (saphenous vein) or an artery from the forearm (radial artery). In almost all cases, the operation requires an incision in the midline of the chest (sternotomy). During most bypass operations, the heart is stopped and is connected to a heart-lung machine that does the work of both the heart and the lungs [22].

The ECASS recruited 768 men under 65-years between 1973 and 1976. While the participants were randomized to medical or surgical treatment, the main weakness of this trial was that nothing was known about the original population from which the trial patients were drawn. There was significant improvement in survival for the total CABG population, and for patients with three-vessel disease, with stenosis in the proximal third of the left anterior descending artery, or with left main coronary disease.

After 5 years of follow up, 30 deaths were reported among the 395 patients treated surgically (7.6%), and 61 deaths among the 373 patients using medical treatment (16.3%) Improved functional status and return to pre-morbid lifestyle is a major goal for most patients undergoing CABG. Relief of angina and dyspnea, level of physical activity, complications of surgery, and re-hospitalization have been investigated when assessing physical functioning [23].

Relief From angina and dyspnea Incapacitating angina is the most common indication for CABG. Results of observational studies and randomized controlled trials of medical versus surgical treatment have demonstrated that in patients with disabling angina pectoris, surgery results in relief from symptoms and decreased need for anti-anginal medication. A review of 14 controlled clinical trials demonstrated that the likelihood of becoming angina-free was approximately 40% greater in the surgical than the medical group. A more recent study found that 80% of CABG patients were angina-free up to 5 years after surgery [24].

The measurement of treatment outcome or QOL for the patient is the keystone of modern scientific medicine. The importance of treatment outcome is recognized throughout clinical practice, particularly when innovative, invasive or costly treatments are evaluated, and the mortality rate is too low to affect decision making. However, there is no universal agreement of the meaning of QOL or how it should be measured [25].

Health related quality of life (HRQoL)
Health-related quality of life (HRQoL) is a multi-dimensional concept that includes domains related to physical, mental, emotional and social functioning. It goes beyond direct measures of population health, life expectancy and causes of death, and focuses on the impact health status has on quality of life [26].

Need for HRQoL
Measuring HRQoL can help determine the burden of preventable disease, injuries, and disabilities, and it can provide valuable new insights into the relationships between HRQoL and risk factors. Measuring HRQoL will help monitor progress in achieving the nation’s health objectives. Analysis of HRQoL surveillance data can identify subgroups with relatively poor perceived health and
help to guide interventions to improve their situations and avert more serious consequences.

Interpretation and publication of these data can help identify needs for health policies and legislation, help to allocate resources based on unmet needs, guide the development of strategic plans, and monitor the effectiveness of broad community interventions. HRQoL assessment is a particularly important public health tool for the elderly in an era when life expectancy is increasing; with the goal of improving the additional years in spite of the cumulative health effects associated with normal aging and pathological disease processes [27].

Measurement of HRQoL

MATERIALS AND METHODS

Study design
A Prospective Observational study will be carried out for studying the functional status in patients with CABG and compare their life before and after treatment.

Study site
The study will be conducted in Department of General Medicine in NARAYANA HRUDAYALAYA HOSPITAL, (1-1-216) Suraram’X’ Roads, Jeedimetla, Hyderabad, Telangana -500055. Which are 300 bedded multispeciality hospitals.

Study period
This study is proposed to be conducted for six months, from November 2015 to April 2016.

Study criteria
Inclusion criteria
1. Patients with Hypertension.
2. Patients with Angina, CAD, Left ventricular dysfunction, heart attack, hyperlipidemia, Atherosclerosis.
3. Out –Patients and In-Patients.

Exclusion criteria

Several measures have been used to assess HRQoL and related concepts of functional status. Among them are the Medical Outcomes Study Short Forms (SF-12 and SF-36), the Sickness Impact Profile, and the Quality of Well-Being Scale. The SF-36 measures are now used by the Health Care Financing Administration (HCFA) and the National Committee for Quality Assurance’s Health Plan Employer Data and Information Set (HEDIS 3.0) to help evaluate the quality of care in managed care plans and other health care applications.

While these measures have been widely used and extensively validated in clinical settings and special population studies, their length often makes them impractical to use in population surveillance [28].

Tools used
1. SF-36 Questionnaire.

Source of data
Patient data was collected prospectively from the case sheets in CCU and Inpatient wards after taking consent from the patient to be included in the study.

Study procedure
1. A Prospective Observational study was carried out for Evaluation of changes in Health Related Quality of Life (HRQoL) in patients before and after CORONARY ARTERY BYPASS GRAFTING (CABG).
2. All patients diagnosed with CAD and undergoing CABG in Inpatient wards and CCU at Narayana Hrudayalaya Hospitals were identified and the aim and data collection procedure of the study, together with the right to withdraw from the study at any time was explained to the patients.
3. The demographic data and laboratory data of the patients was collected in patient data collection form, after taking the consent from the patients.
4. Patients HRQoL was assessed by administering SF-36 questionnaire Before CABG procedure.

5. The second set of data was collected by administering SF-36 questionnaire at 3-month after CABG procedure because clinical findings suggested that patients usually required 1-2 month to recover from the procedure both physically and psychologically and were able to resume normal daily activities.

6. Finally, the prevalence of risk factors contributing to the development of CAD and the HRQoL scores of the patients, Before CABG and 3-months after CABG was analysed using statistical analysis.

Statistical analysis

1. Descriptive Statistics were presented as mean and standard deviation for continuous variables.

2. Percentages were used to present the results of Age, Gender, Prevalence of Risk factors, Classification of CAD and Disease severity.

3. Repeated Measures ANOVAs, a statistical test was done to compare the HRQoL scores of Patients Before and 3-months after CABG. Using Microsoft Excel 2010 and p values were calculated using Graph pad Quick Calcs software.

4. The following parameters were analyzed statistically using Repeated measure ANOVA.

5. The Physical Functioning domain of HRQoL of Patients Before and 3-months after CABG.

6. The Role Physical domain of HRQoL of Patients Before and 3-months after CABG.

7. The Bodily Pain domain of HRQoL of Patients Before and 3-months after CABG.

8. The General Health domain of HRQoL of Patients Before and 3-months after CABG.

9. The Vitality domain of HRQoL of Patients Before and 3-months after CABG.

10. The Social Functioning domain of HRQoL of Patients Before and 3-months after CABG.

11. The Role Physical domain of HRQoL of Patients Before and 3-months after CABG.

12. The Mental Health domain of HRQoL of Patients Before and 3-months after CABG.

Plan of work

Evaluation of changes in Health Related Quality Of Life (HRQoL) of patients before and after CABG in Inpatient wards & CCU at Narayana Hrudayalaya hospitals was carried out.

Annexures

1. Patient consent form

2. Documentation form

3. SF-36 questionnaire
Patient Consent Form

“Evaluation of changes in Health Related Quality of Life before and after Coronary Artery Bypass Grafting (CABG)”

Name of the Patient:

Investigator’s name: 1. B. Sharan
2. P. Vishwas
3. Y. Prashanth Reddy

Name of Institution: Malla Reddy Institute of Pharmaceutical Sciences

For the Patient:

I _____________________________ hereby give my consent to be included as patient in the clinical study - “Evaluation of changes in Health Related Quality of Life before and after Coronary Artery Bypass Grafting (CABG)”

I agree to the following:

- I understand that I will not be given any new study medication for participation in this study.
- I have been informed to my satisfaction about the purpose of this study.
- I have been given the opportunity to question the attending doctor on all the aspects of the study.

__________________________
Signature of the patient with date

Contact Details of the witness:

Name:
Telephone no:
Address:

__________________________
Signature of the witness* with date

Note:
*Signature of the witness is required only if the patient is illiterate; Witness will ensure that the patient consent form was explained to the patient in a language understood by the patient.

For the Investigator:

I confirm that I have explained the nature and purpose of the above study

Investigator’s sign with date: ______________________
**DOCUMENTATION FORM**

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### 1. PATIENT INFORMATION:


### 2. REASON FOR ADMISSION (C/O)

### 3. PAST MEDICAL/MEDICATION HISTORY:

### 4. SMOKING YES NO

- [ ] SMOKING
- [ ] ALCOHOL
- [ ] DIET(VEG)
- [ ] COFFEE

### 5. DIAGNOSIS:

### 6. GRAFT:

Investigator’s sign with date: _________________________
### Lab Data

**Blood:**
- RBC
- WBC
- HB
- PLT
- ESR
- PCV
- HCT
- MCV
- Total Count
- Neutrophils
- Lymphocytes
- Monocytes
- Eosinophils
- PT (Prothrombin time)

**Electrolyte:**
- Na
- K
- Cl
- HCO₃⁻
- HCT
- Sr. Cr
- GFR
- BUN

**Thyroid:**
- TSH
- FSH
- T₃
- T₄

**LFT:**
- SGOT
- SGPT
- Total Bilirubin
- Direct Bilirubin
- Indirect Bilirubin
- PT
- Albumin
- Globulin
- GGT

**Urine:**
- Colour
- Protein
- Glucose
- Pus
- Crystals
- Others

**Blood Sugar:**
- RBS
- FBS
- P.P
- Drugs
SF-36 QUESTIONNAIRE

Name: ____________________  Ref. Dr. ____________________  Date: _______
ID#: ____________________  Age: ________  Gender: M / F

Please answer the 36 questions of the Health Survey completely, honestly, and without interruptions.

1. In general, would you say your health is:
   - Excellent
   - Very good
   - Good
   - Fair
   - Poor

2. Compared to one year ago, how would you rate your health in general now?
   - Much better now than one year ago
   - Somewhat better now than one year ago
   - About the same as one year ago
   - Somewhat worse now than one year ago
   - Much worse now than one year ago

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

   Yes, limited a lot  Yes, limited a little  No, not limited at all

   a Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports
   b Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
   c Lifting or carrying groceries
   d Climbing several flights of stairs
   e Climbing one flight of stairs
   f Bending, kneeling, or stooping
   g Walking more than a mile
   h Walking several blocks
   i Walking one block
   j Bathing or dressing yourself
4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

   a. Cut down on the amount of time you spent on work or other activities
   b. Accomplished less than you would like
   c. Were limited in the kind of work or other activities
   d. Had difficulty performing the work or other activities (for example, it took extra effort)

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

   a. Cut down on the amount of time you spent on work or other activities
   b. Accomplished less than you would like
   c. Did work or other activities less carefully than usual

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

   Not at all   Slightly   Moderately   Quite a bit   Extremely

7. How much bodily pain have you had during the past 4 weeks?

   None   Very mild   Mild   Moderate   Severe   Very severe

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

   Not at all   A little bit   Moderately   Quite a bit   Extremely
9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
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</thead>
<tbody>
<tr>
<td>a. Did you feel full of pep?</td>
<td>☐ ☐ ☐ ☐ ☐ ☐</td>
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<td>b. Have you been a very nervous person?</td>
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<td>c. Have you felt so down in the dumps that nothing could cheer you up?</td>
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<td>d. Have you felt calm and peaceful?</td>
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<td>e. Did you have a lot of energy?</td>
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<td>f. Have you felt downhearted and blue?</td>
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<td>g. Did you feel worn out?</td>
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<td>h. Have you been a happy person?</td>
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<td>i. Did you feel tired?</td>
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10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

<table>
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<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
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11. How TRUE or FALSE is each of the following statements for you?

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<tr>
<th></th>
<th>Definitely true</th>
<th>Mostly true</th>
<th>Don't know</th>
<th>Mostly false</th>
<th>Definitely false</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. I seem to get sick a little easier than other people</td>
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<tr>
<td>b. I am as healthy as anybody I know</td>
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<td>☐</td>
</tr>
<tr>
<td>c. I expect my health to get worse</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>d. My health is excellent</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
RESULTS

Evaluation of changes in Health Related Quality of Life (HRQoL) before and after Coronary artery bypass grafting (CABG) was conducted during the study period of 6 months from 2015 to 2016. A total of 120 cases of CAD patients who were eligible for CABG were identified during the study period [29-32].

Although many studies have focused on HRQoL of patients before and after CABG during 3-12 months period, not all of them have examined the HRQoL before and after CABG during the early recovery period which is during 3 months. Thus, the HRQoL of patients before and after CABG in the early recovery period was studied.

The demographic characteristics of the patients was analysed according to the data collected in the Patient data collection forms. The rate of patients undergoing CABG in NH-Malla Reddy hospitals during the study period & a relative study with respect to age & gender was determined. Risk factors which contribute to the development of CAD and the effect of CABG on HRQoL of patients was analysed.

120 patients enrolled for the study during the study period, of those patients, 22 dropped out during the follow-up period. Thus, a total of 98 patients comprised the study. Out of 98 patients, 80 were male patients & 18 were female patients.

DISCUSSION

On considering the distribution of patients according to age, the patients whose age from 50-60 yrs is 42 patients it accounts 43.4 %. These results were consistent with the results observed by Peric V et al. (Table 1 and Figure 4).

Table 1: Age distribution of patients (n=98)

<table>
<thead>
<tr>
<th>Age(yrs)</th>
<th>No. of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-40</td>
<td>2</td>
<td>2.0</td>
</tr>
<tr>
<td>40-50</td>
<td>20</td>
<td>20.4</td>
</tr>
<tr>
<td>50-60</td>
<td>42</td>
<td>43.0</td>
</tr>
<tr>
<td>60-70</td>
<td>27</td>
<td>27.5</td>
</tr>
<tr>
<td>70-80</td>
<td>7</td>
<td>7.1</td>
</tr>
</tbody>
</table>
The represented figure shows that maximum percentage (43%) of patient was found between the age group of 50-60 years. In the study population, male patients were found to be more (81.6%) compared to the female patients (18.4%). These results were consistent with the results observed by Staniute et al. (Figure 5 and Table 2). The gender distribution for total number of patients was analyzed and represented in the following Table 2.

Table 2: Gender distribution of patients

<table>
<thead>
<tr>
<th>Gender</th>
<th>No. of patients</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>80</td>
<td>82</td>
</tr>
<tr>
<td>Female</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>Total</td>
<td>98</td>
<td>100</td>
</tr>
</tbody>
</table>

The distribution of study population was found to be 82% of male patients and 18% of female patients.
In the study population, the prevalence of non-modifiable risk factors contributing to the development of CAD in patients in descending order were found to be as follows: 81.6% of risk was due to Male gender, 78% was due to Advancing age and 40% was due to Family History. These results were consistent with the results observed by Rajeeva Rivikath Pieris et al. (Figure 6 and Table 3).

**Table 3: The prevalence of modifiable risk factors in patients**

<table>
<thead>
<tr>
<th>RISK FACTOR</th>
<th>No. of population</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcoholic</td>
<td>57</td>
<td>58.0</td>
</tr>
<tr>
<td>Non-Alcoholic</td>
<td>41</td>
<td>42.0</td>
</tr>
</tbody>
</table>

The represented figure shows the % of Prevalence of modifiable Risk factors contributing to the development of CAD in patients. 58 % of risk was due to Alcoholic.

1. On considering the distribution of patients according to age, the patients whose age from 50-60 y is 42 patients it accounts 43.4%. These results were consistent with the results observed by Peric V et al.

2. In the study population, male patients were found to be more (81.6%) compared to the female patients (18.4%). These results were consistent with the results observed by Staniute et al.

3. In the study population, the prevalence of non-modifiable risk factors contributing to the development of CAD in patients in descending order were found to be as follows: 81.6% of risk was due to Male gender, 78% was due to Advancing age and 40% was due to Family History. These results were consistent with the results observed by Rajeeva Rivikath Pieris et al.

4. In the study population, the prevalence of modifiable risk factors contributing to the development of CAD in patients in descending order were found to be as follows: 58% due to 58% Due to Alcohol, 57.1% was due to Smoking and 18% due to obesity. These results were consistent with the results observed by V. Achari et al.
The represented figure shows the % of Prevalence of modifiable Risk factors contributing to the development of CAD in patients. 57 % of risk was due to smoking. Among the patients, 9.2% single vessel and among the patients 20.4% had double vessel disease, 70.4% patients had triple vessel disease.

These results were consistent with the results observed by Ayanian JZ et al. (Figure 8 and Table 5). The Clinical classification of CABG of Patients was analyzed and represented in the Table 5.

### Table 4: The prevalence of modifiable risk factors in patients

<table>
<thead>
<tr>
<th>RISK FACTOR</th>
<th>No. of population</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smokers</td>
<td>56</td>
<td>57.1</td>
</tr>
<tr>
<td>Non-smokers</td>
<td>42</td>
<td>42.9</td>
</tr>
</tbody>
</table>

### Table 5: Clinical classification of CABG GRAFTS of patients

<table>
<thead>
<tr>
<th>CABG GRAFTS</th>
<th>No. of patients</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SVD</td>
<td>9</td>
<td>9.2</td>
</tr>
<tr>
<td>DVD</td>
<td>20</td>
<td>20.4</td>
</tr>
<tr>
<td>TVD</td>
<td>69</td>
<td>70.4</td>
</tr>
</tbody>
</table>
The represented figure shows that total no. of patients with TVD were found to be 71\%, with DVD were found to be 20\%, with SVD were found to be 9\% respectively.

Among 16\% of the female patients had single vessel disease and 30\% female patients had double vessel disease and 54.6\% had triple vessel disease. These results were consistent with the results observed by Ayanian JZ et al. [33].

5. The mean HRQoL scores of patients Before-CABG were calculated and the mean of PF, RP, BP, GH, VT, SF, RE, MH was found to be 29, 34, 38, 41, and 49, 36, 32, 43.2 respectively. These results were consistent with the results observed by Hunt JO et al. (Figure 9 and Table 6). The HRQoL scores of Patients before CABG was calculated and represented in the following Table 6.

Table 6: HRQoL of patients’ before-CABG

<table>
<thead>
<tr>
<th>Domain</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Functioning</td>
<td>29</td>
<td>4.93</td>
</tr>
<tr>
<td>Role Physical</td>
<td>34</td>
<td>4.73</td>
</tr>
<tr>
<td>Bodily Pain</td>
<td>38</td>
<td>6.11</td>
</tr>
<tr>
<td>General Health</td>
<td>41</td>
<td>6.27</td>
</tr>
<tr>
<td>Vitality</td>
<td>49</td>
<td>6.39</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>36</td>
<td>6.29</td>
</tr>
<tr>
<td>Role Emotional</td>
<td>32</td>
<td>6.33</td>
</tr>
<tr>
<td>Mental Health</td>
<td>43.2</td>
<td>7.04</td>
</tr>
</tbody>
</table>

The represented figure shows the mean of HRQoL of patient’s Before-CABG.

6. The mean HRQoL scores of patients 3-months after CABG and the mean of PF, RP, BP, GH, VT, SF, RE, MH was found to be 48, 53, 54, 57.8, 62, 51, 45, 57 respectively. These results were consistent with the results observed by Peric V et al. (Figure 10 and Table 7). The HRQoL scores of patients 3-month after CABG were calculated and represented in the Following Table 7.
Figure 10: Mean of HRQoL of patients 3-month after CABG

Table 7: HRQoL of patients 3-months after CABG

<table>
<thead>
<tr>
<th>Domain</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Functioning</td>
<td>48</td>
<td>5.63</td>
</tr>
<tr>
<td>Role Physical</td>
<td>53</td>
<td>5.97</td>
</tr>
<tr>
<td>Bodily Pain</td>
<td>54</td>
<td>6.55</td>
</tr>
<tr>
<td>General Health</td>
<td>57.8</td>
<td>5.47</td>
</tr>
<tr>
<td>Vitality</td>
<td>62</td>
<td>5.5</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>51</td>
<td>8.85</td>
</tr>
<tr>
<td>Role Emotional</td>
<td>45</td>
<td>10.43</td>
</tr>
<tr>
<td>Mental Health</td>
<td>57.5</td>
<td>7.56</td>
</tr>
</tbody>
</table>

The represented figure shows the mean of HRQoL of patient’s 3-months after CABG.

7. The mean HRQoL scores of patients before and 3-months after CABG were compared and found that the mean HRQoL scores of patients improved significantly before to 3-months after CABG. These results were similar to the results observed by Peric V et al. (Figure 11-19 and Table 8-17). The mean scores of Physical Functioning domain of HRQoL of patients before and 3-months after CABG was compared and represented in the following Table 8.
Table 8: Mean scores of PF before and 3-months after CABG

<table>
<thead>
<tr>
<th>Domain</th>
<th>Before- CABG (mean)</th>
<th>3-months after CABG (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Functioning(PF)</td>
<td>64.9</td>
<td>76.1</td>
</tr>
</tbody>
</table>

The represented figure shows the mean scores of PF of patients before and 3-months after CABG as 64.9 and 76.1 respectively [34-36].

The mean scores of Role Physical domain of HRQoL of patients before and 3-months after CABG was compared and represented in the following Table 9.
Table 9: Mean scores of RP before and 3-months after CABG

<table>
<thead>
<tr>
<th>Domain</th>
<th>Before-CABG (mean)</th>
<th>3-months after CABG (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Role Physical (RP)</td>
<td>34</td>
<td>53</td>
</tr>
</tbody>
</table>

The represented figure shows the mean scores of RP of patients before and 3-months after CABG as 34 and 53 respectively. The mean scores of Bodily Pain domain of HRQoL of patients before and 3-months after CABG was compared and represented in the following Table 10.

Table 10: Mean scores of BP before and 3-months after CABG

<table>
<thead>
<tr>
<th>Domain</th>
<th>Before-CABG (mean)</th>
<th>3-months after CABG (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bodily Pain (BP)</td>
<td>38</td>
<td>54</td>
</tr>
</tbody>
</table>

The represented figure shows the mean scores of BP of patients before and 3-months after CABG as 38 and 54 respectively. The mean scores of General Health domain of HRQoL of patients before and 3-months after CABG was compared and represented in the following Table 11.

Table 11: Mean scores of GH before and 3-months after CABG

<table>
<thead>
<tr>
<th>Domain</th>
<th>Before-CABG (mean)</th>
<th>3-months after CABG (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Health</td>
<td>41</td>
<td>57.8</td>
</tr>
</tbody>
</table>
Table 12: Mean scores of VT before and 3-months after CABG

<table>
<thead>
<tr>
<th>Domain</th>
<th>Before-CABG (mean)</th>
<th>3-months after CABG (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitality</td>
<td>49</td>
<td>62</td>
</tr>
</tbody>
</table>

Figure 14: Mean scores of GH before and 3-months after CABG

The represented figure shows the mean scores of GH of patients before and 3-months after CABG as 57.8 and 41 respectively.

The mean scores of Vitality domain of HRQoL of patients before and 3-months after CABG was compared and represented in the following Table 12.

Figure 15: Mean scores of VT before and 3-months after CABG

The represented figure shows the mean scores of VT of patients before and 3-months after CABG as 49 and 62 respectively.
The mean scores of Social Functioning domain of HRQoL of patients before and 3-months after CABG was compared and represented in the following Table 13.

### Table 13: Mean scores of SF before and 3-months after CABG

<table>
<thead>
<tr>
<th>Domain</th>
<th>Before-CABG (mean)</th>
<th>3-months after CABG (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social Functioning</td>
<td>39</td>
<td>51</td>
</tr>
</tbody>
</table>

The represented figure shows the mean scores of SF of patients before and 3-months after CABG as 51 and 39 respectively.

The mean scores of Role emotional domain of HRQoL of patients before and 3-months after CABG was compared and represented in the following Table 14.

### Table 14: Mean scores of RE before and 3-months after CABG

<table>
<thead>
<tr>
<th>Domain</th>
<th>Before-CABG (mean)</th>
<th>3-months after CABG (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Role Emotional</td>
<td>32</td>
<td>45</td>
</tr>
</tbody>
</table>

The represented figure shows the mean scores of RE of patients before and 3-months after CABG as 32 and 45 respectively. The mean scores of Mental Health domain of HRQoL of patients before and 3-months after CABG was compared and represented in the following Table 15.
The represented figure shows the mean scores of MH of patients before and 3-months after CABG as 57.5 and 43.2 respectively.

The HRQoL scores of patients before and 3-months after CABG was calculated and represented in the following Tables 16 and 17.

Table 15: Mean scores of MH before and 3-months after CABG

<table>
<thead>
<tr>
<th>Domain</th>
<th>Before-CABG (mean)</th>
<th>3-months after CABG (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mental Health</td>
<td>43.2</td>
<td>57.5</td>
</tr>
</tbody>
</table>

Table 16: HRQoL of patients before 3-months after CABG

<table>
<thead>
<tr>
<th>Domain</th>
<th>Before CABG (mean, S.D)</th>
<th>3-months after CABG (mean, S.D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Functioning</td>
<td>29 ± 4.93</td>
<td>48 ± 5.63</td>
</tr>
<tr>
<td>Role Physical</td>
<td>34 ± 4.75</td>
<td>53 ± 5.97</td>
</tr>
<tr>
<td>Bodily Pain</td>
<td>38 ± 6.11</td>
<td>54 ± 6.55</td>
</tr>
<tr>
<td>General Health</td>
<td>41 ± 6.27</td>
<td>57.8 ± 5.47</td>
</tr>
<tr>
<td>Vitality</td>
<td>49 ± 6.39</td>
<td>62 ± 5.5</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>36 ± 6.29</td>
<td>51 ± 8.85</td>
</tr>
<tr>
<td>Role Emotional</td>
<td>32 ± 6.33</td>
<td>45 ± 10.43</td>
</tr>
<tr>
<td>Mental Health</td>
<td>43.2 ± 7.04</td>
<td>57 ± 7.56</td>
</tr>
</tbody>
</table>
The represented figure shows that the mean of HRQoL of patients improved from Before-CABG to 3-months after CABG.

Table 17: P-values

<table>
<thead>
<tr>
<th>Before CABG MEAN</th>
<th>3-months after CABG MEAN</th>
<th>P-Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>29</td>
<td>48</td>
<td>0.0012</td>
</tr>
<tr>
<td>34</td>
<td>53</td>
<td>0.0011</td>
</tr>
<tr>
<td>38</td>
<td>54</td>
<td>0.0014</td>
</tr>
<tr>
<td>41</td>
<td>57.8</td>
<td>0.0017</td>
</tr>
<tr>
<td>49</td>
<td>62</td>
<td>0.0001</td>
</tr>
<tr>
<td>36</td>
<td>51</td>
<td>0.0015</td>
</tr>
<tr>
<td>32</td>
<td>45</td>
<td>0.0013</td>
</tr>
<tr>
<td>43.2</td>
<td>57.5</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

Two tailed P-Values is less than 0.05. Hence the provided data is statistically significant.

CONCLUSIONS
Our results for the first time revealed that HRQOL of CAD patients in Narayana Hrudayalaya Malla Reddy Hospital, and demonstrated that, the HRQOL of CAD patients was significantly improved after CABG.

Through the SF-36 health survey, improvement in patients’ health status was found 3 months after CABG. It has important implications for the cardiologists and CAD patients because CABG improves the QOL [37-39].
Our findings were consistent to previous investigations which also
reported improvements in HRQOL after interventional therapies, as measured with different QOL instrument. SF-36 health survey showed the mean scores in each domains and the total scores (P<0.05) were significantly improved 3 months after CABG, suggesting significant improvement in health status in all 8 domains (PF, RP, BP, GH, VT, SF, RE and MH).

Our patients’ positive outcome of the overall health status improvement implied that, CABG was an effective treatment for CAD patients in improving HRQOL [40,41].

ACKNOLEDGEMENT

It is by the blessings of the God Almighty that we were able to complete our investigational studies successfully and present this work for which we are eternally indebted. We take the privilege to acknowledge all those who have helped us in completion of this work.

It is our proud privilege to express our heartfelt gratitude to our guide Dr. K. S. Sechana, Pharm. D, Assistant Professor Malla Reddy Institute of Pharmaceutical Sciences, for her valuable
guidance, cooperation, affectionate encouragement and moral support throughout the course of this investigation & constant help throughout our course. We take the privilege to express our heartfelt gratitude to our hospital guide Dr. Sudhakar, Cardiologist, Narayana Hrudayalaya-Malla Reddy Hospital, Hyderabad for his guidance, cooperation, help and moral support throughout our project.

We accolade our highest respect to our parents for their moral support and dedicated efforts to educate us to this level. Words, in fact, are inadequate to express our deep sense of gratefulness to all of our friends and we thank them warmly for their endless encouragement, moral support and time to time help in all the way throughout. Lastly, we express our sincere thanks to one and all who have contributed directly and indirectly for completion of our project work.

REFERENCES