A PROSPECTIVE OBSERVATIONAL STUDY OF DRUG TREATMENT IN PATIENTS OF POST PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY

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ABSTRACT

Background: Percutaneous coronary intervention (PCI) is a part of the standard treatment for acute coronary syndromesalong with drug therapy. Study aimed to assessdrugs prescribed to post angioplasty patients at discharge, adverse effects profile and any alteration made to the drug list. **Methods:** A prospective observational study for a period of 6months was conducted in Cardiology unitof Goa Medical College and Hospital. Case records of the patients who underwent PTCAwere followed up at 1st, 3rd, and 6th monthand any adverse effects, alterations made to the drug list of patients (Post PCI) were noted.The data collected was analyzed using MS Excel and results expressed as counts and percentages. **Results:** 100 cases were included for the study, 80 patients followed up. The proportion of ACS was found to be higher in age group of 51-70 years (73.75%). All patients received dual anti-plateletalong with a cholesterol lowering agent as a part of the standardDAPT regimenfollowed by (53.33%) anti-hypertensives. Double dose regimen of P2Y12 inhibitor was continuedtill the 1st month post procedure. The (36.2%) adverse effects of drugs, mostly encountered with (79.3%) ACE-inhibitor. The most common side effect was dry-cough, followed byswelling of ankle. **Conclusion:** Post PTCA, patients are put on cocktail of drugs which should be continued for at least 12 months to get better outcome according to the ACC/AHA guidelines. Such follow-up studies may support or detect variations in standard therapy and rationalize the drug therapy in terms of adverse events.

KEYWORDS: Acute coronary syndrome, Prospective observational studies, PTCA, DAPT, Standard protocol, adverse effects.

INTRODUCTION

Cardiovascular diseases (CVD) are major cause of morbidity and mortality in India. In 2016, the estimated prevalence of CVDs in India was estimated to be 54.5 million. They include coronary artery disease, cerebrovascular disease, peripheral artery diseaseetc. 1 in 4 deaths in India are now because of CVDs with ischemic heart disease and stroke responsible for >80% of this burden.

Acute coronary syndromes (ACS) arecaused by a blockage of blood vessels supplying the heart causing myocardial ischemia. ACS are divided in unstable angina, non-ST elevated myocardial infarction (NSTEMI), ST-elevated myocardial infarction (STEMI).[1] This is due to a combination of risk factors such as, hypertension, diabetes, hyperlipidemia, obesity, physical inactivity, tobacco use, unhealthy diet, and harmful use of alcohol.[2]

Management of heart attack includes pharmacological and non-pharmacological therapies, immediate goal is to relieve symptoms i.e. pain, distress and restore the heart function as quickly as possible. Long term goal is to improvethe heart function, manage risk factors and lower the risk of a myocardial infarction. Percutaneous coronary intervention (PCI) is a part of the standard therapy along with use of anticoagulant and anti-platelet agents which play a crucial role in the acute phase as well as in secondary prevention. Treatment with stent implantation resulted in a lower incidence of restenosis and an improvement of clinical outcome compared to treatment with thrombolysis.[3,4]

In accordance to theguidelinesby the American College of Cardiology (ACC) and the American Heart Association (AHA) in 2010suggest the use of anti-platelets, thrombolytics, Statins, Beta-blocker, and Renin-Angiotensin Aldosterone system inhibitor drug therapies in ACS patients.[5] Dual anti-platelet therapy (DAPT) consisting of Acetylsalicylic acid and a P2Y12 inhibitor along with a cholesterol lowering is the commonly used regimen for coronary stents.[1,5] Complications after PCI may include recurrent ischemia

from restenosis or re-block at the site of revascularization. Hence post PTCA patients are prescribed a cocktail of drugs in order to treat as well as for prophylaxis of further attacks (MI/Angina).[1,2,5] The aim of this study is to assess the drugs prescribed to post angioplasty patients at discharge, adverse effects profile and any alterations made to the drug list of patients during 6month follow-up. The prescribed regimen, treatment of a complication as advised by the cardiologist during follow-up, any deviation from this therapy would be of significance.

METHODS AND MATERIALS
A prospective observational study was conducted in collaboration with Cardiology departmentof Goa Medical College, a tertiary care hospital for a period of 6 months from January 1, 2020 – June 31, 2020. The study was conducted after receiving the approval and clearance of Institutional Ethical Committee. Case records of the patients who underwent PTCA were followed up and reviewed at 1st, 3rd, and 6th months and any adverse effects, alterations made to the drug list of patients (Post PCI) were noted. The data collected was analyzed using MS Excel and results expressed as counts and percentages. Where necessary the results are depicted as graphs and charts.

Patient selection
Inclusion criteria: Patients of either gender, residing in Goa, having undergone PTCA for chronic stable angina, unstable angina, positive TMT, NSTEMI, STEMI or any other cause. Only patients who were admitted in the ward were included in the study.

Exclusion criteria: Pregnant womenand out patients were excluded from the study.

Sample size: 100 patients were included in the study. But due to the COVID pandemic only 80 patients followed up.
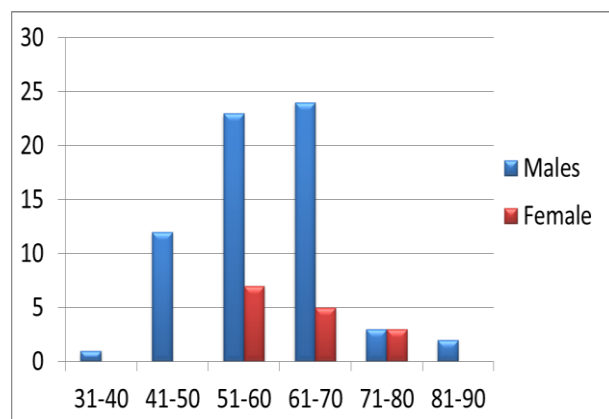
RESULTS

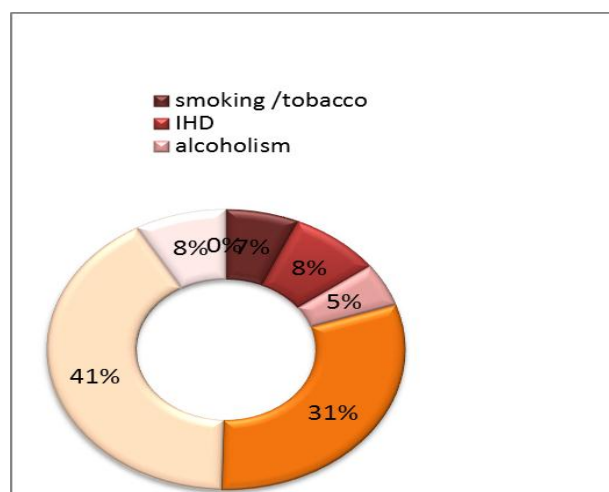**Fig 1: Age distribution of patients.**

Fig. 2: Risk factor distribution among patients.

Table 2: Risk factor distribution amongpatients.

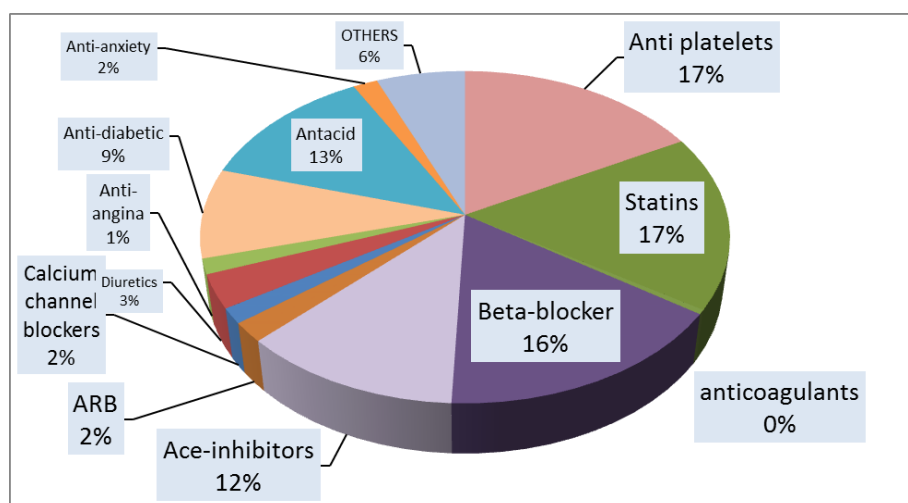| Risk factors	No. of patients	percentage
Smoking/Tobacco use	8	10%
Ischemic Heart Disease	10	12.5%
Alcoholism	6	7.5%
Diabetes mellitus	37	46.2%
Hypertension	50	62.5%
NONE	10	12.5%

Fig. 3: Drugs prescribed post-PTCA at discharge.

Table 3: Drugs prescribed post-PTCA at discharge.

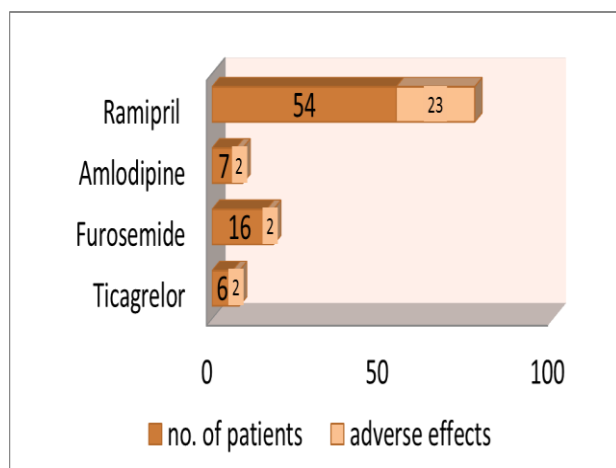| Classes of drugs post PTCA		No. of patients	Percentage
Anti-platelets	Aspirin	80	100%
	Clopidogrel	70	87.5%
	Ticagrelor	6	7.5%
	Prasugrel	4	5%
Statins	Atorvastatin	77	96.2%
Anticoagulants	Dabigatran	1	1.25%
	Heparin	1	1.2%
Antihypertensives			
Beta-blocker	Metoprolol	69	86.25%
	Carvedilol	4	5%
	Nebivolol	2	2.5%
	Bisoprolol	1	1.25%
ACE-inhibitors	Ramipril	55	68.7%
	Enalapril	1	1.25%
Angiotensin receptor blockers	Losartan	6	7.5%
	Telmisartan	3	3.75%
Calcium channel blockers	Amlodipine	7	8.75%
Alpha blocker	Prazosin	1	1.25%
Diuretics	Furosemide	19	23.7%
	Torsemide	1	1.25%
	Indapamide	1	1.25%
	Spironalactone	3	3.75%
Anti-anginal	Isosorbide dinitrate	3	3.75%
	Isosorbide mononitrate	3	3.75%
	Nitroglycerine	1	1.25%
Anti-diabetic	Metformin	25	31.25%
	Glimepiride	3	3.75%
	Linagliptin/Sitagliptin/ Teneligliptin	1/1/2	1.25%/2.5%
	Gliclazide	2	2.5%
	Insulin	7	8.75%
Antacids	Pantoprazole	59	73.75%
Anti-emetics	Ondansetron	0	0
Anti-anxiety	Alprazolam	4	5%
	Clonazepam	2	2.5%
Others Calcium multivitamin	Thyroxine	3	3.75%
	Levetiracetam	1	1.25%
	Divalproex sodium	1	1.25%
	Calcium	13	16.25%
	Methyl cobalamin	11	13.75%

Fig. 4: Adverse effects associated with the drugs.

RESULTS
In this study 100 patientswere considered however due to COVID pandemic only 80 patients followed up respectively.Out of the 80 patients, 65 patients (81.2%) were males and 15 (18.7%) were females (Figure1), which indicates that cardiovascular emergency and hence PTCA was more in male when compared to female. The incidence of patients undergoing PTCA was found to be more in the age group of 51-70 years in both the genders and was significantly low in age group of 31-50 years and 71-90. Table 2 shows the association of other comorbidities with the cardiovascular emergencies. In our study, hypertensionand diabetes mellitus were the most commonly found comorbidity followed by smoking/tobacco chewing and alcoholism.10 patients (12.5%) had none of the above comorbidities.

All patients (100%) received dual anti-platelet consisting of Acetylsalicylic acid and a P2Y12 inhibitor along with a cholesterol lowering agent as a part of the standardDAPT regimenas shown in Table 3 and graph 3followed by (53.33%) anti-hypertensives, (13%) β-blockers, (10%) ACE inhibitors, (3%) diuretics, (1%) calcium channel blockers and others respectively. Double dose regimen of P2Y12 inhibitor was continued up until the 1st month post procedure. Table 4 shows the (36.2%) 54/80 adverse effects of drugs, were mostly encountered with (79.3%)23/54 ACE-inhibitor-(Ramipril) had experienced dry cough which was then replaced with Telmisartan or Losartan which is an ARB and (6.9 %)2/7 in Calcium channel blockers, experienced swelling of the ankle which was then stopped immediately. (6.9 %) 2/16 on Diureticsi.e. Furosemide experienced dizziness and light headedness, 2/6 on theanti-platelet drugTicagrelor experienced bleeding after which the dose was decreased or stopped respectively.

DISCUSSION
In the present study out of 80 patients, 65 (81.2%) were male and 15 (18.7%) were female. The incidence of ACS was found to be higher in age group of 51-70 years (73.75%) with mean age of 59.61in both the genders.

Increase in male dominance suggests it's a predominantly a disease of men which correlates to the study conducted by Singh et al.[7] Decline in the estrogen's protective effect on cardiac health after menopause, could be a reason for rise of cardiovascular disease in female patients in the age groups 51-70 as in our study.[7] Most common comorbidity was found to be hypertension(62.5%) and diabetes 46.2%,similar to those of H. Nagabhushan et al, and Pendhari SR et al.[9,7] In our study Antiplatelets 80/80 (100%) and hypolipidemics 80/80(100%) followed by anti-hypertensives 69/80, (86.2%) were the most commonly prescribed drug classes post PTCA which is comparable as in other studies.[8,9,10] Among the anti-hypertensive medication, the use of (86.2%)beta blockers, (68.7%) ACE-inhibitors, (23.7%) diuretics, (3.75%) antianginals were consistently high which are in accordance with the AHA guidelines for Percutaneous Coronary Intervention.[1,5,11]

Dual Anti Platelet Therapy regimen of Aspirin150mg (Acetylsalicylic acid) + Clopidogrel 75mg (P2Y12 inhibitor)(87.5%) was the most commonly prescribed medication to help prevent clotsas recommended by ACC/AHA for management of CAD cases post PCI.[11,12] Double dose regimen of P2Y12 inhibitor was continued up until the 1st month post procedure as supported by studies suggesting a high decline in stent thrombosis, MI post PTCA.[12] Clopidogrel reduced the relative risk of death from any cause by 7% and the relative risk of the combination of re-infarction, stroke or death by 9%.[13] The other P2Y12 inhibitors used in combination with Aspirin were Ticagrelor 90mg (7.5%) and Prasugrel 10mg (5%) use of which was individualized for each patient.

Atorvastatin (100%) was the commonest prescribed hypolipidemic agent, as similar to another study.[9] It exerts cardioprotective effect by stabilizing plaques and help stop heart attacks. Amongst the ACE inhibitors-Ramipril (68.7%) and Beta blockers-Metoprolol (86.25%) were commonly prescribed. Metoprolol which provides cardioprotective effects, reduce recurrent infarction and sudden death (ventricular arrhythmias). Further our study showed that 2/ 6 (33.3%) patients put on Ticagrelor experienced bleeding. The combination of Ticagrelor + Aspirin although associated with a significantly increased risk of bleeding, is also beneficial in reducing in major adverse cardiac/cerebrovascular.[14,15] events(MACE) as compared to clopidogrel[14,15] About 23/54 patients (42.5%) people experienced dry cough with Ramipril, incidence of which is about 5%-35%[16] in patients taking ACE-inhibitors which was then replaced by an ARBi.e., Losartan or Telmisartan. Incidence of cough,which is comparatively lower in this class of drugs compared to ACEI with similar effects on high blood pressure.[16,17] 2/7 patients onAmlodipine, a Calcium channel blocker experienced swelling of ankles following which the drug was stopped immediately. 2/16 on Furosemideexperienced dizziness/light headedness.

CONCLUSION

Sample size used in this study was very small (80) and also the duration of study was short (6 months). Results of this study cannot be extrapolated to general population since study was single centered (i.e. it was carried out in a single government hospital). If other regional hospitals had been included in the study better results would have been generated.Patientspost PTCA, may return with a wide range of complications hence mandatory follow ups after the procedure is necessary. Standard treatment should be continued for at least 12 months in order to get better outcome according to the ACC/AHA guidelines.

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