WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
Volume 10, Issue 6, 1109-1132. Research Article ISSN 2277– 7105

A PROSPECTIVE COMPARITIVE STUDY OF HEALTH RELATED QUALITY OF LIFE OF TICAGRELOR ANDCLOPIDOGREL IN PATIENTS WITH ACUTE CORONARYSYNDROME – A PILOT STUDY

Aadarsh V.S.*[1], Jisna K. Philip[1], Shilpa S. Nair[1], Tasnim Nazeer[1], Dr. Subash Chandran M.P.[2] and Dr. Karthika Lal B.[3]

[1]Fifth Pharm D. Students, Sree Krishna College of Pharmacy and Research Centre, Thiruvananthapuram, Kerala, India.

[2]Professor and Head, Department of Pharmaceutics, Sree Krishna College of Pharmacy and Research Centre, Thiruvananthapuram, Kerala, India.

[3]Assistant professor, Pharmacy Practice Department, Sree Krishna College of Pharmacy and Research Centre, Thiruvananthapuram, Kerala, India.

Article Received on
5 April 2021,

Revised on 25 April 2021,
Accepted on 15 May 2021

DOI: 10.20959/wjpr20216-20553

***Corresponding Author**
Aadarsh V.S.
Fifth Pharm D. Students,
Sree Krishna College of Pharmacy and Research Centre,
Thiruvananthapuram,
Kerala, India.

ABSTRACT

Background: Acute coronary syndrome describes a range of conditions associated with sudden, reduced blood flow to the heart. Ticagrelor and Clopidogrel are common anti Platelet drugs used along with Aspirin in Dual anti-platelet therapy. Ticagrelor is a direct acting P2Y12 receptor antagonist whereas Clopidogrel is an anti-platelet drug in prodrug form. **Methods:** The study was carried out in 24 patients with ACS. The study was conducted by categorising them into two groups, 12 patients taking Ticagrelor and 12 patients taking Clopidogrel. Health related QOL of Ticagrelor and Clopidogrel was assessed using SF-36 questionnaire in patients with acute coronary syndrome. **Result:** By using SF-36 questionnaire, it was found that Ticagrelor and Clopidogrel showed almost similar effect in QOL of patients. A slight increase in the QOL was found in patients taking Ticagrelor. There was a significant improvement in QOL after patient counselling. **Conclusion:** It was concluded that, Ticagrelor is slightly more efficient than Clopidogrel. There is a significant improvement in the QOL scoring in patients taking Ticagrelor when compared to that of patients taking Clopidogrel. A significant improvement was found in the QOL of patients

after patient counselling.

KEYWORDS: Acute coronary syndrome, Ticagrelor, Clopidogrel, Quality of life.

INTRODUCTION

Acute Coronary Syndrome[1] is a term used to describe a range of conditions associated with sudden, reduced blood flow to the heart. ACS is most often caused by plaque rupture or clot formation in the heart's arteries. Acute coronary syndrome characterized as any class of clinical feature appropriate with Acute Myocardial Ischemia and the spectrum of clinical conditions from unstable angina to NSTEMI to STEMI. ACS include;

- ❖ STEMI (ST-Elevation Myocardial Infarction)
- ❖ NSTEMI (Non ST- Elevated Myocardial Infarction)
- ❖ Unstable Angina

Etiology

Stages in the development of ACS include:

- ❖ Ischemic cascade
- ❖ Plaque formation and rupture
- ❖ Coronary occlusion and MI
- ❖ Ventricular remodeling[2]

Clinical Features

- ❖ Chest pain (Most common)
- ❖ Dyspnea
- ❖ Nausea/ Vomiting
- ❖ Arms, shoulders, jaw, back or upper abdomen pain
- ❖ Sweating
- ❖ Shortness of breath[3]
- ❖ Atypical symptoms include
- ✓ Without classic chest pain (acute confusion, pulmonary oedema) in diabetics and elderly patients.
- ✓ Fullness or burning in the chest
- ✓ Epigastric discomfort
- ✓ Heart palpitations
- ✓ Feeling restless

- ✓ Indigestion
- ✓ Shoulder or arm pain
- ✓ Discomfort between scapula or in the midback region
- ✓ Dizziness / syncope
- ✓ Fatigue or weakness not related to neurologic problems
- ✓ Throat, neck, tooth discomfort

Risk Factors

- ❖ Smoking
- ❖ High blood cholesterol
- ❖ High blood pressure
- ❖ Aging
- ❖ Diabetes
- ❖ Prothrombotic factors (e.g. fibrinogen)
- ❖ Markers of inflammation
- ❖ Chronic kidney disease
- ❖ Age >45 for male / 55 for female
- ❖ Physical inactivity
- ❖ A family history of chest pain, heart disease, stroke.[4]
- ❖ Being overweight or obese

Diagnosis[4]

- ❖ Electrocardiogram (ECG)
- ❖ Blood tests
- ❖ Coronary angiogram
- ❖ Echocardiogram
- ❖ Myocardial perfusion imaging
- ❖ Computerized tomography (CT) angiogram
- ❖ Serum cardiac markers
- ❖ Creatine kinase
- ❖ Ck-mb Isoenzyme
- ❖ Ck-mb subforms
- ❖ Cardiac troponins
- ❖ Myoglobin

Treatment[4]

The initial treatment for all Acute Coronary Syndrome (ACS) includes aspirin (300 mg) and heparin bolus and intravenous (IV) heparin infusion if there are no contraindications to the same. Antiplatelet therapy with Ticagrelor (BRILINTA) or Clopidogrel (PLAVIX) is also recommended.

Clopidogrel[5]

Clopidogrel, a thienopyridine derivative, binds specifically and irreversibly to the platelet P2Y12 purinergic receptor, inhibiting ADP-mediated platelet activation and aggregation. Clopidogrel is a prodrug used to inhibit platelet aggregation, which activated in the liver. It mainly used to treat ACS (Acute coronary syndrome), ST-segment elevated myocardial infarction, NON ST-segment elevated myocardial infarction, unstable angina etc. Commonly used as dual-antiplatelet therapy combined with Aspirin.

Ticagrelor[6]

Ticagrelor is an orally administered direct-acting P2Y12 receptor antagonist. In vitro studies have demonstrated that Ticagrelor binds reversibly and noncompetitively to the P2Y12 receptor at a site distinct from that of the endogenous agonist adenosine diphosphate (ADP). In contrast, the thienopyridine compounds Clopidogrel and Prasugrel bind irreversibly to the P2Y12 receptor for the life of the platelet.

MATERIALS AND METHODS[7]

Data source: All the relevant information regarding the study was collected from case records and direct interview with patients and care givers. Data from case records and care givers was collected by using suitably designed proforma. The study was approved by Research and Ethical Committee of Cosmopolitan hospital, Thiruvananthapuram.

Study population: Patients were taken from Cardiology department of Cosmopolitian Hospital. Informed consent was obtained. The study was conducted for the period of 2 months.

Assessment of QOL: Details were collected from case records of the ACS patients and direct interview with the patients and caregivers which is been recorded in SF-36 questionnaire.

Assessment of side effect: Details were collected from case records of the ACS patients and

direct interview with the patients caregivers.

Impact of patient counselling: Patients with ACS taking Ticagrelor or Clopidogrel are included in the study. They were provided with SF-36 questionnaire and the impact of counselling was assessed by comparing the questionnaire before and after one month of patient counselling.

Statistical Analysis: Comparison of quantitative variables between two groups was analyzed by unpaired t test or Mann Whitney U test according to the nature of the data.

OBSERVATION AND RESULTS

The proposed study entitled, "Health Related Quality of Life of Ticagrelor versus Clopidogrel in Patients with Acute Coronary Syndrome" was a prospective observational study carried out in a multispeciality tertiary care hospital. In this study, the data was collected from 24 patients diagnosed with ACS and was analyzed. Among the 24 patients selected, 12 were taking Ticagrelor and 12 were taking Clopidogrel. The study aimed to compare the effect of Ticagrelor and Clopidogrel on health related quality of life using SF-36 scale, to assess the side effect profile of Ticagrelor and Clopidogrel and to evaluate the impact of patient counselling on improving the quality of life of patients with ACS.

Demographic Details of The Patients

The data related to demographic details of patients were collected and recorded.

Percentage Distribution of Patients Based on Gender

The percentage distribution of patients based on gender is shown in the following table

Table 1: Percentage distribution of patients based on gender.

Gender	Ticagrelor		Clopidogrel		Total	
	N	%	N	%	N	%
Male	11	91.7	10	83.3	21	87.5
Female	1	8.3	2	16.7	3	12.5
Total	12	100	12	100	24	100

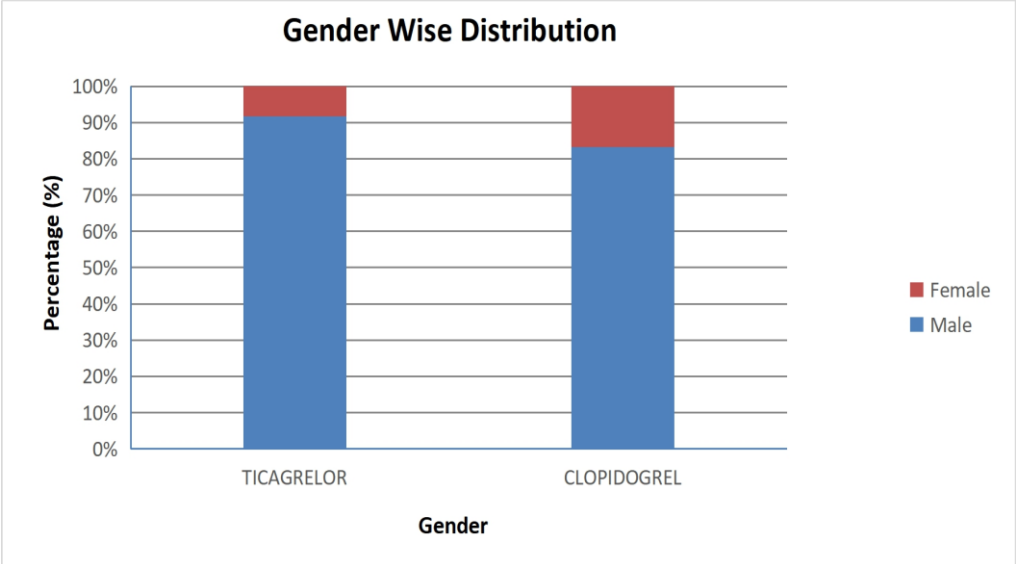

Figure 1: Diagrammatic representation of patients based on gender.

From the Table 1, it was observed that out of the total patients with ACS, 87.5% were male and 12.5% were female. It was also found that 91.7% male patients and 8.3% female patients were taking Ticagrelor whereas 83.3% male patients and 16.7% female patients were taking Clopidogrel. Thus from the above table we concluded that there is a higher incidence of ACS in males compared to that of females.

Percentage Distribution of Patients Based on Age

The percentage distribution of patients based on age is shown in the following table.

Table 2: Percentage of patients based on age.

Age in years	Ticagrelor		Clopidogrel		Total	
	N	%	N	%	N	%
≤ 50	2	16.7	2	16.7	4	16.7
51 - 60	3	25	1	8.3	4	16.7
61 - 70	3	25	4	33.3	7	29.2
71 - 80	4	33.3	2	16.7	6	25
>80	0	0	3	25	3	12.5
Total	12	100	12	100	24	100

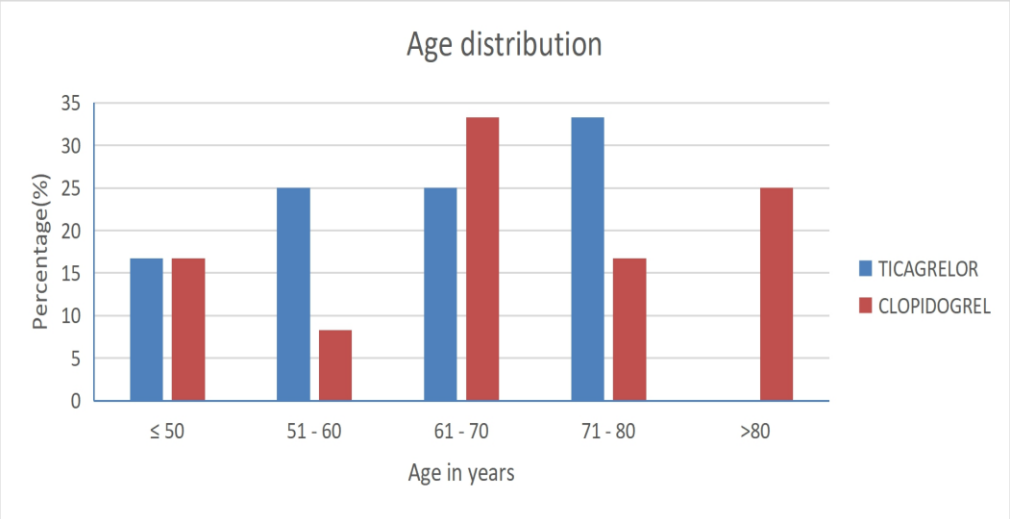

Figure 2: Diagrammatic representation of patients based on age.

From the Table 2, it was observed that out of the total patients with ACS, 16.7% of patients were ≤ 50 years, out of which 16.7% patients were taking Ticagrelor and 16.7% patients were taking Clopidogrel. About 16.7% of patients were between 51 – 60 years, out of which 25% patients were taking Ticagrelor and 8.3% patients were taking Clopidogrel. About 29.2% of patients were between 61 – 70 years out of which 25% patients were taking Ticagrelor and 33.3% patients were taking Clopidogrel. It was found that 25% of patients were between 71 – 80 years, out of which 33% patients were taking Ticagrelor and 16.7% patients were taking Clopidogrel and 12.5% of patients were >80 years out of which no patients were taking Ticagrelor and 33.3% patients were taking Clopidogrel.

Table 3: Mean Age of Distribution In Patients Having Ticagrelor And Clopidogrel.

Age in years	**Ticagrelor**		**Clopidogrel**	
	Mean	sd	Mean	sd
	62.6	11.8	68.7	12.4

From Table 3, mean age of distribution in taking Ticagrelor was found to be 62.6 and Clopidogrel was found to be 68.7. Thus from the above table it was concluded that the higher chance of occurrence of ACS was found to be between 61-70 years.

Percent of Distribution of Patients Based on Their Marital Status

The percent of distribution of patients based on their marital status is shown in the following table.

Table 4: Percent of distribution based on their marital status.

Maritalstatus	Ticagrelor		Clopidogrel		Total	
	N	%	N	%	N	%
Married	12	100	12	100	24	100
Unmarried	0	0	0	0	0	0
Total	12	100	12	100	24	100

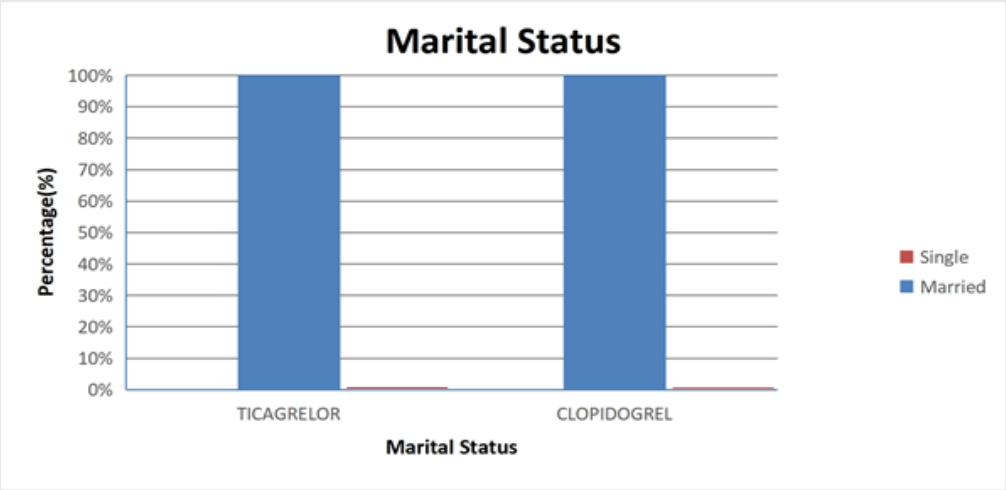

Figure 3: Diagrammatic representation of distribution based on their marital status.

From the Table 4, it was observed that out of the total patients with ACS, 100% were married and0% were unmarried. Thus it was concluded that there is a higher chance of occurrence of ACS in married people when compared to unmarried people.

Percentage of Distribution Based on Diagnosis

The percentage of distribution based on diagnosis is shown in the following table.

Table 5: Percentage of distribution based on diagnosis.

Diagnosis	Ticagrelor		Clopidogrel		Total	
	N	%	N	%	N	%
ACS	12	100	12	100	24	100
STEMI	4	33.3	6	50	10	41.7
NSTEMI	7	58.3	5	41.7	12	50
UNSTABLE ANGINA	1	8.3	3	25	4	16.7

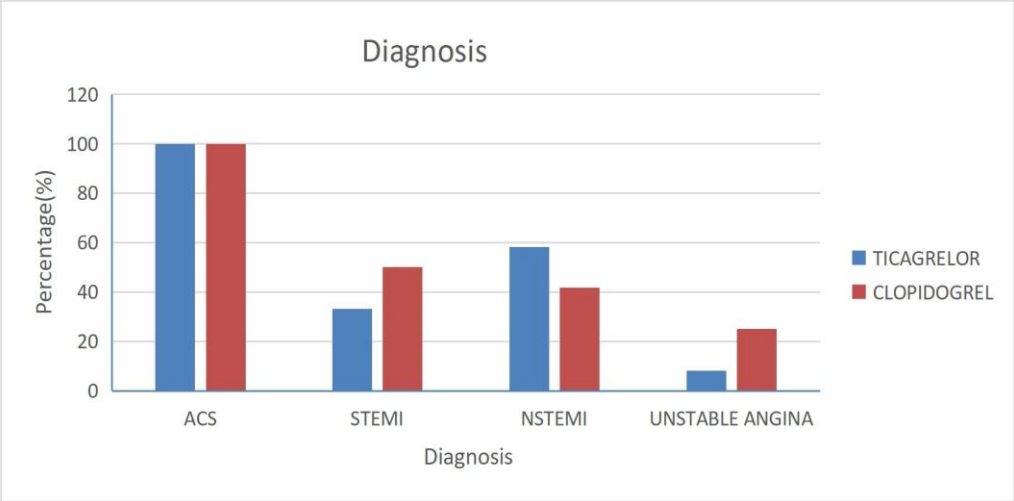

Figure 4: Diagrammatic distribution of patients based on diagnosis.

From the Table 5, it was observed that, out of 100% of ACS patients, 50% were taking Ticagrelor and 50% were taking Clopidogrel. It was also found that out of 41.7% diagnosed with STEMI, 33.3% were taking Ticagrelor and 50% were taking Clopidogrel. Out of 50% diagnosed with NSTEMI, 58.3% were taking Ticagrelor and 41.7% were taking Clopidogrel. Out of 16.7% diagnosed with Unstable angina, 8.3% were taking Ticagrelor and 25% were taking Clopidogrel.

Percentage Distribution of Patients Based on Symptoms

The percentage distribution of patients based on symptoms is shown in the following table.

Table 6: Percentage of distribution of patients based on symptoms.

Symptoms	TICAGRELOR		CLOPIDOGREL		Total	
	N	%	N	%	N	%
Chest pain	12	100	10	83.3	22	91.7
Fatigue	4	33.3	9	75	13	54.2
Anxiety	2	16.7	4	33.3	6	25
Nausea	6	50	1	8.3	7	29.2
Shortness of breath	10	83.3	8	66.7	18	75
Lethargy	0	0	0	0	0	0
Numbness	4	33.3	3	25	7	29.2
Sweating	11	91.7	9	75	20	83.3
Chest discomfort	12	100	11	91.7	23	95.8

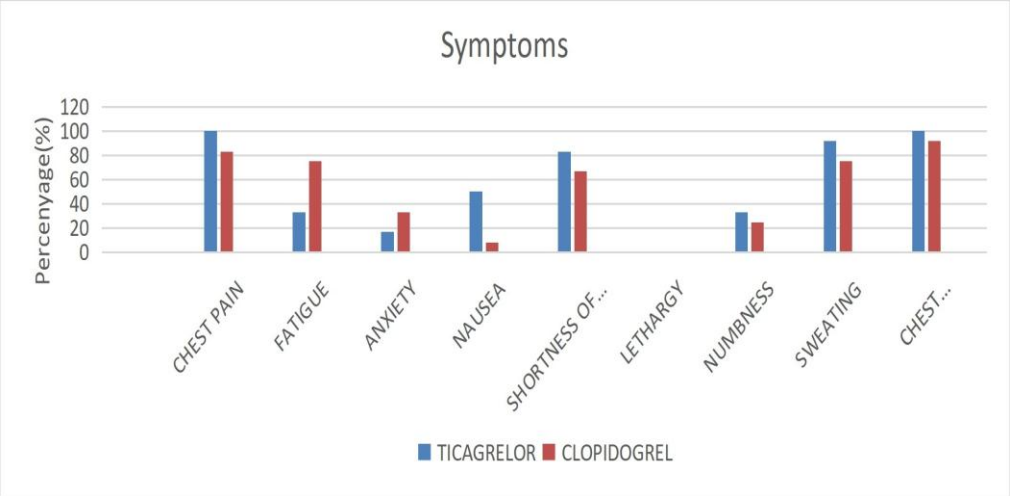

Figure 5: Diagrammatic representation of patient based on symptoms.

From the Table 6, it was observed that out of the total patients taking Ticagrelor, 100% had chest pain, 33% had fatigue, 16.7% had anxiety, 6% had nausea, 10% had shortness of breath, 4% had numbness, 11% had sweating and 12% had chest dicomfort. Out of total patients taking Clopidogrel, 83.3% had chest pain, 75% had fatigue, 33.3% had anxiety, 8.3% had nausea, 66.7% had shortness of breath, 7% had numbness, 20% had sweating and 23% had chest discomfort.

PERCENTAGE OF DISTRIBUTION OF PATIENTS BASED ON SIDE EFFECTS

Ticagrelor

The percentage of distribution based on occurrence of side effects of Ticagrelor is shown in thefollowing table.

Table 7: Percentage of patients based on side effects of Ticagrelor.

Side effects	N	%	Side effects	N	%
Dyspnea	3	25	Headache	1	8.3
Nausea	2	16.7	Diarrhoea	0	0
Dizziness	3	25	Constipation	1	8.3
Abdominal pain	2	16.7	Itchy skin	0	0
Cough	0	0	Decreased sleep	2	16.7
Hypotension	1	8.3	Back pain	2	16.7
Bleeding	2	16.7	Fatigue	1	8.3

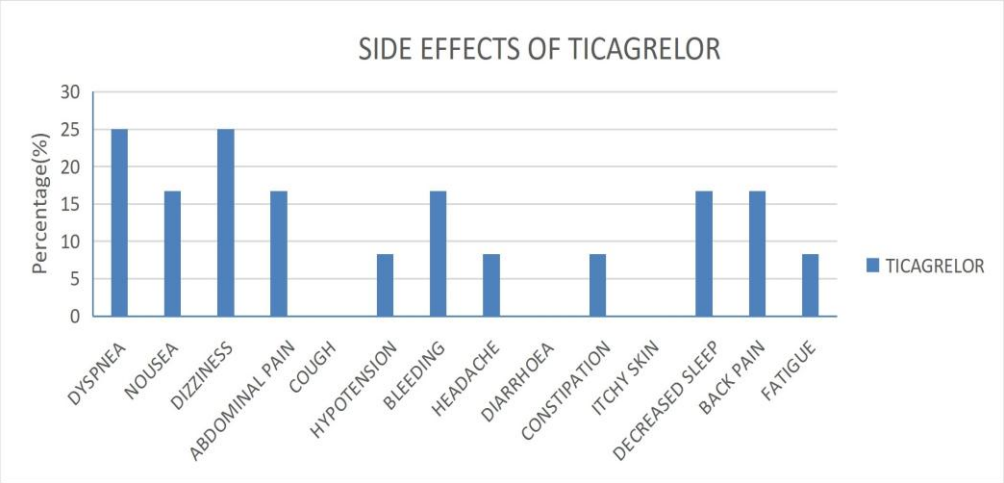

Figure 6: Diagrammatic representation of patients based on side effects of Ticagrelor.

From the Table 7, it was observed that out of the total 12 patients taking Ticagrelor, 25% has dyspnea and dizziness, 16.7% has nausea, abdominal pain, back pain, bleeding, decreased sleep, 8.3% has hypotension, head ache, constipation and fatigue.

Clopidogrel

The percentage of distribution based on occurrence of side effects of Clopidogrel is shown in thefollowing table.

Table 8: Percentage of patients based on side effects of Clopidogrel.

Side effects	N	%	Side effects	N	%
DYSPNEA	2	16.7	HEADACHE	1	8.3
NAUSEA	2	16.7	DIARRHOEA	0	0
DIZZINESS	2	16.7	CONSTIPATION	1	8.3
ABDOMINAL PAIN	3	25	ITCHY SKIN	0	0
COUGH	2	16.7	DECREASED SLEEP	2	16.7
HYPOTENSION	1	8.3	BACK PAIN	1	8.3
BLEEDING	1	8.3	FATIGUE	1	8.3

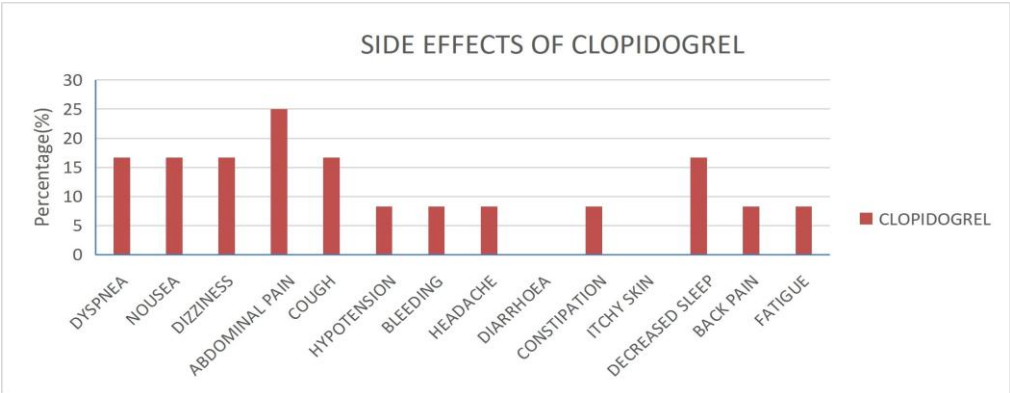

Figure 7: Diagrammatic representation of patients based on side effects of Clopidogrel.

From the Table 8, it was observed that out of 12 patients taking Clopidogrel, 16.7% had abdominal pain, 16.7% had dyspnea, headache, dizziness, cough and decreased sleep and 8.3% had hypotension, bleeding, headache, constipation, back pain and fatigue.

Assessing Quality of Life Based on Sf-36 Scale

The data related to Assessment of Quality of life of patients with ACS taking Ticagrelor or Clopidogrel, before and after patients counselling were collected and recorded. The collecteddata is shown in the following tables.

BEFORE COUNSELLING

Table 9: Pre-test Assessment of patients having Ticagrelor and Clopidogrel by using SF-36 Scale.

Pre Test	TICAGRELOR		CLOPIDOGREL	
	Mean	sd	Mean	sd
Physical function	24.6	9.2	20.4	9.2
Role-physical	2.1	7.2	4.2	14.4
Body pain	21.4	9.7	21.8	10.4
General health	21.7	6.2	24.8	8.6
Vitality	24.6	7.2	30.0	9.3
Social functioning	20.0	12.5	30.5	11.3
Role emotional	2.8	9.5	0.0	0.0
Mental health	24.7	5.1	25.7	6.3

After Counselling

Table 10: Post-test Assessment of patients having Ticagrelor and Clopidogrel by using SF-36 Scale.

Post test	TICAGRELOR		CLOPIDOGREL	
	Mean	sd	Mean	sd
Physical function	90.0	7.7	75.8	9.7
Role-physical	100.0	0.0	95.8	9.7
Body pain	92.7	11.1	64.5	8.0
General health	88.3	8.0	70.8	6.4
Vitality	77.1	6.6	66.7	7.8
Social functioning	89.8	8.9	67.9	8.2
Role emotional	100.0	0.0	86.2	22.3
Mental health	84.7	4.1	67.7	6.3

Percentage Change in QOL

Table 11: Percentage change in patients taking Ticagrelor and Clopidogrel.

Percentage change	TICAGRELOR		CLOPIDOGREL	
	Mean	sd	Mean	sd
Physical function	65.4	9.4	55.4	12.3
Role-physical	97.9	7.2	91.7	16.3
Body pain	71.3	14.7	42.8	12.3
General health	66.7	9.2	46.0	14.2
Vitality	52.5	10.8	36.7	11.7
Social functioning	69.8	17.3	37.4	15.1
Role emotional	97.3	9.5	86.2	22.3
Mental health	60.0	7.2	42.0	10.6

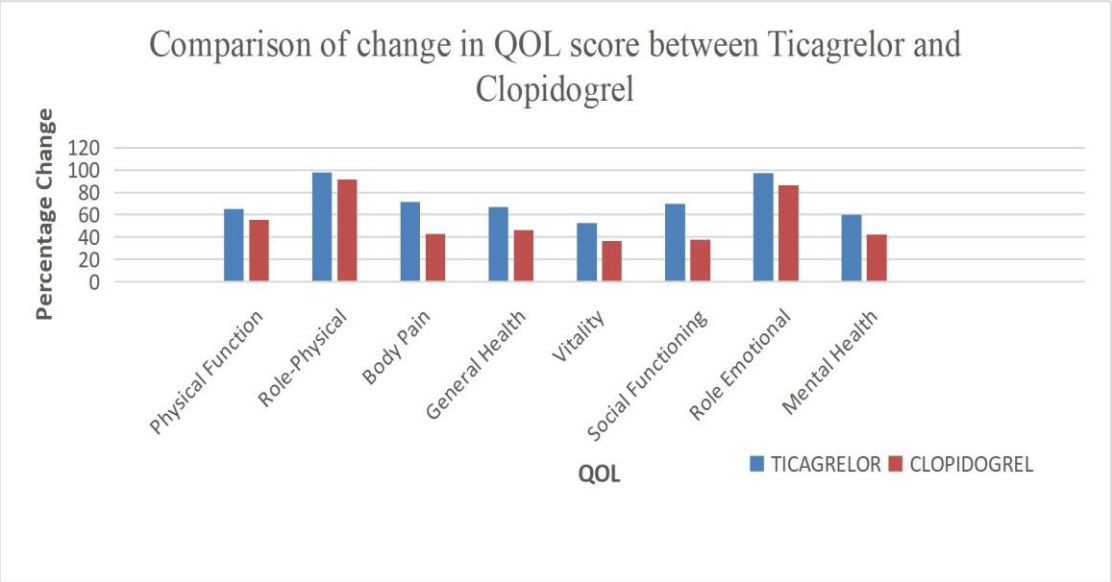

Figure 8: Comparison of change in Quality of Life Score(QOL) between Ticagrelor and Clopidogrel.

In this study, these drugs was given to both the groups of patients and improvement of quality of life was assessed using SF-36 questionnaire. The review was done after one month. After comparing the change in QOL score before counselling and after counselling, it was found that Ticagrelor showed slightly improved quality of life than Clopidogrel. From table 9, 10 and 11, it was found that Ticagrelor had improved QOL score when compared to the score of Clopidogrel.

PHYSICAL FUNCTION

Table 12: Percentage change PHYSICAL FUNCTION in patients taking TICAGRELOR andCLOPIDOGREL.

QOL	Drug	Test	Score		Paired difference		Paired t test	
			Mean	sd	Mean	sd	t	p
Physical Function	TICAGRELOR	Pre test	24.6	9.2	65.4	9.4	24.096	<0.001
		Post test	90.0	7.7				
	CLOPIDOGREL	Pre test	20.4	9.2	55.4	12.3	15.566	<0.001
		Post test	75.8	9.7				

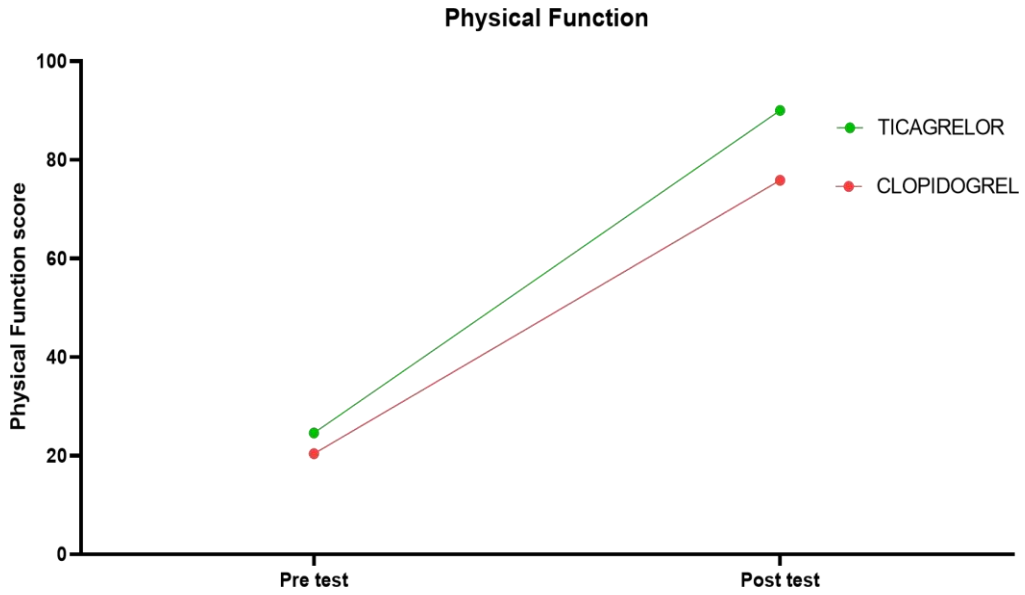

Figure 9: Comparison of change in Physical Function Score between TICAGRELOR and CLOPIDOGREL.

From the above table, it was found that the average physical function score before counselling was 24.6±9.2 and after counselling was 90.0±7.7 in patients taking Ticagrelor whereas the average physical function score before counselling was 20.4±9.2 and after counselling was 75.8±9.7 in those patients taking Clopidogrel. The observed difference was statistically significant ($p<0.05$). There was a significant improvement in physical function score after intervention.

ROLE- PHYSICAL

Table 13: Percentage change of ROLE- PHYSICAL in patients taking TICAGRELOR andCLOPIDOGREL.

QOL	Drug	Test	Score		Paired difference		Paired t test	
			Mean	sd	Mean	sd	t	p
Role- Physical	TICAGRELOR	Pre test	2.1	7.2	97.9	7.2	47.000	<0.001
		Post test	100.0	0.0				
	CLOPIDOGREL	Pre test	4.2	14.4	91.7	16.3	19.501	<0.001
		Post test	95.8	9.7				

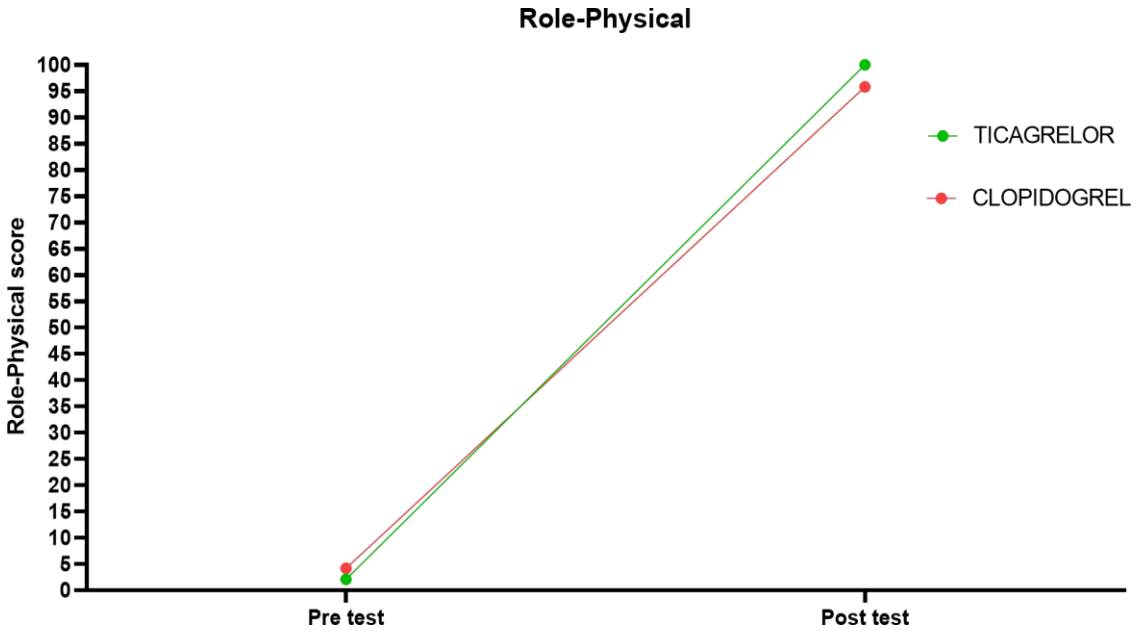

Figure 10: Comparison of change in ROLE PHYSICAL SCORE between TICAGRELOR and CLOPIDOGREL.

From the above table, it was found that the average role physical score before counselling was 2.1±7.2 and after counselling was 100±0.0 in patients taking Ticagrelor or where as the average role physical score before counselling was 4.2±14.4 and after counselling was 95.8±9.7 in those patients taking Clopidogrel. The observed difference was statistically significant ($p<0.05$). There was a significant improvement in role physical score after intervention.

BODY PAIN

Table 14: Percentage change of BODY PAIN in patients taking TICAGRELOR andCLOPIDOGREL.

QOL	Drug	Test	Score		Paired difference		Paired t test	
			Mean	sd	Mean	sd	t	p
Body Pain	TICAGRELOR	Pre test	21.4	9.7	71.3	14.7	16.779	<0.001
		Post test	92.7	11.1				
	CLOPIDOGREL	Pre test	21.8	10.4	42.8	12.3	12.040	<0.001
		Post test	64.5	8.0				

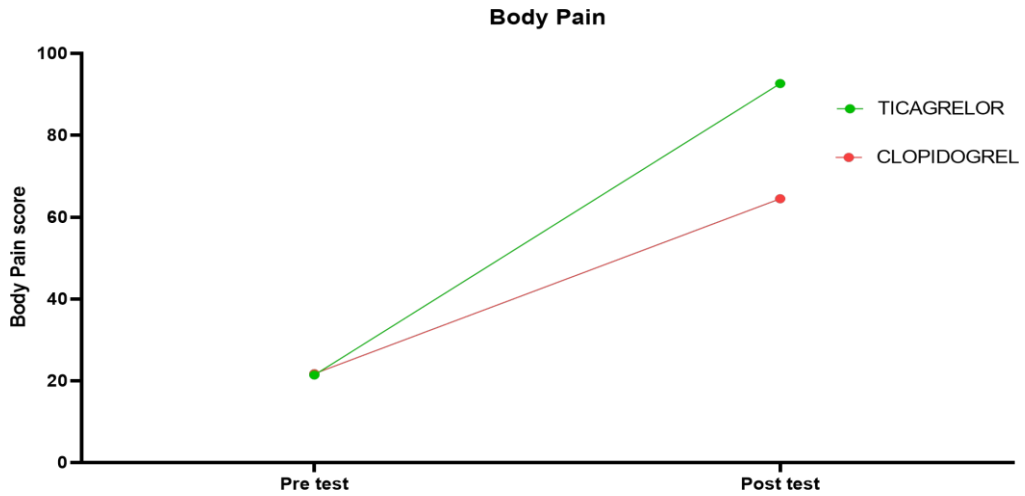

Figure 11: Comparison of change in BODY PAIN SCORE between TICAGRELOR and CLOPIDOGREL.

From the above table, it was found that the average body pain score before counselling was 21.4±9.7 and after counselling was 92.7±11.1. In patients taking Ticagrelor where as the average body pain score before counselling was 21.8±10.4 and after counselling was 64.5±8.0 in those patients taking Clopidogrel. The observed difference was statistically significant ($p<0.05$). There was a significant improvement in body pain score after intervention.

GENERAL HEALTH

Table 15: Percentage change of GENERAL HEALTH in patients taking TICAGRELOR and CLOPIDOGREL.

QOL	Drug	Test	Score		Paired difference		Paired t test	
			Mean	sd	Mean	sd	t	p
General Health	TICAGRELOR	Pre test	21.7	6.2	66.7	9.2	25.161	<0.001
		Post test	88.3	8.0				
	CLOPIDOGREL	Pre test	24.8	8.6	46.0	14.2	11.237	<0.001
		Post test	70.8	6.4				

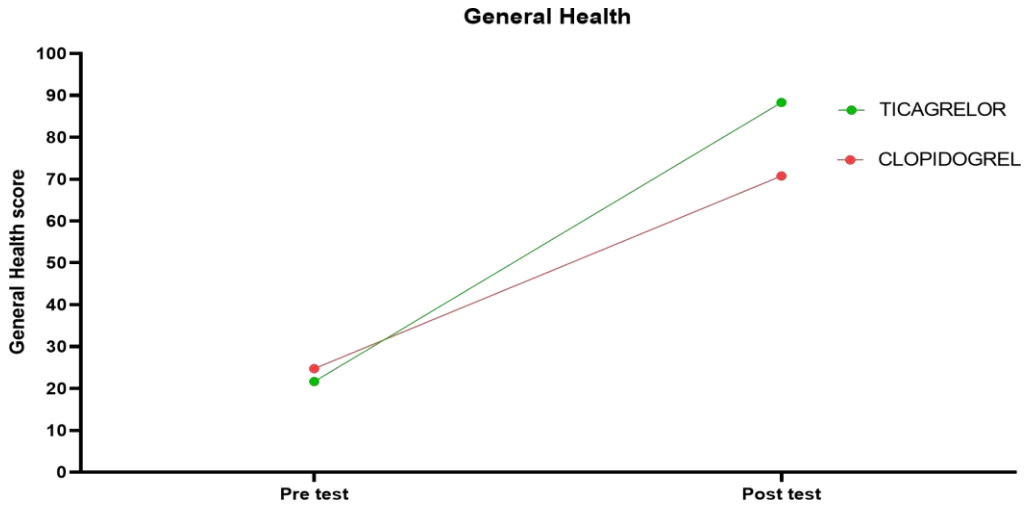

Figure 12: Comparison of change in GENERAL HEALTH SCORE between TICAGRELOR and CLOPIDOGREL.

From the above table, it was found that the average general health score before counselling was 21.7±6.2 and after counselling was 88.3±8.0. In patients taking Ticagrelor where as the average general health score before counselling was 24.8±8.6 and after counselling was 70.8±6.4 in those patients taking Clopidogrel. The observed difference was statistically significant ($p<0.05$). There was a significant improvement in general health score after intervention.

VITALITY

Table 16: Percentage change of VITALITY in patients taking TICAGRELOR and CLOPIDOGREL.

QOL	Drug	Test	Score		Paired difference		Paired t test	
			Mean	sd	Mean	Sd	t	p
Vitality	TICAGRELOR	Pre test	24.6	7.2	52.5	10.8	16.892	<0.001
		Post test	77.1	6.6				
	CLOPIDOGREL	Pre test	30.0	9.3	36.7	11.7	10.817	<0.001
		Post test	66.7	7.8				

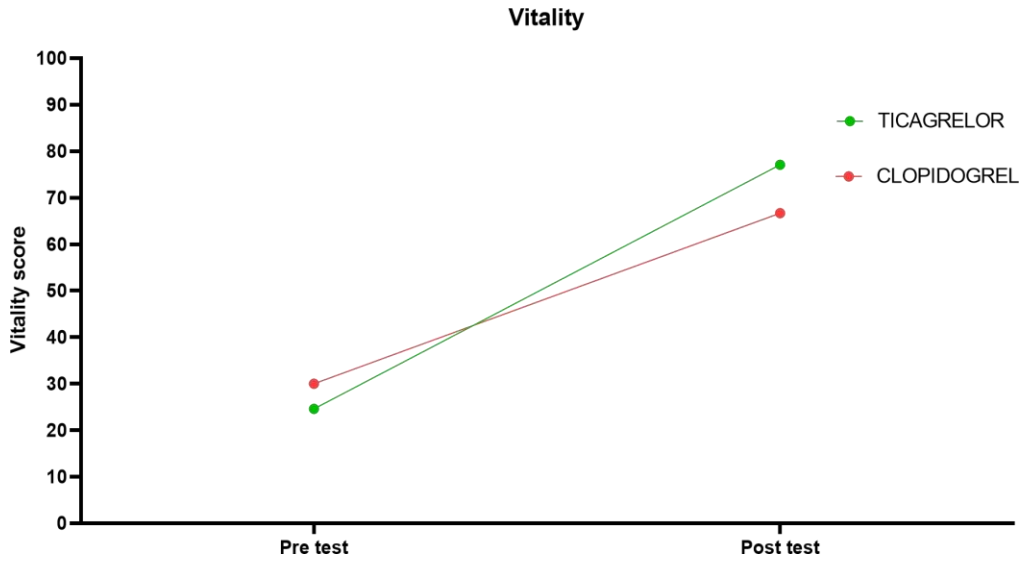

Figure 13: Comparison of change in VITALITY between TICAGRELOR and CLOPIDOGREL.

From the above table, it was found that the average vitality score before counselling was 24.6±7.2 and after counselling was 77.1±6.6 in patients taking Ticagrelor where as the average vitalityscore before counselling was 30.0±9.3 and after counselling was 66.7± 7.8 in those patients taking Clopidogrel. The observed difference was statistically significant ($p<0.05$). There was a significant improvement in vitality score after intervention.

SOCIAL FUNCTIONING

Table 17: Percentage change of SOCIAL FUNCTIONING in patients taking TICAGRELOR and CLOPIDOGREL.

QOL	Drug	Test	Score		Paired difference		Paired t test	
			Mean	sd	Mean	sd	t	p
Social Functioning	Ticagrelor	Pre test	20.0	12.5	69.8	17.3	13.993	<0.001
		Post test	89.8	8.9				
	Clopidogrel	Pre test	30.5	11.3	37.4	15.1	8.596	<0.001
		Post test	67.9	8.2				

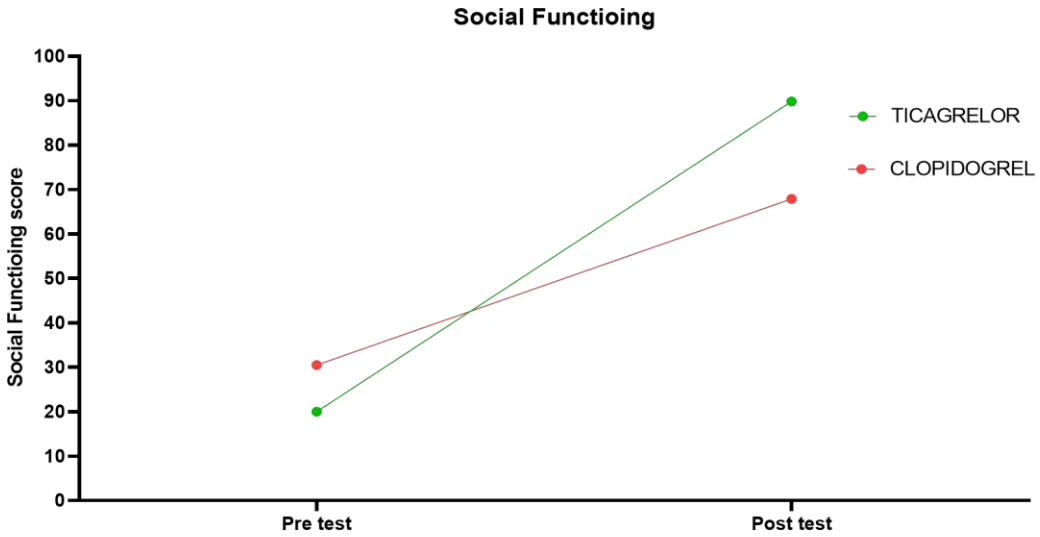

Figure 14: Comparison of change in SOCIAL FUNCTIONING SCORE between Ticagrelor and Clopidogrel.

From the above table, we found that the average social functioning score before counselling was 20.0±12.5 and after counselling was 89.8±8.9 in patients taking Ticagrelor where as the average social functioning score before counselling was 30.5±11.3 and after counselling was 67.9±8.2 in those patients taking Clopidogrel. The observed difference was statistically significant ($p<0.05$). There was a significant improvement in social functioning score after intervention.

ROLE- EMOTIONAL

Table 18: Percentage change of ROLE-EMOTIONAL in patients taking Ticagrelor and Clopidogrel.

QOL	Drug	Test	Score		Paired difference		Paired t test	
			Mean	sd	Mean	sd	t	p
Role Emotional	Ticagrelor	Pre test	2.8	9.5	97.3	9.5	35.364	<0.001
		Post test	100.0	0.0				
	Clopidogrel	Pre test	0.0	0.0	86.2	22.3	13.398	<0.001
		Post test	86.2	22.3				

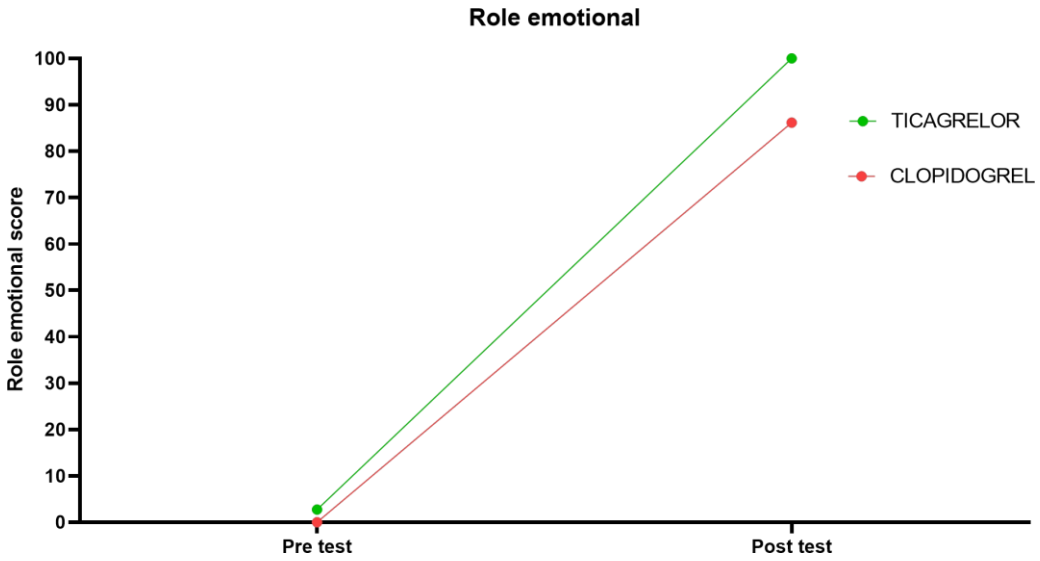

Figure 15: Comparison of change in ROLE EMOTIONAL SCORE between Ticagrelor and Clopidogrel.

From the above table, it was found that the average role emotional score before counselling was 2.8±9.5 and after counselling was 100.0±0.0 in patients taking Ticagrelor where as the average role emotional score before counselling was 0.0±0.0 and after counselling was 86.2±22.3 in those patients taking Clopidogrel. The observed difference was statistically significant ($p<0.05$). There was a significant improvement in role emotional score after intervention.

MENTAL HEALTH

Table 19: Percentage change of MENTAL HEALTH in patients taking TICAGRELOR and Clopidogrel.

QOL	Drug	Test	Score		Paired difference		Paired t test	
			Mean	sd	Mean	sd	t	p
Mental Health	TICAGRELOR	Pre test	24.7	5.1	60.0	7.2	28.723	<0.001
		Post test	84.7	4.1				
	CLOPIDOGREL	Pre test	25.7	6.3	42.0	10.6	13.748	<0.001
		Post test	24.7	5.1				

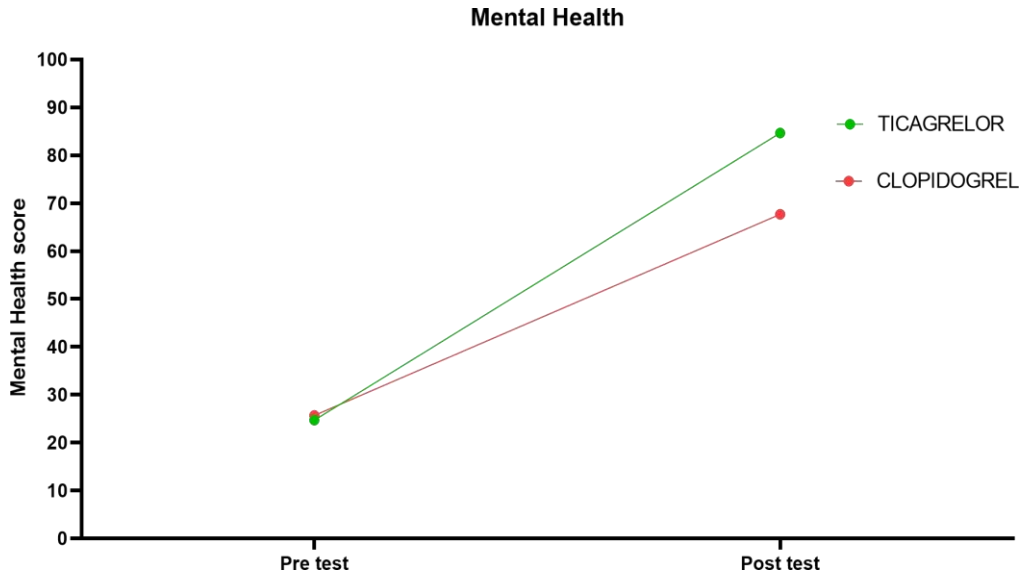

Figure 16: Comparison of change in MENTAL HEALTH SCORE between TICAGRELOR and CLOPIDOGREL.

From the above table, it was found that the average mental health score before counselling was 24.7±5.1 and after counselling was 84.7±4.1. in patients taking Ticagrelor where as the average mental health score before counselling was 25.7±6.3 and after counselling was 67.7±6.3 in those patients taking Clopidogrel. The observed difference was statistically significant ($p<0.05$). There was a significant improvement in mental health score after intervention.

DISCUSSION

This study aims to compare the effect of Ticagrelor and Clopidogrel on Health related Quality of life using SF-36scale, to assess the side effect profile of Ticagrelor and Clopidogrel and to evaluate the impact of patient counselling on improving the quality of life of patients with acute coronary syndrome. The two drugs considered in this study is Ticagrelor and Clopidogrel which are antiplatelet drugs used for the treatment of ACS.[6]

Ticagrelor is an oral antiplatelet drug that is used in dual antiplatelet therapy along with low dose Aspirin to decrease the risk of MI and stroke in ACS.[12] Ticagrelor is direct acting $P2Y_{12}$ receptor antagonist which binds reversibly and noncompetitively to $P2Y_{12}$ receptor and thus inhibit platelet aggregation.[1]

Clopidogrel, is a thienopyridine derivative. It is most commonly used as dual-Antiplatelet therapy when combined with Aspirin.[3] It binds irreversibly and specifically to the platelet

P2Y12 purinergic receptor, and thus inhibit activation and aggregation of platelet by ADP. Clopidogrel is an antiplatelet drug. Initially it is in a prodrug form which gets activated in the liver and is mainly used to inhibit platelet aggregation.[2] It mainly used to treat ACS which may include ST-segment elevated myocardial infarction, NON ST-segment elevated myocardial infarction, unstable angina etc.[11]

In this study 24 patients with ACS where taken. Among this, 12 patients taking Ticagrelor and 12 patients taking Clopidogrel were selected. Statistical analysis was performed using paired t test and a detailed analysis was performed.

In this study demonstrated that there is no significant difference in QOL of patients with ACS taking Ticagrelor and Clopidogrel, but a slight increase in QOL based on parameters such as pain and social activity was seen in some patients taking Ticagrelor. A better result was achieved in patients treated with Ticagrelor. The observations of this study was similar to the results of a study conducted by ***L. Kopaleishvil and I. Jashi.***[7] In their study on "Clinical outcomes and quality of life in patients with ACS treated with concomitant use of Ticagrelor and Clopidogrel in Ticagrelor showed slight increase in the QOL of patients based on parameters such as pain and social activity when compared to Clopidogrel.

This study also assessed the age group which is more prevalent to ACE cases. The result was similar to that of the study conducted by ***Mohamed Khayata et.al,***[10] which concluded that the mean age was 65±14 years. In this study we categorized the age groups with ACE in to 2 groups, that is those patients taking Ticagrelor and those who are taking Clopidogrel and the result was 62.6±11.8 years and 68.7±12.4 years respectively.

In a study done by ***Monica Pathania et.al***,[9] there was a significant difference in the Prasugrel, Ticagrelor and Clopidogrel in rates of ischemic attack per week. It was found that the statistically significant major side effects were constipation, sleep disturbances and ecchymosis.

The side effect profile of patients taking Ticagrelor and Clopidogrel was also assessed and concluded that out of 14 different side effects observed in this study, dyspnoea in the side effect observed in about 25 % patients taking Ticagrelor and abdominal pain is seen in 16.7% of patientstaking Clopidogrel.

Similarly in the study on Effect of Ticagrelor versus Clopidogrel in Elderly Patients with

Acute coronary syndrome by ***Steen Husted et.al***[7], they found that patients ≥80 years old had a 17% increased risk of death and a 48% higher risk of bleeding when discharged on ticagrelor versus Clopidogrel after a myocardial infarction, whereas there was a 20% lower risk of a new myocardial infarction and a 28% lower risk of stroke.

This study also showed a remarkable increase in QOL of patients with ACS after patient counselling which was done by evaluating the SF-36 questionnaire which was filled before and after patient counseling.[3] Responses were taken before and after counselling and compared. It was evident from the comparison that the patients had an improvement in lifestyle and mental and physical health after patient counseling.[7] The importance of patient counselling can be understood through this study.[9]

Ticagrelor and Clopidogrel were similar in efficacy and safety. There were no significant differences found between the two drugs.[4] Ticagrelor works more quickly than Clopidogrel and has a slightly increased effect on the quality of life of patients with ACS when compared to Clopidogrel.

CONCLUSION

From this study, it was concluded that Ticagrelor and Clopidogrel have almost similar effect in the improvement of QOL of patients with ACS. However in patients taking Ticagrelor there is a slight improvement in the average social functioning and pain score when compared to that of Clopidogrel. By assessing the side effect profile of both the drugs it was found that Ticagrelor has dyspnea, head ache, dizziness, bleeding and back pain as side effects where as Clopidogrel has headache, dizziness, nausea, abdominal pain and diarrhoea as side effects. It was also found that patient counselling has an important role in improving the quality of life of patients. Understanding about the aspects of ACS, effect of Ticagrelor and Clopidogrel on health related quality of life, side effect profile of both drugs, impact of patient counselling yields bettertherapeutic outcomes. Hence the well-being of the patients is ensured.

REFERENCES

1. Amit Kumar, Christopher P. Cannon, et al. Acute Coronary Syndromes Diagnosis and management, Part 1, Oct, 2009; 84(10): 917-938.
2. Wallentin L. Becker RC. Budaj A, et al. Ticagrelor versus Clopidogrel in patients with acutecoronary syndromes, 2009; 361: 1045-57.
3. Jennifer N. Smith, Jenna M. Negrelli, Megha B. Manek, Emily M. Hawes and Anthony J.

Viera, et.al. Diagnosis and Management of Acute Coronary Syndrome, 2008; 855-910.

4. Moreno PR, Falk E, Palacios IF, Newell JB. Fuster V., Fallon JT. et.al. Macrophage infiltration in Acute Coronary Syndromes: implications for plaque rupture. Circulation, 1994; 90(2): 775-778.
5. Kinlay S, Libby P, et al. Endothelial Function and Coronary Artery Disease.Curr opin Lipidol, 2001; 12(4): 383-389.
6. Gao C Z et al. Comparison of the effects of Ticagrelor and Clopidogrel on inflammoatory factors, vascular endothelium functions and short –term prognosis in patients with Acute ST- Segment elevation MI undergoing emergency percutaneous coronary intervention, 2013; 1198-1576.
7. L. Kopaleishvil and I. Joshy et al. Clinical outcome and quality of life of patient with ACS treated with concomitant use of Ticagrelor and Clopidogrel, 2017; 2023-3000.
8. Steen Husted et al. Ticagrelor versus Clopidogrel in elderly patients with Acute Coronary Syndrome, 2012; 689-876.
9. Monica Pathania et al. Comparison of Short term efficacy and side effect profile of Ticagrelor, Clopidogrel and Prasugrel in Patients with acute coronary Syndrome, 2018; 3301-3378.
10. Mohammed Khayata et al. Comparison of Clopidogrel With Prasugrel and Ticagrelor in Patients with Acute Coronary Syndrome, 2017; 256-310.
11. Stone GW, McLaurin BT, Cox DA, et al. ACUITY Investigators Bivalirudin for patients with Acute Coronary Syndrome, 2006; 3559(21): 2203-2216.
12. Boersma E, Harrington RA, Moliterno DJ, et al. Platelet Glycoprotein II b/IIIa Inhibitors in Acute Coronary Syndromes:a meta analysis of all major randomized Clinical trials, 2002; 359(9302): 189-198.