

ASSESSMENT OF QUALITY OF LIFE IN PATIENTS UNDERGONE ANGIOPLASTY AND TAKING TICAGRELOR: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

BACKGROUND INFORMATION

Acute Coronary Syndrome encompasses life-threatening conditions including STEMI, NSTEMI, UA. Ticagrelor, an antiplatelet drug, reduces cardiac events but increases bleeding risk. DAPT with ticagrelor and aspirin is recommended post-PCI, with the duration determined by individual factors. Comprehensive prospective studies are essential to assess ticagrelor's real-world effectiveness and impact on patients' quality of life.

MATERIALS AND METHODS

A six-month cohort study was conducted at the Sri Jayadeva Institute of Cardiovascular Sciences and Research with 288 participants based on specific criteria. Subject enrolment was based on the inclusion of patients above 18 years of age undergoing angioplasty and the exclusion of lactating, pregnant women along with other severe comorbid conditions (HIV, COPD). Data were collected, including patient demographics, medical history, and medication records. Quality of life was assessed using the SF36 scale, documented in Microsoft Excel.

RESULTS

The study was conducted at a 350-bed tertiary care teaching hospital, Out of 750 ACS patients, 350 had angioplasty, and 288 were selected based on specific criteria. Gender distribution showed 76.04% male, suggesting a higher male prevalence. ACS categorization revealed 24.30% with Inferior Wall Myocardial Infarction, 1.38% with Posterior Wall Myocardial Infarction, and 24.65% with Anterior Wall Myocardial Infarction. SF-36 questionnaire indicated improvements in some aspects but deterioration in others over two months.

CONCLUSION

There was a significant benefit of using ticagrelor in patients undergoing angioplasty as it showed less prevalent side effects. In a few aspects, the quality of life showed an improvement. Furthermore, patient counseling is required for a better outcome.

Keywords: Ticagrelor; Acute Coronary Syndrome; Angioplasty; Safety.

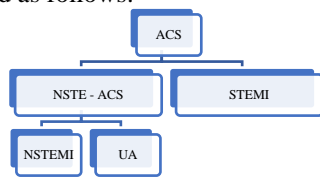
1. INTRODUCTION

The European Society of Cardiology (ESC) and the American Heart Association (AHA) provide guidelines for the management of Acute Coronary Syndrome (ACS), which recommend the inclusion of antiplatelet therapy alongside percutaneous coronary intervention. In modern medical practice, ticagrelor is a commonly used antiplatelet medication for the treatment of ACS. Being a P2Y₁₂ inhibitor, ticagrelor blocks platelet activation and aggregation, reducing the risk of arterial thrombosis. Besides lowering the risk of adverse cardiovascular events, it is known for its faster onset and offset of action. Though ticagrelor has remarkable benefits, it also has certain risks that may include dyspnea and bleeding. Therefore, ticagrelor must be employed considering the individual characteristics of patients like age, bleeding risk, comorbidities, and potential drug interactions.

Acute coronary syndrome (ACS)

Acute coronary syndrome is a subcategory of coronary artery syndrome that presents symptoms such as Prinzmetal angina and frequent myocardial infarction. It is a life-threatening emergency condition that is mainly caused because of reduced blood flow to the heart. It is a common type of cardiac disease that affects approximately one million people throughout the world. Based on

electrocardiographic (ECG) changes, ACS can be categorized as follows:



Angioplasty

A diagnostic technique called an angiogram employs X-ray imaging to identify the kind and location of a blockage in the heart or blood vessels.

"Angioplasty" means to employ a balloon to widen a clogged or constricting artery. In current practice, a stent is placed during the surgery and remains there permanently to improve blood flow. Percutaneous transluminal coronary angioplasty (PTCA) is another name for coronary angioplasty. Percutaneous coronary intervention is the term used when coronary angioplasty and stenting are performed together. A catheter with a small balloon attached to its tip is introduced into a blood vessel and guided to the blocked coronary artery as part of the surgery. The balloon is inflated at the point of occlusion once the catheter has been positioned. As a result, there is greater room for blood flow since the thrombus or plaque is compressed against the artery walls. Before inserting the balloon, a little expandable metal mesh coil (stent), if stenting is necessary for the stenosis, will be put around it. The stent will then be deployed at the location of the intervention. This prevents arterial blockage from happening again. A layer of vascular tissue begins to develop on top of the stent after it has been implanted. Depending on the kind of stent, it can take three to twelve months for the artery tissue to align perfectly with the stent. Antiplatelet medications may be administered to stop restenosis. Infection at the catheter insertion site, bleeding at the catheter insertion site (typically the wrist, arm, or groin), hypersensitivity reaction to the contrast dye, blood clot within the treated blood vessel, damage to the treated blood vessel caused by the catheter, rupture of the coronary artery, complete closure of the coronary artery, need for open-heart surgery, occasionally abnormal heart rhythms, stroke, chest pain, or other complications are some of the risks associated with stenting or angioplasty.

DAPT

Dual antiplatelet therapy (DAPT) involves two types of antiplatelet agents, where one drug is aspirin and the other is a P2Y12 receptor inhibitor.

Ticagrelor Monotherapy

Recent studies show ticagrelor monotherapy was associated with a lower risk for major bleeding compared with standard DAPT, without a concomitant increase in ischemic events.

Quality of Life in patients taking Ticagrelor, undergone angioplasty

The impact of ticagrelor on the quality of life in patients undergoing angioplasty can vary based on several variables, including each patient's health status, reaction to therapy, and lifestyle.

Positive Effects on Quality of Life:

Reduced risk of major cardiovascular events: By minimizing blood clots and decreasing the risk of heart attacks and strokes, ticagrelor could potentially be likely to enhance the patient's sense of psychological well-being and optimism regarding their cardiovascular health.

Better disease management: By taking ticagrelor as prescribed, patients may feel a greater sense of control over their condition, leading to improved psychological well-being.

Negative Effects on Quality of Life:

Medication Adherence: The need to take ticagrelor regularly and the potential side effects may affect medication adherence, which could impact treatment efficacy and patient outcomes.

METHODOLOGY

Study site:

The study was conducted at Sri Jayadeva Institute of Cardiovascular Sciences and Research, Mysuru

Study design:

The study was a cohort study.

Study period The study was carried out for a period of six months from April 2023 to September 2023.

Ethical approval:

Ethical clearance was obtained from the institutional ethics committee of Sri Jayadeva Institute of Cardiovascular Sciences and Research.

Sources of data:

- Medical and Medication records of the patient
- Interviewing patient and caretaker
- Telephonic contact or direct meeting with the patient if needed
- Various questionnaires
- Any other relevant source

Study criteria:

Inclusion criteria:

- Patients aged 18 years and above
- Patients undergoing angioplasty
- Patients who are on ticagrelor medication

Exclusion criteria:

- Pregnant or lactating women.
- Severe comorbid conditions (end-stage renal disease, advanced cancer, HIV infection, severe COPD).
- Incomplete case sheets and medication information.
- Patients who are not willing to participate in the study.

Study procedure:

Preparation of data collection form:

A data collection form was suitably designed that includes all relevant data of the enrolled patients, such as patient name, IP number, unit name, gender, age, phone number, date of admission, and date of discharge. Objective evidence collected were vitals like blood pressure (BP), pulse, body temperature, respiratory rate, oxygen saturation (SPO2), and ejection fraction (EF); laboratory data such as haematology, electrolytes, biochemistry, lipid profile, and cardiac biomarkers along with 2D echocardiography and Doppler test, coronary angiogram (CAG) and percutaneous transluminal coronary angioplasty (PTCA). Certain questionnaires such as SF36 scale was used.

Informed consent:

An informed consent form was designed in English and the same was translated into the regional language that is Kannada to acquire consent from patients who will be enrolled in the study. The study was properly explained to the patients. In illiterate patients the study aspects were explained to the caretakers and consent was obtained willingly.

Patient enrolment:

Patients who met the study criteria were enrolled in the study after obtaining informed consent. Patients were enrolled in intensive care units, general wards, deluxe wards, and semi-deluxe wards of the cardiology department.

Data collection:

The in-charge authority of cardiology was informed and permission was obtained. Data of the patients matching the inclusion criteria were recorded. The patient consent form was given to the patient initially and all the aspects of the study were explained. Signature or thumb impression was obtained from the patients as well as caretakers in the case of illiterate patients. All relevant details of the enrolled patients including the demographics and treatment details were obtained from the patient's medical records and documented in the data collection form. The collected data were entered into the Excel sheet for analysis purposes.

SF36 questionnaire:

SF36 is a questionnaire used to assess the quality of life of patients. We interviewed patients in the hospital using the SF36 form after they underwent angioplasty and recorded the scores ranging between 0-100. Later we re-interviewed patients over the telephone using the same SF36 form after 2 months from the date of procedure. The scores were compared with the initial assessment of the quality of life of patients and difference was obtained.

Statistical analysis

The data was collected, entered, and segregated in Microsoft Excel. The entered data was analyzed with the help of Excel using descriptive analysis.

RESULTS

The proposed work was carried out in a 350-bed tertiary care teaching hospital for 6 months.

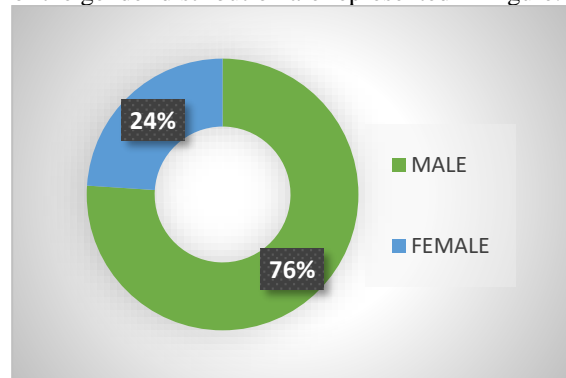
Prevalence of Acute Coronary Syndrome Patients Undergone Angioplasty

There was a total of 750 patients diagnosed with ACS in a month, among which 350 had undergone angioplasty. We selected 288 patients who had undergone angioplasty as our study population (n=288) based on our study criteria.

| DIAGNOSIS | FREQUENCY(n) | PERCENTAGE |
|-------------|--------------|------------|
| ACS | 750 | 100% |
| Angioplasty | 350 | 46.66% |

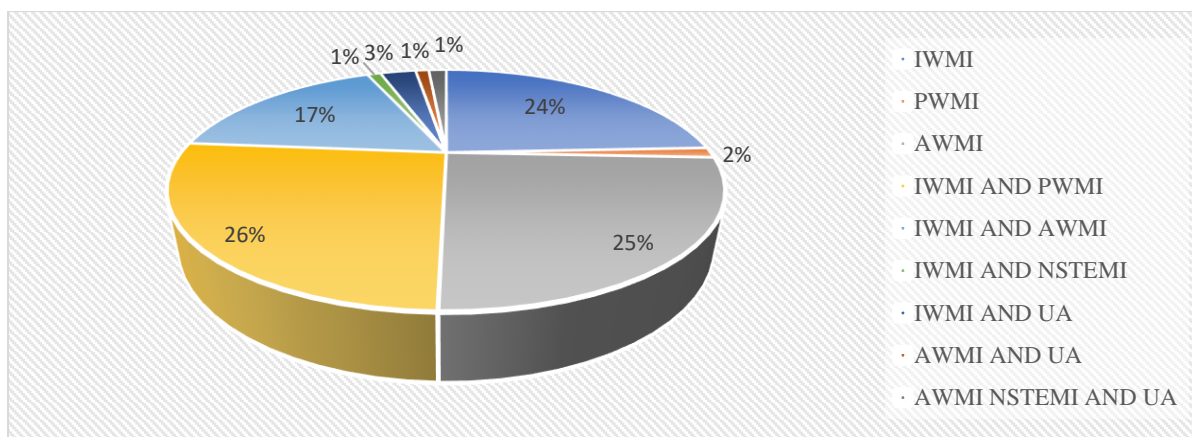
Gender Distribution in the Study

Among the study population (n=288), 76.04% (219) were male and 23.95% (69) were female. The details of the gender distribution are represented in Figure.



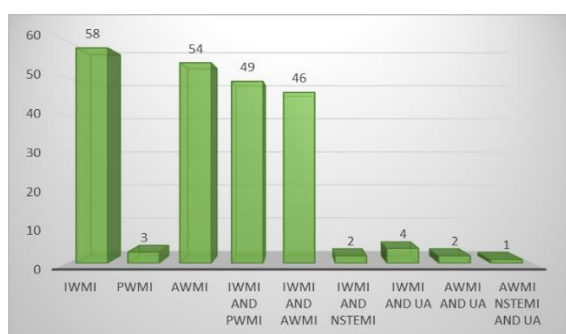
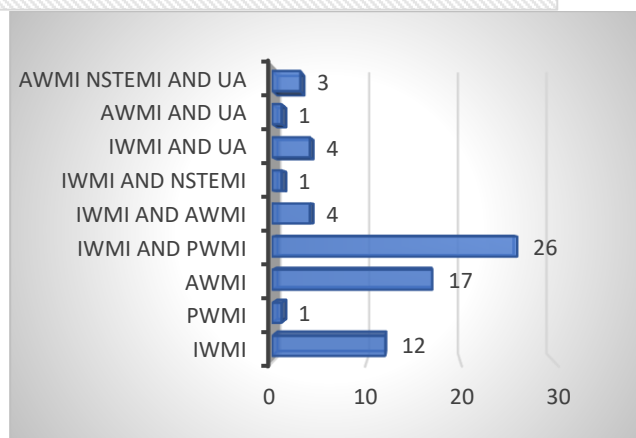
ACS Categorization in the Study Population

Among the study population (n=288), 24.30% (n=70) patients had IWMI, 1.38% (n=4) patients had PWMI and 24.65% (n=71) patients had AWMI. The remaining patients had a combination of two or more diseases such as 26.71% (n=75) patients had IWMI and PWMI, 17.36% (n=50) patients had IWMI and AWMI, 1.48% (n=3) patients had IWMI and NSTEMI, 2.08% (n=6) patients had IWMI and UA, 1.48% (n=3) patients had AWMI and UA and only 2 patients had a combination of AWMI NSTEMI and UA. The details of the ACS categorization are represented in Figure.



ACS Categorization of Male Patients in the Study Population

Among 219 male patients, 26.48% (n=58) patients had IWMI, 1.36% (n=3) patients had PWMI, 24.65% (n=54) patients had AWMI, remaining patients had combination of two or more diseases such as 22.37% (n=49) patients had IWMI and PWMI, 21.32% (n=42) patients had IWMI and AWMI, 0.91% (n=2) patients had IWMI and NSTEMI, 1.89% (n=4) patients had IWMI and UA, 0.91% (n=2) had AWMI and UA and 0.45% (n=1) patient had a combination of AWMI NSTEMI and UA. The details of the ACS categorization of male patients in the study population are given in Figure



ACS Categorization of Female Patients in the Study Population

Among 69 female patients, 17.39% (n=12) patients had IWMI, 1.44% (n=1) patients had PWMI, 24.63% (n=17) patients had AWMI, remaining patients had combination of two or more diseases such as 37.68% (n=26) patients had IWMI and PWMI, 5.79% (n=4) patients had IWMI and AWMI, 1.44% (n=1) patients had IWMI and NSTEMI, 5.79% (n=4) patients had IWMI and UA, 1.44% (n=1) had AWMI and UA and 4.34% (n=3) patient had a combination of AWMI NSTEMI and UA. The details of the ACS categorization of female patients in the study population are given in Figure

Habits

Alcoholic:

Among the study population (n=288), 30.9% (n=89) were identified as alcoholics and 60.09% (n=199) patients were non-alcoholics. Details of alcoholic and non-alcoholic patients are as follows.

| ALCOHOLIC | NO. OF PATIENTS (n) | PERCENTAGE |
|-----------|---------------------|------------|
| YES | 89 | 30.9% |
| NO | 199 | 69.09% |

Smoker:

Among the study population (n=288) 43.4% (n=125) were identified as smokers and 56.59% (163) patients were non-smokers. Details of patients who smoke and who do not smoke are given in Table

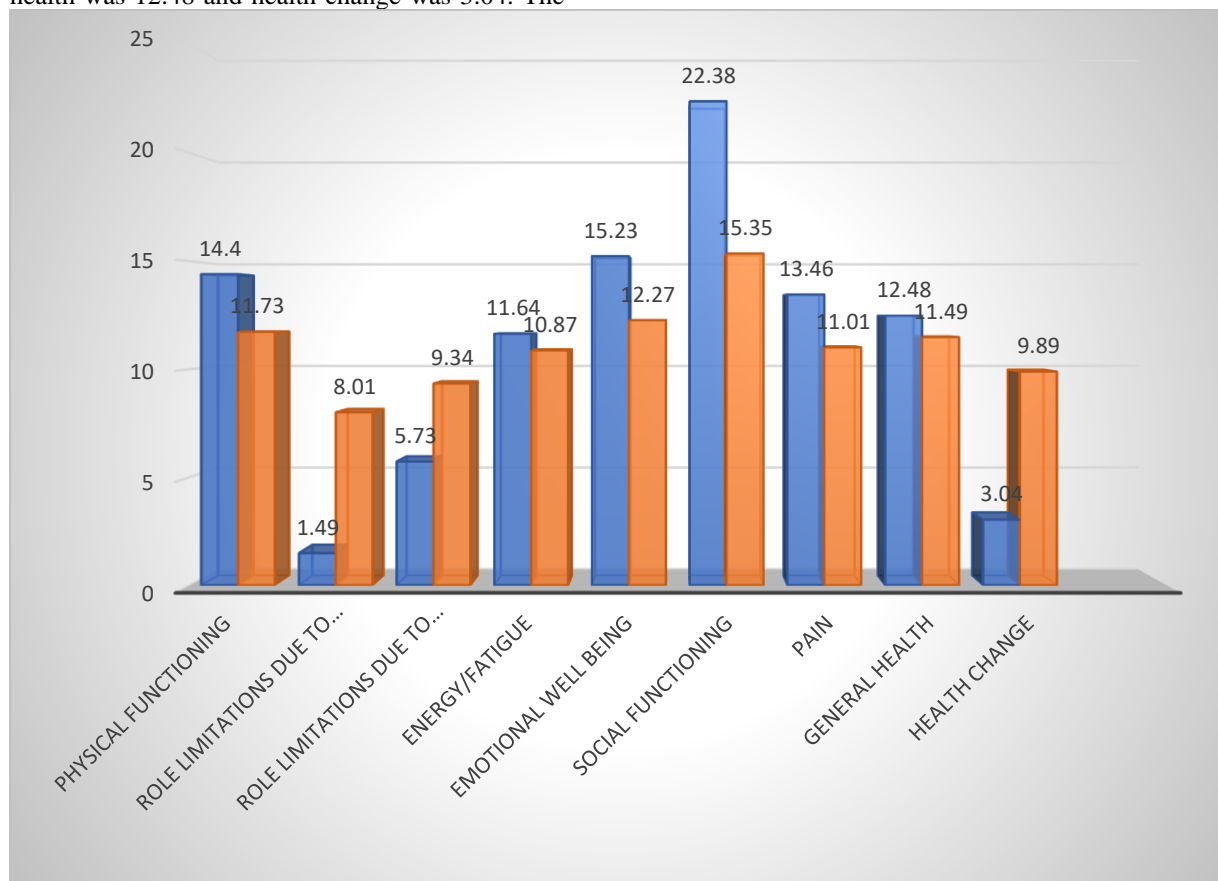
| SMOKING | NO. OF PATIENTS (n) | PERCENTAGE |
|---------|---------------------|------------|
| YES | 125 | 43.4% |
| NO | 163 | 56.59% |

Quality of Life

The quality of life of patients were assessed twice using the SF-36 questionnaire, initially after the patients underwent angioplasty and finally after two

months from the date of angioplasty. The quality of life was calculated based on 9 domains and scores were given from the range 0 to 100. The mean of the initial quality of life was as follows: physical functioning was 14.4, role limitations due to physical health were 1.49, role limitations due to emotional problems was 5.73, energy/fatigue was 11.64, emotional well-being was 15.23, social functioning was 22.38, the pain was 13.46, general health was 12.48 and health change was 3.04. The

mean of the final quality of life was as follows: physical functioning was 11.73, role limitations due to physical health were 8.01, role limitations due to emotional problems was 9.34, energy/fatigue was 10.87, emotional well-being was 12.27, social functioning was 15.35, pain was 11.01, general health was 11.49 and health change was 9.89. The details of the assessment of quality of life are shown in Figure.

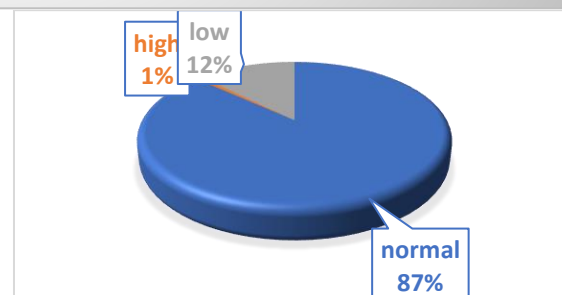


Change in Quality of Life

Difference between the initial and final quality of life was obtained to assess the change in the quality of life of study patients. The difference of 9 domains was as follows; physical functioning – 9.55, role limitations due to physical health – 13.18, role limitations due to emotional problems – 12.21, energy/fatigue – 10.26, emotional well-being – 12.21, energy/fatigue – 10.26, emotional well-being – 9.92, social functioning – 9.78, pain – 9.05, general health – 10.71, health change – 15.3.

Appetite

Among the study population (n= 288) 86.8% (250) patients had a normal appetite, 0.69% (2) patients had high appetite, and 12.5% (36) patients had a low appetite. From the details obtained from the figure, and table, we can say that the drug had no significant effect on appetite.



DISCUSSION

A total of 288 patients who met the study criteria and their case profile sheets were analyzed. The present study set out to assess the quality of life in patients undergoing angioplasty. The study was carried out for 6 months at SJICR, Mysore.

Out of the study population, ACS was found more in men than in women. In a study conducted by Chandrasekhar Dilip, Shinu Cholamugath et.al, similar to our study they found 74% were males and 26% were females in their study population, indicating there was a preponderance of male

patients with ACS. This may be due to the reason that males are more prone to alcohol and smoking, also males are subjected to physical stress than females. The mean average age of patients in the study population was found to be 56.82 ± 10.2 years. An identical result was obtained in the study conducted by Chandrasekhar Dilip, Shinu Chalamugath et.al, where the mean age of the population was found to be 62.57 years ± 12.18 years.

CONCLUSION

Ticagrelor is primarily used for the treatment of Acute Coronary Syndrome (ACS). Among the cases collected, the common sub-classifications of ACS that is being treated with ticagrelor are ST segment Elevation Myocardial Infarction (STEMI) and Non ST segment Elevation Myocardial infarction (NSTEMI).

Although studies have proven that ticagrelor is not associated with any mortality, it has a risk of bleeding and is being used rampantly in patients diagnosed with ACS, especially those who have undergone angioplasty.

From the above discussed study, it was found that certain aspects of quality of life, such as role limitations due to physical health, role limitations due to emotional problems, and health change, improved over a two-month period following angioplasty. However, other domains deteriorated, which included physical functioning, energy/fatigue, emotional well-being, social functioning, pain, and general health.

The study also comprises of the data on prevalence of ACS patients undergoing angioplasty which shows that among 750 patients diagnosed with ACS, 350 patients underwent angioplasty that is 46.66% of the total ACS population.

This study provides valuable insights into the prevalence, and quality of life among ACS patients who underwent angioplasty in a tertiary care teaching hospital. These findings contribute to our understanding of ACS management and can inform healthcare providers in tailoring treatment approaches for this patient population. However, it's important to note that further research and larger-scale studies are needed to confirm and expand upon these findings.

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