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A PROSPECTIVE OBSERVATIONAL STUDY ON ESTIMATION OF RISK FOR MAJOR ADVERSE CARDIAC EVENTS IN ACUTE CORONAY SYNDROME UNDERGOING PERCUTANEOUS CORONARY INTERVENTION

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Abstract:

Introduction: In worldwide, Cardiovascular disease has a considerable impact on morbidity and mortality. According to the WHO, 17.9 million people died from cardiovascular diseases in 2019, accounting 32% of global mortality. Acute coronary syndrome (ACS), which includes ST-segment elevated myocardial infarction (STEMI), non-STEMI, unstable angina (UA), is the most significant contributor to cardiovascular disease. Percutaneous coronary intervention (PCI) is a minimally invasive, non-surgical method used to treat coronary artery occlusion and enhance blood flow to ischemic tissue. A Major Adverse Cardiovascular Event (MACE) in the setting of PCI has been characterized as death, Myocardial Infarction (MI), repeat revascularization with bypass graft. Thrombolysis in Myocardial Infarction (TIMI) score and Global Registry for Acute Coronary Events (GRACE) score are used to predict the risk of mortality in ACS patient.

Materials and Methods: It is a prospective observational study which was conducted among 155 patients admitted to cardiology department with symptoms of ACS in the Government General Hospital (GGH), Vijayawada, Andhra Pradesh. By referring the patient's profile, TIMI and GRACE risk scores were calculated. Risk for MACE events were determined by assessing these risk scores in ACS patients undergoing PCI.

Results: A total of 155 patients, 53 (34 %) were STE-ACS, 102 (66 %) were NSTE-ACS. Serum creatinine (SCr), ejection fraction (EF), troponin levels, systolic blood pressure (SBP), pulse rate, TIMI score and GRACE scores are the factors independently associated with the occurrence of MACE. MACE were 5.16 % in STEMI groups and 9.03 % in NSTEMI group. Univariate regression analysis for potential variables were performed and these variables are significantly associated with the occurrence of MACE.

Conclusion: Males were mostly affected among study population. Chest pain was the commonly reported symptom and hypertension was the most commonly observed comorbidity. The commonly observed MACE was urgent revascularization which was higher in NSTE-ACS patients compared to STE-ACS patients.

Key Words: ST elevated acute coronary syndrome, Non ST elevated acute coronary syndromes, Major adverse cardiac events, Percutaneous coronary intervention, GRACE, TIMI.

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INTRODUCTION

The term "acute coronary syndrome" (ACS) refers to a group of disorders that includes unstable angina (UA), ST-elevation myocardial infarction (STEMI), and non-ST elevation myocardial infarction (NSTEMI). UA, one of various ACS, is characterized by sudden chest discomfort that typically happens while resting. About 50% of admissions to coronary care units each year, with > 2.5 million hospitalizations worldwide. The coronary arteries are restricted by fatty buildups (atherosclerosis), which can burst, injuring the coronary blood vessel. This is the most prevalent cause of diminished blood flow to the heart muscle. This causes blood to clot, which prevents the heart muscle from receiving blood flow. Myocardial Infarction (MI) is identified by the presence of myocardial cell necrosis brought on by severe and prolonged ischaemia. ACS or overt MI are frequently caused by the rupture of atherosclerotic plaques.[1]

The worst kind of heart attack, a ST-Segment Elevation Myocardial Infarction, is referred to as a STEMI. The 12-lead EKG detects cardiac attacks of this kind. Although there is no ST elevationon the ECG in an NSTEMI, there may be ST/T wave alterations in nearby leads.[2]

ACS can result in a number of serious consequences, often referred to as major adverse cardiac events (MACE). MACE typically consists of cardiovascular death, non-fatal MI, and non-fatal stroke. The term "MACE" may occasionally be used to refer to other major ischemic cardiovascular disease-related events, such as heart failure, coronary revascularization, and associated complications.[3]

The most common method of treatment for people with ACS is Percutaneous Coronary Intervention (PCI). Patients with coronary artery disease are frequently treated with PCI, a minimally invasive, and non-surgical treatment.[4]

Therefore, the aim of this prospective observational study is to estimate the risk of MACE in ACS patients undergoing PCI using both the TIMI and GRACE scores and to evaluate the accuracy of these scores in predicting MACE in a real-world clinical setting. The study will enroll a large cohort of ACS patients who undergo PCI at a single center and will collect demographic details, clinical and procedural data. Patients who were hospitalized with complaints of cardiovascular events with-in one month of PCI, should be assessed for the incidence of MACE, including non-fatal stroke, non-fatal MI, cardiovascular death, heart failure, coronary revascularization, and ischemic cardiovascular events.[5]

AIM & OBJECTIVES

AIM: The aim of the present study is to estimate the risk for Major Adverse Cardiac Events in AcuteCoronary Syndrome undergoing Percutaneous Coronary Intervention.

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OBJECTIVES:

- To estimate the risk for MACE in ACS patients undergoing PCI by using TIMI and GRACErisk scores.
- To determine the risk of mortality in ACS patients undergoing PCI.
- To measure the MACE occurrence in ACS patients who undergone PCI and re-hospitalizedwith C/o MACE within one month.

MATERIALS AND METHODS

Study Site: Department of Cardiology, Government General Hospital, Vijayawada.
Study Duration: Study was carried out for a period of 6 months (October 2022 – March 2023).
Study Design: A prospective observational study.
Sample Size: 155 patients who undergone PCI in cardiology department.
STUDY CRITERIA: The study will be carried out by considering the following criteria:

INCLUSION CRITERIA:

Patients those who have given written consent form for study participation.

Patients age > 25 years diagnosed with ACS.

Patients who are diagnosed with ACS undergoing PCI and also the patients who are rehospitalized with the c/o cardiac events within one month of post-PCI.

EXCLUSION CRITERIA:

- Patients who are unwilling to give written consent for study participation.
- Patients age < 25 years.
- Patients with tumour (or) Chronic Inflammatory Disease.
- Chronic kidney disease patients who are under haemodialysis with acute coronary syndrome.
- Patients who are diagnosed with cardiovascular disease but not underwent any intervention techniques.
- Patients who are previously underwent PCI, few months ago.
- With missing variables needed to calculate the risk score.

Source of Data: The Demographic details, ECG, 2D Echo report, laboratory investigations, Coronary Angiogram report, PTCA/PCI report and other relevant information from medical records of patients with ACS admitted to the cardiology department of the hospital were collected and entered in a designed data entry form.

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Design of Data Collection Form: The data collection form was designed for collecting the demographic details of the patient, medical condition, ECG, 2D Echo report, laboratory investigations, Coronary Angiogram report, PTCA/PCI report of patients who were admitted to cardiology department with symptoms of ACS.

Ethical Approval : The institutional ethical committee (IEC) of Vijaya Institute of Pharmaceutical Sciences for Women (VIPW), Enikepadu, Vijayawada, NTR district has approved the study, the ethical approval number **VIPW/IEC-PD/PROJECT-4 /2022 - 2023 dated 21.10.22**

METHODOLOGY

Study Procedure: After approval from the IEC, the study was conducted in Department of Cardiology, Government General Hospital. Patient demographic details like name, age, gender, chief complaints, past medical and medication history, laboratory data along with diagnosis which was confirmed by coronary angiogram report, PTCA/PCI report were collected from medical records were noted in the data collection forms

Data Analysis: The collected data was analysed to assess the risk of MACE by using TIMI score and GRACE score.

Statistical Analysis: Data was entered into Microsoft Excel Sheet for analysis. Statistical analysis was performed by Chi square test, T-test, univariate regression analysis.

RESULTS AND DISCUSSION

A Prospective Observational Study was conducted in the Cardiology department, Government General Hospital, Vijayawada over a period of 6months from October 2022 – March 2023.

DEMOGRAPHICS PROFILES

DISTRIBUTION OF STUDY POPULATION WITH ACS

Distribution of study population with ACS was presented in Table-1 and Fig-1.

Table-1: Distribution of study population with ACS

DIAGNOSIS	NUMBER OF POPULATION	PERCENTAGE
STE-ACS	53	34%
NSTE-ACS	102	66%
TOTAL	**155**	**100%**

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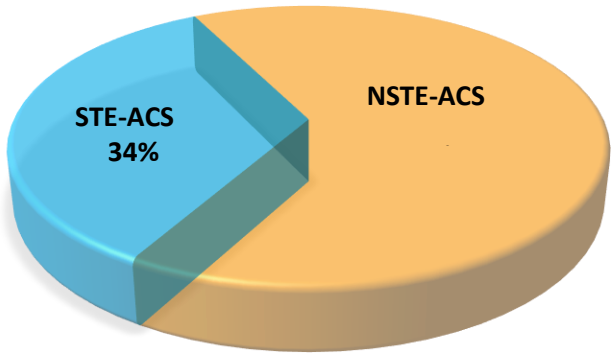

Fig-1: Distribution of study population with ACS

In this study, among 155 patients 102 (66%) were diagnosed with NSTE-ACS and 53 (34%) patients were diagnosed with STE-ACS.

GENDER WISE DISTRIBUTION OF STUDY POPULATION

Gender wise distribution of study population was presented in Table-2 .

Table-2: Gender wise distribution of study population

GENDER	STE-ACS	PERCENTAGE	NSTE-ACS	PERCENTAGE
MALE	35	66%	71	70%
FEMALE	18	34%	31	30%
TOTAL	53	100%	102	100%

In this study, among 155 patients diagnosed with NSTE-ACS, males were 71 (70%) and females were 31 (30%). Among those diagnosed with STE-ACS, males were 35 (66%) and females were 18 (34%). Males were mostly diagnosed with NSTE-ACS and STE-ACS when comparedto females.

AGE WISE DISTRIBUTION OF STUDY POPULATION

Age wise distribution of study population was presented in Table-3.

Table-3: Age wise distribution

AGE GROUPS	STE-ACS	PERCENTAGE	NSTE-ACS	PERCENTAGE
26 - 35	1	2%	5	5%

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36 - 45	8	15%	7	7%
46 - 55	18	34%	39	38%
56 - 65	17	32%	29	28%
66 - 75	6	11%	20	20%
76 - 85	3	6%	2	2%

In this study, we have included patients in the age group between 26 - 85 yrs. Of the total 155 patients, 39 were NSTE-ACS and 18 were STE-ACS between 46 - 55 yrs; 29 were NSTE-ACS and 17 were STE-ACS between 56 - 65 yrs; 20 were NSTE-ACS and 6 were STE-ACS between 66 - 75 yrs; 7 were NSTE-ACS and 8 were STE-ACS between 36 - 45 yrs; 5 were NSTE-ACS and 1 were STE-ACS between 26 - 35 yrs; 2 were NSTE-ACS and 3 were STE-ACS between 76 - 85 yrs. Most affected patients were between the age groups of 46-55 yrs.

SYMPTOM WISE DISTRIBUTION OF STUDY POPULATION

Symptom wise distribution of study population was presented in Table-4.

Table-4: Symptom wise distribution

SYMPTOMS	STE-ACS	PERCENTAGE	NSTE-ACS	PERCENTAGE
ENERALIZED CHEST PAIN	53	100%	102	100%
CHEST PAIN (Last 24 hrs)	44	83%	76	75%
SHORTNESS OF BREATH	29	55%	62	61%
PALPITATIONS	25	47%	38	37%

In this study, symptoms considered were generalised chest pain, shortness of breath, Palpitations and chest pain (last 24 hrs). Of which 102 NSTE-ACS and 53 STE-ACS patients presented with chest pain, 76 NSTE-ACS and 44 STE-ACS patients complained of chest pain (last 24 hrs), 62 NSTE-ACS and 29 STE-ACS patients had shortness of breath and 38 NSTE- ACS and 25 STE-ACS patients had palpitations. Of all these symptoms, majority of STE-ACSand NSTE-ACS patients had chest pain.[6]

COMORBIDITIES WISE DISTRIBUTION OF POPULATION

Comorbidities wise distribution of study population was presented in Table-5, Figure 2.

Table-5: Comorbidities wise distribution

COMORBIDITIES	TOTAL NO. OF POPULATION	PERCENTAGE
HYPERTENSION	102	52%

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DIABETES	72	36%
CAD	13	7%
CVA	4	2%
HYPOTHYROIDISM	5	3%
OTHERS	3	1%

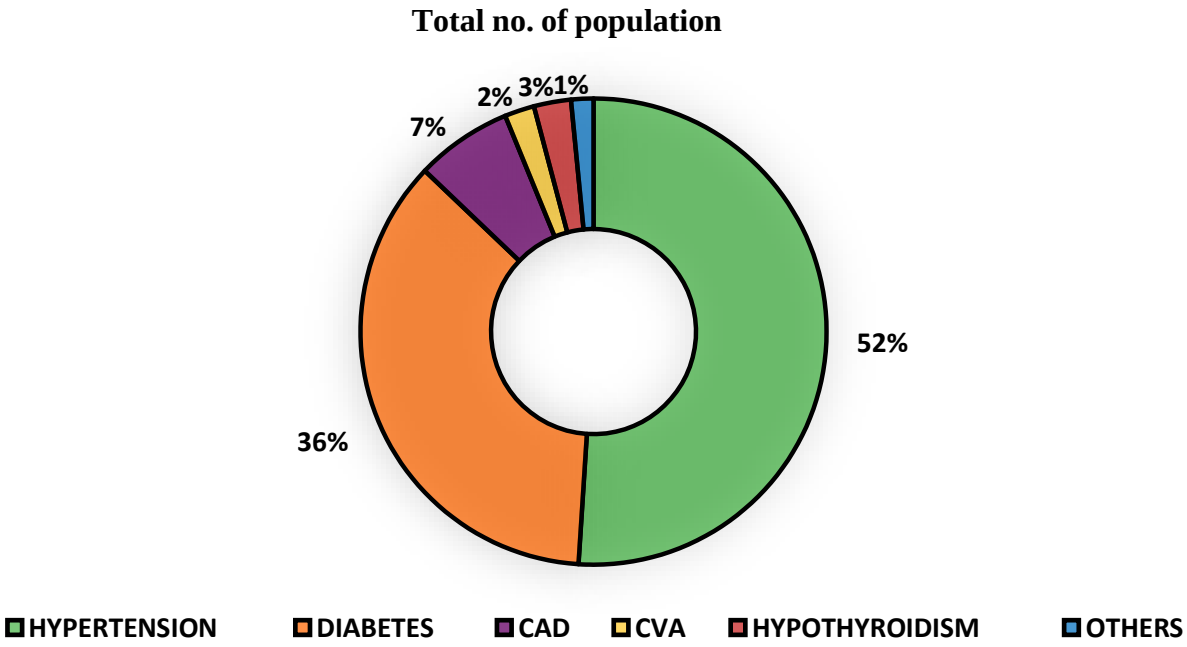

Fig-2: Comorbidities wise distribution

In this study, comorbidities like hypertension, diabetes, CAD, CVA, hypothyroidism and others (COPD, parkinsonism) are considered. Of the total population 51% had hypertension, 36% had diabetes, 7% had CAD, 2% had CVA, 3% had hypothyroidism and 1% had Others (COPD, parkinsonism). Of all the comorbidities, hypertension was seen in the majority of the population.[7]

SERUM CREATININE

Serum Creatinine (SCr) values in study population in STE-ACS and NSTE-ACS was presentedin Table-6.

Table-6: Serum creatinine in STE-ACS and NSTE-ACS population

SERUM CREATININE	STE-ACS	NSTE-ACS	CHI-SQUARE P-VALUE
<0.6	5	7	

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>1.2	30	11	0.04268
TOTAL	**35**	**18**	

Out of 35 STE-ACS 5 had <0.6 and 30 were having >1.2 serum creatinine values, out of 18 NSTE-ACS 7 had <0.6 and 11 were having >1.2 serum creatinine levels. We performed chi-square test for serum creatinine in STE-ACS and NSTE-ACS to analyse the influence of serum creatinine in STE-ACS and NSTE-ACS. 4.10803 is the calculated value which is greater than table 3.84 at 1 degree of freedom and 5% level significance. This indicates the serum creatinineindependently asscociated with MACE.[8]

EJECTION FRACTION

Ejection Fraction (EF) values in study population in STE-ACS and NSTE-ACS was presentedin Table-7.

Table-7: Ejection Fraction in STE-ACS and NSTE-ACS population

EJECTION FRACTION	STE-ACS	NSTE-ACS	HI-SQUARE P-VALUE
<40%	25	30	0.0073
40 - 50%	17	25	
50 - 60%	11	47	

We performed Chi Square test for EF in STE-ACS and NSTE-ACS groups to analyse the influence of EF in the population. 9.8136 is the calculated value which is more than table value 5.99 at 2 degree of freedom and 5% level of significance (p value <0.00001-significant). Thisshows that EF influence the occurrence of MACE.[9]

TROPONIN LEVELS

Troponin levels in study population in STE-ACS and NSTE-ACS was presented in Table-8.

Table-8: Troponin levels in STE-ACS AND NSTE-ACS population

TROPONIN	STE-ACS	NSTE-ACS	HI-SQUAREP-VALUE
POSITIVE	23	67	0.00763
NEGATIVE	30	35	

We performed Chi-square test for Troponin levels in STE-ACS and NSTE-ACS groups to analyse the influence of troponin. 7.11 is the calculated value which is greater than table value

3.84 at 1 degree of freedom and 5% level significance. This indicates positive troponin value influence the occurance of MACE.

SYSTOLIC BLOOD PRESSURE

Systolic Blood Pressure (SBP) in study population in STE-ACS and NSTE-ACS was presentedin

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Table-9.

Table-9: Systolic Blood Pressure in STE-ACS and NSTE-ACS population

SYSTOLIC BP	STE-ACS	NSTE-ACS	HI-SQUAREP-VALUE
<100	9	7	0.0046942
>100	43	94	

We performed Chi-square test for SBP levels in STE-ACS and NSTE-ACS groups to analyse the influence of SBP levels.3.945 is the calculated value which is greater than table value 3.841 at 1 degree of freedom and 5% level significance. This indicates SBP levels influence the occurrence of MACE.

PULSE RATE

Pulse Rate (PR) in study population in STE-ACS and NSTE-ACS was presented in Table-10.

Table-10: Pulse Rate in STE-ACS and NSTE-ACS population

PULSE RATE	STE-ACS	NSTE-ACS	CHI-SQUAREP-VALUE
<100	42	86	0.853353
>100	8	15	

We performed Chi-square test for PR in STE-ACS and NSTE-ACS groups to analyse the influence of PR. 0.8533 is the calculated value which is less than table value 3.841 at 1 degree of freedom and 5% level significance. Above data, indicates that PR may not influence the occurrence of MACE.

TIMI SCORE

TIMI score in study population in STE-ACS and NSTE-ACS was presented in Table-19.

Table-11: TIMI Score in STE-ACS and NSTE-ACS population

TIMI SCORE	STE-ACS	NSTE-ACS	t- TEST P-VALUE
0-2	5	20	0.0001
3-4	25	48	
5-7	23	34	

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MEAN ± SD	17.66 ± 8.99	34 ± 11.43	
ST- DEVIATION	53	51	-

(SD- Standard Deviaton)

We performed t-test for TIMI score in STE-ACS and NSTE-ACS groups to analyse the influence of TIMI score, t = 9.0495 and p-value = 0.0001, which indicates TIMI score influences the occurance of MACE. ST-deviation was seen in 53 STE-ACS and 51 NSTE-ACSpopulation.

GRACE SCORE

GRACE score in study population in STE-ACS and NSTE-ACS was presented in Table-12.

Table-12: GRACE Score in STE-ACS and NSTE-ACS population

GRACE SCORE		**STE-ACS**	**NSTE-ACS**	**t- TEST P-VALUE**
TOTAL SCORE	LOW	45	71	0.0013
	INTERMEDIATE	5	20	
	HIGH	3	11	
MEAN ± SD		17.6 ± 23.6	34 ± 32.3	
POD%	LOW	4	7	0.0001
	INTERMEDIATE	27	47	
	HIGH	22	48	
MEAN ± SD		17.6 ± 12.09	34 ± 23.38	
KILIP CLASSIFICATION	I	50	100	-
	II-IV	3	2	

(SD- Standard Deviation, POD- Probability Of Death)

We performed t-test for GRACE score in STE-ACS and NSTE-ACS groups to analyse the influence of GRACE total score- t=3.2687, P-value=0.0013 and POD%- t = 4.7802, P-value = 0.0001, which indicates GRACE score influence the occurance of MACE. Kilip classification, class-I was seen in 50 STE-ACS and 100 NSTE-ACS population, while class II-IV was seen in3 STE-ACS and 2 NSTE-ACS population.

DISTRIBUTION OF PATIENTS BY MAJOR ADVERSE CARDIAC EVENTS

VARIABLES	**STE-ACS**	**NSTE-ACS**	**P-VALUE**

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	No.	%	No.	%	
ADVERSE EVENTS	8	5.16%	14	9.03%	
DEATH	3	1.93%	4	2.58%	0.9107
RECURRENT MI	3	1.93%	6	3.87%	
REVASCULARIZATION	2	1.29%	4	2.58%	

5.16 % in STE-ACS groups and 9.03% in NSTE-ACS group which was similar in both groups(P>0.05). In case of STE-ACS 1.93% death, 1.93% recurrent MI, 1.29% urgent revascularization. In case of NSTE-ACS 2.58% death, 2.58% recurrent MI and 3.87% urgent revascularization respectively.

Table-14: Univariate Regression Analysis (STE-ACS)

PARAMETERS	OVER ALL(n=8)	OR	95 %CI	P - VALUE
AGE ≥ 65 Yrs	6	19.5	3.17-119.9	0.0014
FEMALE	2	0.77	0.14-4.2	0.76
CHEST PAIN (Last 24 hrs)	7	32.3	3.4-301.1	0.002
≥3MAJOR RISK FACTORS	8	17.7	0.96-326.0	0.05
CURRENT SMOKER	4	1.36	0.30-6.17	0.6
HYPERTENSION	6	6.0	1.07-33.3	0.04
DIABETES	3	0.007	0.003-0.15	0.0017
FAMILY HISTORY	2	4.66	0.64-33.9	0.12
ASPIRIN INTAKE (Last 7 days)	8	30.3	1.64-560.8	0.02
PRIOR CORONARY DISEASE	5	5.8	1.18-28.7	0.03
PULSE >100/min	3	9.7	1.45-65.3	0.01
SYSTOLIC BP <100mmHg	7	4.17	1.22-31.5	0.01
KILLIP CLASS II-IV	2	35.0	1.5-813.2	0.02
ST DEVIATION ≥0.5mm	8	40.9	2.2-760.3	0.01
TROPONIN POSITIVE	6	7.6	1.35-42.7	0.02

Out of them Age ≥ 65 years, chest pain (last 24 hrs), diabetes were significantly associated with MACE (P<0.005), ≥ 3 major risk factors, aspirin intake in last 7 days, prior coronary

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disease, PR >100/min, SBP < 100mmHg, killip class II-IV, ST deviation ≥ 0.5mm, troponin positive were also significantly associated with MACE (P<0.05). Female, current smoker, family history were not associated with MACE.[9]

Table-15: Univariate Regression Analysis (NSTE-ACS)

PARAMETERS	OVERALL (n=14)	OR	95 %CI	P - VALUE
AGE ≥ 65 YEARS	8	5.56	1.705-8.18	0.00045
FEMALE	3	0.8	0.23-3.2	0.82
CHEST PAIN (Last 24 hrs)	9	7.45	0.41-132.7	0.17
≥3MAJOR RISK FACTORS	11	5.5	1.43-21.5	0.01
CURRENT SMOKER	8	2.8	0.90-9.02	0.07
HYPERTENSION	12	8.27	1.74-39.1	0.007
DIABETES	8	3.55	1.11-11.3	0.03
FAMILY HISTORY	8	10.2	26.7-39.3	0.007
ASPIRIN INTAKE (Last 7 days)	5	0.2	0.07-0.7	0.01
PRIOR CORONARY DISEASE	10	7.95	2.2-27.8	0.0012
PULSE RATE >100	8	24	5.76-99.9	0.0001
SYSTOLIC BP <100mmHg	7	43	7.42-47.4	0.0001
KILLIP CLASS II-IV	2	15.7	4.22-58.6	0.0001
ST DEVIATION ≥0.5mm	10	2.8	0.83-9.83	0.09
Troponin positive	10	5.2	1.08-25.2	0.03

Out of them Age ≥ 65 years, prior coronary disease, PR >100/min, SBP < 100mmHg, killip class II-IV were significantly associated with MACE (P<0.005), ≥ 3 major risk factors, diabetes, aspirin intake in last 7 days, hypertension, family history, troponin positive were also significantly associated with MACE (P<0.05). Female, chest pain (last 24 hrs), current smoker,ST deviation ≥0.5mm were not associated with MACE.[10]

CONCLUSION

From this study, we conclude that, males were more commonly affected in both STE-ACS and NSTE-ACS, the most common comorbidity and symptom reported was HTN and chest pain respectively. The study also found that SCr, EF, troponin levels, SBP, TIMI score, and GRACE score were all significantly associated with the occurrence of MACE. The Killip

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classification were also found to be associated with MACE. We conclude that there are significant differences in the incidence of MACE between STEMI and NSTEMI groups, with higher rates observed in the NSTEMI group. Specifically, the incidence of death, recurrent MI, and urgent revascularization is higher in the NSTEMI group. Furthermore, univariate analysis of potential predictor variables in STE-ACS and NSTE-ACS patients reveals that several factors are significantly associated with MACE in both groups.

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