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RESEARCH ARTICLE
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EVALUATION OF HRQOL IN PATIENTS WITH CORONARY ARTERY DISEASE AFTER PCI

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ABSTRACT

Background: The background of the study of Health-Related Quality of Life (HRQoL) in individuals who have undergone Percutaneous Coronary Intervention (PCI) for coronary artery disease is rooted in the intersection of cardiovascular medicine and patient-centered outcomes.

Methodology: A prospective observational study was carried out in the Cardiology Department of Vivekanandha Medical Care Hospital, Tamil Nadu over a span of six months. The cases were randomly assigned and Major adverse cardiac events (MACE) were evaluated in patients having Coronary Artery Disease (CAD) who underwent PCI. The health-related quality of life using the EQ-5D-5L questionnaire was assessed in CAD patients who underwent PCI. The study's results were comprehensively scrutinized, and the data were analyzed with the ANOVA using Graph Pad Prism 10.0.2.

Result: A total of 152 participants with valid monitoring person-day records were included. During the third visit, assessed the Patient's health-related quality of life using the EQ- 5D-5L questionnaire who underwent Percutaneous Coronary Intervention for Coronary Artery Disease. In Our study's findings, out of 112 patients MACE were evaluated which included (myocardial infarction, stroke, recurrent hospitalization, coronary revascularization, and death) and patient HRQOL was assessed.

Conclusion: In this specific investigation, researchers utilized the EQ-5D-5L questionnaire as a systematic tool for gathering organized data on various aspects of patient well-being. The conclusion likely encapsulates the key findings related to the impact, or lack of PCI on the HRQoL in patients with CAD. This encompasses a comprehensive understanding of the influence of PCI on physical well-being and may provide insights into strategies for improvement.

Keywords: Coronary Artery Disease, Percutaneous Coronary Intervention Quality of Life, MACE

INTRODUCTION

CAD is a common ailment that commonly affects older persons in developed nations and significantly increases their morbidity. It is described as the pathological process when

atherosclerotic plaque builds up in the coronary arteries, causing arterial constriction and reducing cardiac flow. One of the leading causes of death is still CAD, a condition of the heart caused by deviations in the structure or operation of the coronary artery. CAD endpoints generally include MI and CAD death (1). CAD includes Sudden Cardiac Death (SCD) in circumstances when the death has occurred within 24 hours of the abrupt onset of symptoms, and the term non-SCD applies when the time course from the clinical presentation until the time of death exceeds 24 hours or has not been specifically identified (2). MACE are myocardial infarction (MI), target lesion revascularization (TLR), and cardiac death at one year. Cardiac death refers to the occurrence of death resulting from cardiovascular events such as acute myocardial infarction (AMI), sudden demise due to heart failure, stroke, cardiovascular procedures, cardiovascular hemorrhage, or other cardiovascular-related causes. Myocardial infarction is identified by elevated levels of cardiac biomarkers exceeding the upper limit, occurring simultaneously with the event. MACE, for instance, may also be referred to as "adverse" or "acute cardiovascular events "major adverse cardio vascular and cerebrovascular events", or simply "cardiovascular events". Therefore, we considered studies if the composite outcome under investigation included a combination of various MACE endpoints employing diagnosis (3). An increase in Quality-Adjusted Life Year (QALY) gains may be encouraged by the EQ-5D-5L's enhanced sensitivity. The five-level (5L) EQ-5D version was first released a few years ago by the Euro-Qol Group. For each of the five dimensions mobility, self-care, participation in daily activities, pain or discomfort, and anxiety or depression. The new measure produces a total of 3125 distinct health states, with 11111 signifying the best possible health states and 55555 the worst. Each health state is identified by a five-digit number that indicates the severity level of each dimension (4). The PCI procedure requires arterial access. While the femoral approach is most commonly used, a brachial or radial artery approach is gaining acceptance due to lower rates of bleeding compared to a femoral approach. A sheath is placed in the artery to maintain access during the procedure. Stents provide a stainless-steel scaffold within coronary arterials that can treat acute vessel closure but mainly reduce restenosis. The stent is placed over the deflated balloon and advanced to the area of coronary stenosis. When the balloon is inflated, the stent expands into the coronary vascular wall (5). DES (Drug Eluting Stent) is a balloon-expandable stent, a durable or absorbable polymer coating that provides sustained drug delivery, and the pharmacologic agent used to limit intimal hyperplasia. DES has proven efficacy in patients with focal, de novo, and "workhorse" lesions that include reference vessel diameters between 25 and 3.5 mm and lesion lengths between 15- and 30-mm. DES in patients with long (>30 mm in length) and small (<2.5 mm) vessels, chronic total occlusions, SVG and internal mammary artery disease, in-stent restenosis, and STEMI. Stents called drug-eluting stents have medication on them to inhibit or prevent this tissue growth. Drug-eluting stents are placed in a fashion similar to other stents; however, their markedly reduces the rate of re-narrowing (6). As stents expose some foreign material to the bloodstream, a small risk exists that a blood clot may develop in the stent, a process called stent thrombosis. These blood clots can occur many months and even years after stent implantation and may lead to a heart attack or death. All stents can potentially be affected by stets thrombosis. For this reason, most patients with stents are instructed to take anti-clotting medication, usually a combination of aspirin and Clopidogrel or Ticlopidine. Each of these medications stops platelet (particles in the blood that help clots to form) formation with functioning to their full capacity. The precise duration of the anti-clotting medication dose depends on the type of stent placed (7).

DES a certain amount of anti-inflammatory drug is loaded in the coating over the base stent. During the development of a DES, any mechanical injury incurred in the vessel leads to an immediate healing response in the arterial wall. This healing response is initially characterized by the activation of platelets within the intima, leading to thrombus formation and the recruitment of blood-borne monocytes, neutrophils, and lymphocytes. These cells produce mitogenic and chemotactic factors

which trigger the activation of Smooth Muscle Cells (SMCs). Drug-eluting stents have been demonstrated to decrease dramatically the rate of restenosis (8).

METHODS

Data Source

The prospective observational study was carried out in the Vivekanandha Medical Care Hospital, Tamil Nadu for a period of 6 months. Ethical approval was obtained with reference number SVCP/IEC/2021/07 before the study. The prospective participants visited the cardiology department of the hospital with incidents of coronary artery disease were selectively chosen. They were briefed on the research purpose and objectives. Subsequently, these individuals underwent a thorough history check to confirm their eligibility after providing the consent. Upon participants' enrolment in the study, a comprehensive set of demographic details, including age, gender, BMI, social history, family history, existing health conditions, details of any prior surgical procedures, and cholesterol levels, were systematically collected. The collection process involved individual interviews conducted during clinic visits to ensure accuracy and completeness. The collected demographic data were then meticulously entered into a database, setting the stage for a thorough analysis and assessment. Subsequently, in a collaborative effort between patients and clinical pharmacists, an assessment of the HRQOL in individuals with CAD who underwent PCI was conducted.

Study Population

The sample size was calculated using a "Finite Population Correction Factor" formula by considering the coronary artery disease with a margin of error is 5% and a 95% confidence interval. The estimated sample size for the study was 152 patients. A total of 112 patients with coronary artery disease were targeted during the study period to reduce errors in results and increase the reliability of the study. The inclusion criteria were both inpatients and outpatients above 30 and below 70 years, Patient who has been diagnosed with CAD and underwent PCI were included. Patients who require single or multiple vessels were included. A patient who agrees to participate by knowing the nature and the objectives of the study, and is willing to take informed consent. The exclusion criteria were Patients who underwent PCI before 6 months, Acute or chronic renal dysfunction patients' Cerebrovascular accident patients who were excluded, and Patients who were not willing to participate in the study. Patients who fulfilled the inclusion/exclusion criteria were grouped, then MACE was evaluated in patients, and using the EQ-5D-5L questionnaire Health health-related quality of life was assessed in CAD patients who underwent PCI. Patients was followed up four-weekly for a period of 6 months.

Study Definition

The clinical parameters used for this study: Demographics and clinical information, EQ-5D-5L questionnaire in patients were obtained directly from the patients which include Mobility, Self-care, Usual activities, Pain/Discomfort, and Anxiety/ Depression. The scoring rate included in this questionnaire was 5 to 1 (Extreme, Severe, Moderate, Mild, No) pain. Then by using the EQ-5D-5L crosswalk calculator finding the index value 0 to 100 (0 means worst health and 100 means best health) is used to calculate the patient Health health-related quality of life.

Study Outcome

At the end of the 12-week treatment period, out of 112 patients with the measurement of myocardial infarction, stroke, coronary revascularization, recurrent hospitalization, death. Major Adverse Cardiac Event were assessed. we employed the EQ-5D-5L Questionnaire to evaluate the MACE and HRQOL assessed. This particular questionnaire was selected due to its ability to differentiate predominantly so that participants would easily understand the questions without requiring a clinical examination. This questionnaire requires 0 to 100 (0 means worst health and 100 means best health) This is used to calculate the patient Health health-related quality of life.

Follow-Up

A group of patients who underwent a procedure involving the implantation of DES participants were monitored through different time intervals: the baseline period from 0 to 30 days, follow-up 1 occurring between 30 and 60 days, and follow-up 2 taking place from 60 to 90 days post-procedure. In the initial phase (Baseline), encompassing the assessment of demographic details, cholesterol levels and HRQOL. This evaluation was facilitated through the utilization of the EQ-5D-5L questionnaire, a tool designed to gauge various dimensions of health-related well-being. Moving forward to follow-up 1, which occurred within the timeframe of 30 to 60 days, the same group of patients underwent a revaluation of their cholesterol levels and HRQOL using the EQ-5D-5L questionnaire. Finally, after the completion of 90 days following the DES procedure, the HRQOL of the patients was subjected to a comprehensive examination. This comprehensive evaluation aimed to provide insights into the longer-term impact of the intervention on the patients' well-being and overall quality of life.

Statistical analysis:

Patient characteristics were stratified the data obtained was analyzed using Graph pad Prism 10.0.2. ANOVA was used to analyze the quantitative data. Descriptive analysis was used for Frequency distribution. The cholesterol level and EQ-5D-5L Questionnaire were calculated by Mean ± SD were analyzed by ANOVA Using Graph pad prism 10.0.2. EQ-5D-5L Value sets are based on general population values, the score rate was calculated using EQ-5D-5L Questionnaire. According to this index value were calculated using EQ-5D-5L Crosswalk calculator. Quantitative data were analyzed using ANOVA. $P<0.05$ was considered statistically significant.

RESULT

A total of 152 patients were met during the study period, 40 were excluded 1atients included. And they did not meet the inclusion criteria of our study. **Table 1** describes Gender wise distribution, 99 (88.39%) were males and 11.60% were females. Age-wise distribution Based on age-wise categorization, 23 (20.53%) patients were within the age group of 30-40 years, 31 (27.67%) patients were within 41-50 years, 27.67% patients were within 51-60 years, and 27 (24.10%) patients were within 61-70 years. In our study, the highest frequency of coronary artery disease patients after PCI was from the age group of 41-50 and 51-60 years. Body
mass index Out of 112 patients. 21.42% patients were obese, 37 (33.03%) patients were overweight, 29 (25.89%) patients were underweighting and 22 (19.644%) patients were normal. Percentage of co-morbidities among cardiovascular patients Among 112 patients 26 (23.21%) patients were found with Hypertension, 24 (21.42%) patients with DM, 15 (13.39%) patients with HTN with DM, and 21 (18.75%) patients were with others. **Figure 1** illustrates Major adverse cardiac events 27 (24.10%) patients were found with Myocardial infarction, 15 (13.39%) patients found with Coronary revascularization, 35 (31.25%) patients found with Recurrent hospitalization, 3 (2.67%) patients found with Death and 7 (6.25%) patients found with Stroke. **Table 2 & Figure 2** demonstrates, the overall cholesterol level of the patients was assessed among 112 patients in the categorization of Baseline, follow up 1, Follow up 2. **Table 3 & Figure 3** illustrates, the overall EQ 5D 5L questionnaire was assessed in the categorization of Baseline, Follow up 1.

Table 1. Distribution of study variables, including gender, age, BMI, comorbidities, and major adverse cardiac events (MACE), with corresponding percentages for each category.

VARIABLE	DESCRIPTION	PERCENTAGE
GENDER	Male	88.39
	Female	11.60
AGE	30 – 40	20.53
	41 – 50	27.67
	51 – 60	27.67
	61 – 70	24.10
BMI	Obese	21.42
	Overweight	33.03
	Underweight	25.89
	Normal	19.64
CO-MORBITIES	Hypertension	21.42
	DM	13.39
	Hypertension with DM	18.75
MACE	Myocardial infarction	27.10
	Coronary revascularisarion	13.39
	Recurrent hospitalization	31.25
	Death	2.67
	Stroke	6.25

Figure 1. Distribution of Major Adverse Cardiac Events (MACE) among patients, showing the number and percentage of patients with recurrent hospitalization, myocardial infarction, coronary revascularization, stroke, and death.

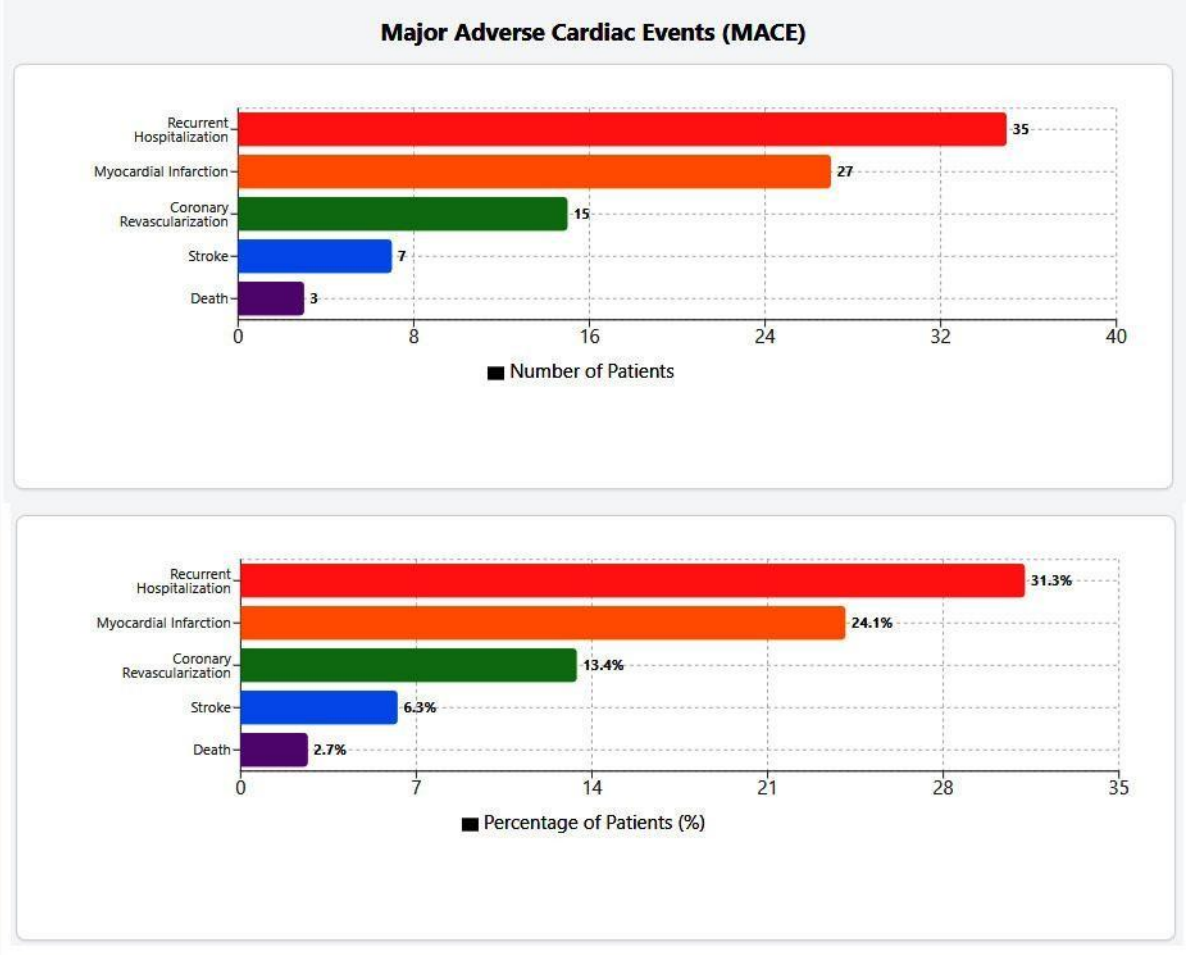


Table 2. Changes in lipid profiles (HDL, LDL, VLDL, and triglycerides) from baseline to follow-up, with significant improvement observed in HDL and triglycerides ($p<0.05$) across the follow-up sessions.

DESCRIPTION	Mean ± Standard deviation			P VALUE
	Baseline	Follow up 1	Follow up 2	
HDL	47.66 ±13.61	46.30 ± 10.13	46.69 ± 7.52	< 0.05
LDL	156.69 ± 24.48	141.69 ± 12.73	145.84 ± 18.32	
VLDL	44.44 ± 14.45	36.82 ± 8.81	36.67 ± 8.07	
TRIGLYCERIDES	171.57 ± 18.20	163.75± 13.26	154.34±10.43	

Figure 2. Lipid profile measurements (HDL, LDL, VLDL, and triglycerides) across time points, showing variations in lipid parameters over the study period, with error bars representing standard deviations.

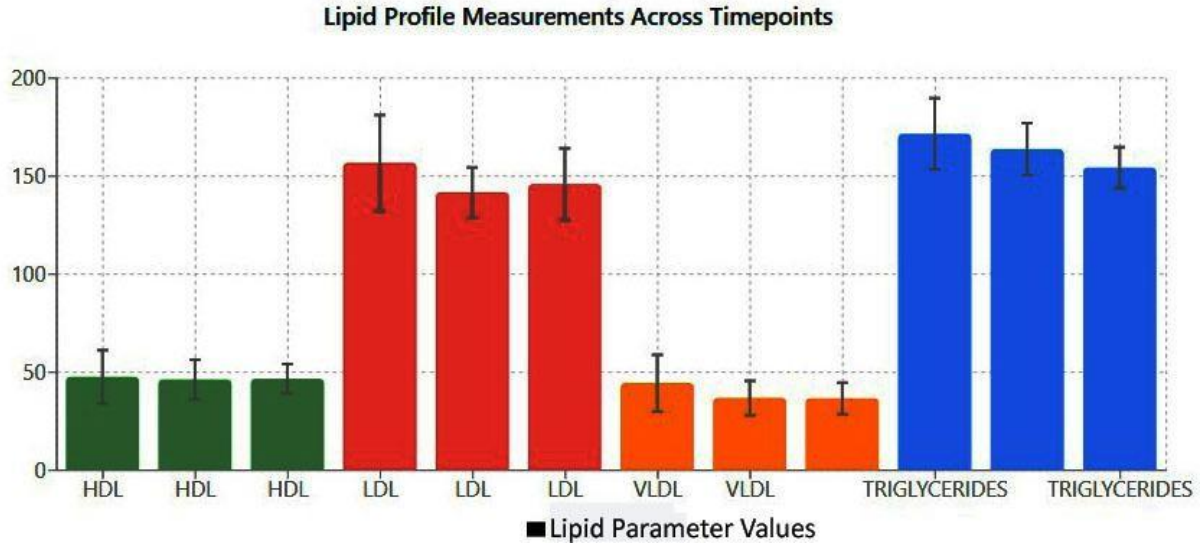
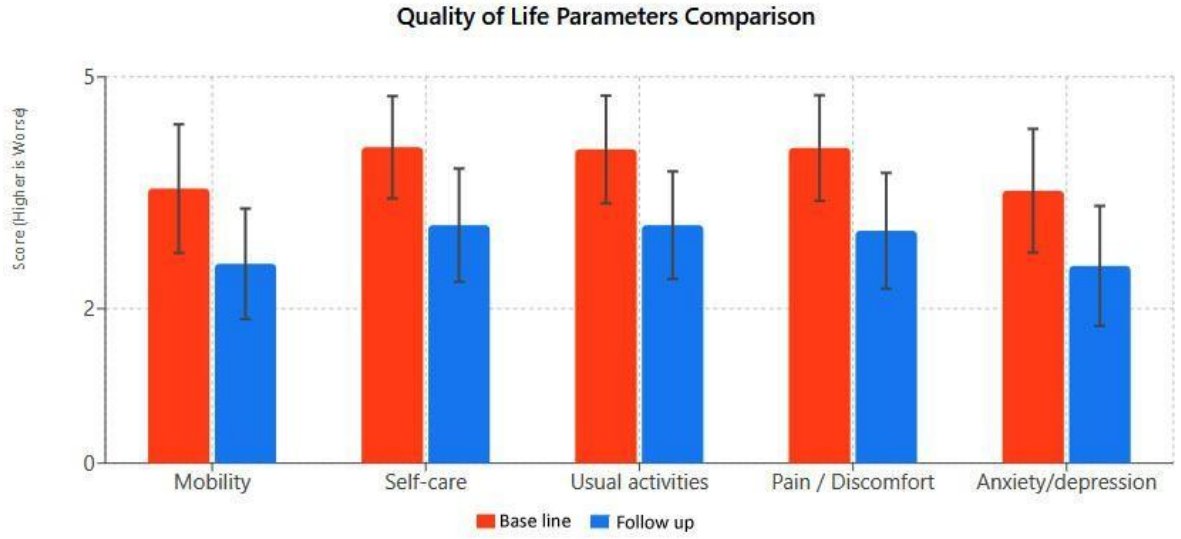


Table 3. Changes in EQ-5D-5L domains (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) from baseline to follow-up. No significant difference observed for mobility ($p > 0.05$) across follow-ups.

Description	Baseline	Follow Up 1	P Value
	Mean ± Std	Mean ± Std	
Mobility	3.553 ± 0.832	2.580 ± 0.715	> 0.05
Self-care	4.089 ± 0.662	3.080 ± 0.733	
Usual activities	4.062 ± 0.697	3.080 ± 0.696	
Pain / Discomfort	4.080 ± 0.683	3.008 ± 0.749	
Anxiety/depression	3.526 ± 0.801	2.553 ± 0.777	

Figure 3. Comparison of quality-of-life parameters (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) at baseline and follow-up. Lower scores indicate better quality of life, with error bars representing standard deviations.



DISCUSSION

In our study, we initially assessed 152 patients, of which 138 were selected for inclusion. However, only 112 patients of them participated in the follow-up session. The study aimed to enhance the HRQOL in patients through the implementation EQ-5D-5L questionnaire. Patients were counselled after assessing their knowledge, attitude, and practice toward medication. indicated a higher incidence of Coronary Artery Disease among males (88.39%) compared to females (11.60%), aligning (9). Regarding age-wise distribution, patients in the age group of 41-50 and 51-60 were found to be more susceptible to the development of CAD, accounting for (27.67%) of cases, which was consistent with the results (10). In terms of gender-wise distribution among age groups, males aged 51-60 and females aged 41-50 exhibited a stronger association with CAD, which was consistent (11). **Additionally, in the** previous study, it was discovered that (47.32%) of enrolled patients had at least one co-morbidity, and (29.46%) had more than one co-morbidity. (12). The present study observed that the majority of patients had a history of hypertension (23.21%) than other comorbidities (13).

Furthermore, among 112 patients, (41.96%) were smokers and (26.78%) were alcoholics. This states that smoking is one of the major risk factors for Coronary Artery Disease, (14). In the evaluation of the mean difference in cholesterol level, the majority of patients had a higher Triglycerides level in Baseline (171.571 ± 18.20) and had a significant improvement in follow-up 2 (154.348 ± 10.43) consistent with similar results (10).

The EQ-5D-5L questionnaire was a valuable tool in assessing the quality of life of patients with coronary artery disease. It comprehensively evaluated physical and emotional dimensions which include Mobility, self-care, Usual activities, Pain/Discomfort, and Anxiety/Depression making it a holistic assessment. In the physical dimension, the EQ-5D-5L examined factors like pain/discomfort, usual activities, self-care, and the impact of heart failure on daily activities. This insight aided healthcare professionals in providing treatment plans to improve patients' physical well-being. On the emotional dimension, the EQ-5D-5L examined factors like psychological impact including Anxiety or Depression, allowing health care professionals to improve patients' well-being which was equally important. Our study has shown that patients who underwent PCI after CAD provided better patient outcomes. The EQ-5D-5L questionnaire played a crucial role in these studies, helping to highlight the comprehensive benefits of PCI patients which include Mobility, Self-care, Usual activities, Pain/Discomfort, and Anxiety/Depression, ultimately contributing to assessing overall quality of life in patients.

Conclusion

In our comprehensive study, the health-related quality of life in patients who underwent PCI after CAD. Firstly, MACE includes MI, Hospitalization, Death, Revascularization, and Stroke to reduce unplanned readmissions in the hospital. Secondly, our research emphasized the crucial role of monitoring and assessing patients' quality of life, utilizing the EQ-5D-5L as a valuable tool in this study. Co-morbidities, Smoking, and alcohol use were identified as contributing factors to CAD development. In conclusion, this project underscores that these measures are used for assessing health-related quality of life for patients who underwent PCI. As a clinical pharmacist patient's future risks were identified according to their score rate by using the EQ-5D-5L questionnaire and by MACE identification.

ABBREVIATIONS:

AMI Acute Myocardial Infarction
CAD Coronary Artery Disease
CHD Chronic Heart Disease
DES Drug Eluting Stent
FPC Finite Population Correction
HRQOL Health Related Quality of Life
MACE Major Adverse Cardiac Event
MI Myocardial Infarction
PCI Percutaneous Coronary Intervention
QALY Quality Adjusted Life Year
SCD Sudden Cardiac Death
SMC Smooth Muscle Cells
STEMI ST Elevated Myocardial Infarction
TLR Target Lesion Revascularization

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Disclosures

The other authors report no conflict of interest.

Declarations

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Conflicts of Interests: We declares no competing interests.

Availability of data and material: The data sets generated and/or analysed during the current study are available.

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