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A Study on the Effectiveness of Mono and Dual Antiplatelet Therapy in Secondary Prevention of Vascular Events

Suroju Nikhil Chary[1*], Jupaka Rohith[2], Pothappa Rishik Chary[3], Sehrish Tazeen[4], Amatul Ali Sameera[5*]

[1]Sree Dattha Institute of Pharmacy,Sheriguda, Ibrahimpatnam, Hyderabad, Telangana, India*
[2,3,4] Sree Dattha Institute of Pharmacy,Sheriguda, Ibrahimpatnam, Hyderabad, Telangana, India
[5] Sree Dattha Institute of Pharmacy, Sheriguda, Ibrahimpatnam, Hyderabad, Telangana, India*

***Corresponding Author: Dr.Amatul Ali Sameera,** Department of Pharmacy Practice Assistant Professor, Sree Dattha Institute of Pharmacy, Hyderabad, Telanagana**, Suroju Nikhil chary,** Pharm D, Sree Dattha Institute of Pharmacy, Hyderabad, Telanagana,
E-Mail addresses: amatulsameera2207@gmail.com
E-Mail addresses: nikhilsuroju99@gmail.com

Abstract:

The aim of the study was to determine whether addition of aspirin to clopidogrel could have a greater benefit than clopidogrel alone in the prevention of secondary vascular events in patients after TIA or ischemic stroke. Out of the total patients, 34.2 % of patients had recurrence of vascular events. 36.3 % patients reached the primary endpoint in the group receiving dual therapy compared to 20% in the monotherapy group. 31% in dual therapy group had Ischemic stroke as qualifying event compared to 5 % in monotherapy. Our study focused on the prevalence of risk factors in patients with recurrence of vascular events. Risk factors found were previous ischemic stroke in 12 % of dual therapy group and 1% in mono group. Hypertension was found in 30 % of dual group and 3 % of mono group. Diabetes was risk factor in 16% of dual therapy patients and 4% in mono group Hypercholesterolemia was found in 19% of dual group and 4 % of mono group11% of dual therapy patients and 2 % of mono therapy patients were smokers. The primary events were found to have a significant association with gender, risk factors and therapy. No bleeding complications were observed in the study population.

Keywords: Dual Antiplatelet Therapy, Secondary Prevention, Vascular Events

INTRODUCTION

According to the Center's for Disease Control and Prevention (CDC), stroke is the fifth leading cause of death in Americans.[1] The most common type of stroke is ischemic stroke and represents about 87% of all strokes in the United States.[1] More than 795 000 people in the United States have a stroke every year, and about 25% of strokes are recurrent strokes.[1] A recent study demonstrated that minor strokes and transient

ischemic attacks (TIA) are strongly associated with subsequent ischemic stroke.[2] Johnston et al found that the first 48 hours after an initial TIA or minor stroke represents a particularly high-risk period for subsequent ischemic stroke.[3] This study found that half of all recurrent strokes within a 90-day period occur within the first 2 days after initial TIA.[3] Hill et al found stroke risk after TIA to be 9.5% at 90 days and 14.5% at 1 year.[4] These studies highlight the need to provide early, optimised secondary stroke prevention to reduce the risk of recurrent TIA or stroke after an initial ischemic event.

Antiplatelet therapy is a standard treatment for the secondary prevention of non-cardioembolic ischemic stroke based on the American Heart Association/American Stroke Association (AHA/ ASA) guidelines.[5] The use of early antiplatelet therapy with aspirin is supported by large clinical trials that demonstrated reduced rates of secondary stroke recurrence.[6,7] There is also evidence that clopidogrel has superior efficacy and similar safety profile relative to aspirin in reducing the combined risk of ischemic stroke, myocardial infarction, or vascular death in patients with atherosclerotic vascular disease.[8] There is evidence also that the use of combined aspirin plus dipyridamole has superior efficacy relative to aspirin alone in reducing a composite of death from all vascular causes, non-fatal stroke, non-fatal myocardial infarction, or major bleeding complication in patients with TIA or minor stroke of presumed arterial origin.[9] In another study comparing combined aspirin plus dipyridamole with clopidogrel, both agents showed similar rates of recurrent stroke and there was no evidence to suggest the superiority of one of the two treatments.[10] Although there are three antiplatelet agents available for secondary prevention of ischemic stroke (aspirin, clopidogrel and combined aspirin plus dipyridamole), aspirin and clopidogrel dual antiplatelet therapy combination has been widely compared with mono antiplatelet therapy.

While the benefit of monotherapy with aspirin or clopidogrel for secondary stroke prevention has been established, the use of these two antiplatelet agents together for a more aggressive approach to secondary prevention may be considered and has been investigated with divergent findings. The AHA/ASA guideline recommends treatment for 21 days with dual antiplatelet therapy (aspirin and clopidogrel) to be started within 24 hours for early secondary stroke prevention for patients with minor stroke; with the full benefit of early secondary stroke prevention experienced up to 90 days from symptom onset.[5] This recommendation is vastly based on the results of the Clopidogrel in High-Risk Patients with Acute Nondisabling Cerebrovascular Events (CHANCE) trial, which was conducted on Chinese patients, and provides support for considering short-term (21 days) dual antiplatelet therapy within 24 hours for secondary prevention over aspirin alone in patients with a TIA or acute minor ischemic stroke.[11] The CHANCE trial found improved outcomes (risk of stroke) at 90 days and no increased risk of haemorrhage associated with dual antiplatelet therapy.[11] A CHANCE sub study found improved functional outcomes at 90 days for those in the dual antiplatelet therapy group.[12] The POINT trial, which had similar inclusion criteria to the CHANCE but was conducted in an international population, found that 90 days of dual antiplatelet therapy (clopidogrel and aspirin) compared with aspirin alone was associated with a significant reduction in the primary composite end-point of major ischemic events (ischemic stroke, myocardial infarction, or death from ischemic vascular causes), a difference driven by a reduction in recurrent ischemic stroke.[13] The Platelet-Oriented Inhibition in New TIA and Minor Ischemic Stroke (POINT) trial finding of reduction in the primary efficacy outcome of major ischemic events was consistent with the results obtained from the CHANCE trial.[11,13] The POINT trial, however, found significant excess in the number of patients with major haemorrhage in the dual antiplatelet therapy group compared with patients who received aspirin alone and this led to early discontinuation.[13] The Aspirin and Clopidogrel Compared with Clodidogrel Alone after Recent Ischaemic Stroke or Transient Ischaemic Attack in High-Risk patients (MATCH) trial and the Secondary Prevention of Small Subcortical Study (SPS3) trial have shown that delayed, long-term dual antiplatelet therapy has been associated with a non-significant reduction in recurrent stroke compared with mono antiplatelet therapy for patients after a recent ischemic stroke/TIA[14] or lacunar stroke,[15] respectively. These studies also demonstrated that delayed, long-term dual antiplatelet therapy is associated with a statistically significant increased risk of major bleeding when treatment duration lasts 18 months[14] and 3.4 years.[15] In studies of patients with ischemic stroke caused by large artery atherosclerosis, dual antiplatelet therapy has been associated with conflicting results. A study by Wang et al found a significant reduction in recurrent ischemic stroke at 30 days with dual antiplatelet therapy (clopidogrel plus aspirin) compared with mono antiplatelet therapy with aspirin, while a study by Hong et al did not find a significant difference between dual antiplatelet therapy (clopidogrel plus aspirin) and aspirin monotherapy in preventing new symptomatic or asymptomatic ischemic lesions on magnetic resonance imaging within 30 days of their acute ischemic stroke.[16,17] Both of these studies found no significant differences in bleeding in dual antiplatelet therapy compared with mono antiplatelet aspirin monotherapy alone.[16,17] Based on these conflicting results, there is a need for more evidence to further establish the benefit vs risk of dual antiplatelet therapy for secondary stroke prevention. A stroke is a

neurological disorder in which poor blood supply causes cell death when the blood flow to a part of the brain is interrupted by a ruptured or blocked blood vessel. Brain cells which may not receive a steady supply of oxygenated blood may die, resulting in prolonged brain damage.[18]
A study on the effectiveness of mono and dual antiplatelet therapy in secondary prevention of vascular events. The study was aimed to determine whether addition of aspirin to clopidogrel could have a greater benefit than clopidogrel alone in prevention of secondary vascular events in patients after TIA or ischemic stroke.

METHODOLOGY

Study design
It was a retrospective observational study with duration of six months.

Study setting
The study was conducted in the Department of Neurology.

Study period
The study was conducted over a period of six months from July 2023 to December 2023.

Study population
Patients diagnosed with stroke attending the Neurology Clinic between January 2022 to January 2023, conforming to the study criteria.

Study criteria
Inclusion criteria
Patients of age > 40 years who are diagnosed with ischaemic stroke and treated with either mono (Clopidogrel) or dual (Clopidogrel +Aspirin) antiplatelet therapy.

Exclusion criteria
a) Patients who are less than 40 years of age.
b) Patients who are diagnosed with hemorrhagic stroke.

Sources of data
Data were collected from patients' case reports and treatment charts**.**

Study protocol
Patients who met the study criteria were included in the study. Demographic characteristics of the patient including age, sex, occupation, smoking habits were collected. The other necessary findings like type of stroke, history of stroke, past medication history, type of antiplatelet therapy prescribed, number of recurrences were noted from patient's case reports and treatment charts. Data were entered in the data entry sheet. Analysis was based on the first recurrence of a cardiovascular event which was taken as the primary endpoint at any point during the follow-up period. The follow up period was taken as18 months.

Statistical analysis
Demographic characteristics of the study population were expressed in percentage. Relative risks and associations were determined by using the 'chi-square test'. Values of $P \leq 0.05$ were considered to be significant**.**

RESULTS

In this retrospective study, the effectiveness of mono and dual antiplatelet therapy in secondary prevention of vascular events was evaluated in a total of 38 patients with ischemic stroke. The identified patients were either on aspirin plus clopidogrel (dual) or only clopidogrel (mono) antiplatelet therapy.
Among the stroke patients, visiting the neurology clinic, 34.2 % of patients were found to have recurrence of vascular events after the study period. The mean age of the study population was found to be 61.36 years. In the population identified, the number of male patients were found to be 30 and female patients were 8 (Table 1, Figure 1).

The age of onset of the study population was found to be varying from 41 to 90 years. About 31% of the total study population, were in the age group of 61-70 years and they constituted the highest percentage of the total patients.29% were found to be in the 51-60 age group and 20% in the age group of 71-80 years. In the age group of 41-50, the percentage was 14% and 6% were noted in 81-90 age group. (Table 2, Figure 2). Mean age of patients taking dual therapy was found to be 61 and mean age in mono group was 64. In dual therapy group, 31% of patients had Ischemic stroke as qualifying event compared to 5 % in monotherapy.

In the male population, 86.6 % were prescribed dual therapy and 13.3 were prescribed with monotherapy (Table3, Figure3). In the female group, 87.5 % were prescribed dual therapy and 12.5 % were given monotherapy (Table 4, Figure 4).

In the total study population, 86.8 % were having hypertension as the risk factor.52.6 % patients were identified to be having diabetes and 28.9 % of patients had a previous history of stroke 60.5% had hypercholesterolemia and 10.5% were smokers (Table 5, Figure 5).

The mean age of the patients being prescribed dual therapy was found out to be 60.93 and mean age of the patients taking monotherapy was found to be 64.2 (Table 6).According to TOAST classification,2% were found to be having cardio embolism, 20% were having large artery atherothrombosis,12 % with small vessel occlusion in dual therapy group.20 % had cardio embolism and 60 % had small vessel occlusion in mono group (Figure 6).

Previous ischemic stroke, hypertension, diabetes, hypercholesterolemia were foundto be the most common risk factors in the population studied. Previous ischemic stroke was reported in 12 % of dual therapy group and 1% in mono group. Hypertension was found in 30.

% of dual group and 3 % of mono group. Diabetes was found to be a risk factor in 16% of dual therapy patients and 4% in mono group. Hypercholesterolemia was identified as risk factor in 19% of dual group and 4 % of mono group.11% of dual therapy patients and 2 % of mono therapy patients were smokers (Figure 7).

Out of the total study population, 36 patients had ischemic stroke as the qualifying event and 2 patients were having Transient Ischemic Attack. The event rate for ischemic stroke in dual therapy group was found to be 35.48 % and 0.2% for TIA. The event rate for TIA was found to be 0.5 % in dual group. The event rate was found to be 31.2 % in dual therapy group in patients whose age is greater than 61 and 41.1% in patients of age greater than or equal to 61 compared to the 33.3 % in mono group. The event rate in dual therapy group for males was found to be 42.3 % and 0.25 % in mono group. The event rate in dual therapy group for females was found to be 14.2 %. In patients having hypertension 0.4 % event rate was noted in dual therapy compared to 33.3 % in monotherapy. Diabetes patients had 0.25 % event rate in dual therapy and 0.25 % in monotherapy. Event rate in patients with previous ischemic stroke was found to be 1% in dual therapy and 1 % in monotherapy (Table 7).

The frequency of primary endpoint event was found out from the plot between the follow up period in months and number of patients at risk. The number of patients at risk of primary endpoints was found to be more increase in the follow up period in patients receivingdual therapy than those on mono therapy (Figure 8).

Univariate analysis of factors affecting primary endpoint showed that there was an association between recurrence of cardiovascular event and factors like gender, hypertension, previous ischemic stroke, and antiplatelet therapy. Out of the total study population,8 patients having age less than 61 had recurrence with a p value < 0.20.In the age group ≥ 61, five patients were found to have recurrence.12 male patients and 1 female patient were found to have recurrence with a p value < 0.01.In patients with hypertension,13 cases of recurrences were found with a p value < 0.01.In patients with diabetes,5 cases were recorded with a p value < 0.7.In dual therapy group 12 cases of recurrences were noted compared to 1 case in mono therapy group with a p value <0.01 (Table 8).

The relative risk for recurrence were found out in the study population. In patients having ischemic stroke as qualifying event the relative risk of dual therapy was found to be 1.7742 times that of mono therapy. When TIA was the qualifying event, the relative risk was found to be the same for both mono and dual therapy. Relative risk with dual therapy was 0.9412 times than that of mono therapy in patients of age < 61 years and 1.2353 times in age.

≥ 61 years. In male patients, relative risk with dual therapy was 1.6923 times than with mono therapy and in females it was found to be 0.7500 times that of monotherapy. Patients with hypertension had 0.9744 times the risk and those with previous ischemic stroke had 1.2821 times risk than with mono therapy. The relative risk in patients having diabetes was found to be equal in both dual and mono therapy (Table 9)

TABLE 1: Gender wise distribution of total study population

Sl. No	Gender	Percentage of patients
1.	Male	79%
2.	Female	21%

FIGURE 1: Gender wise distribution of total study population

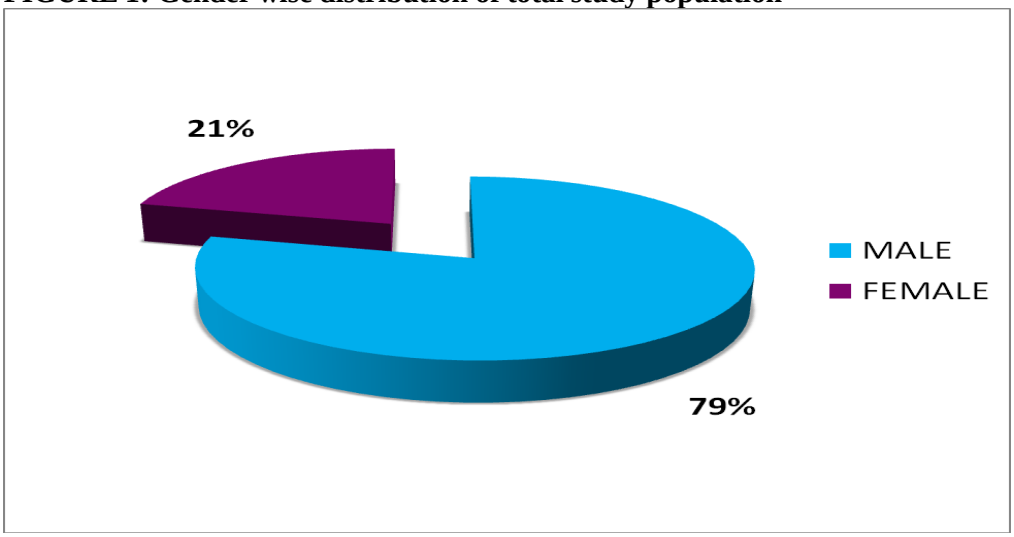


TABLE 2: Age wise distribution of the study population

Sl. No	Age group	Percentage of patients
1.	41-50	14
2.	51-60	29
3.	61-70	31
4.	71-80	20
5.	81-90	6

FIGURE 2: Age wise distribution of the study population

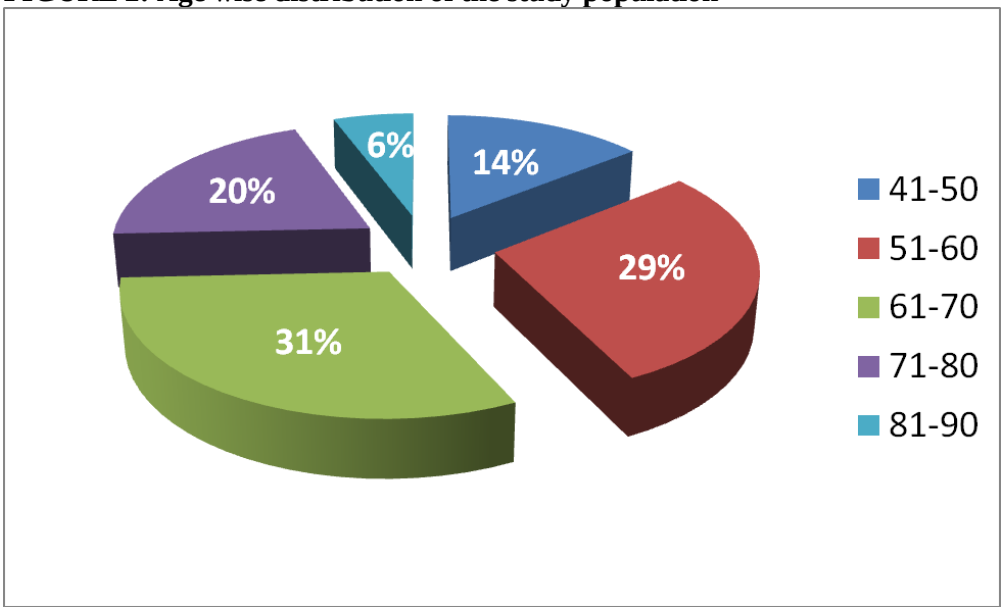


TABLE 3: Type of Antiplatelet therapy prescribed in male patients

MALE

Sl.No	Antiplatelet therapy prescribed	Percentage of patients
1.	DUAL	86.6
2.	MONO	13.3

Dual: Aspirin + Clopidogrel Mono: Clopidogrel

FIGURE 3: Type of Antiplatelet therapy prescribed

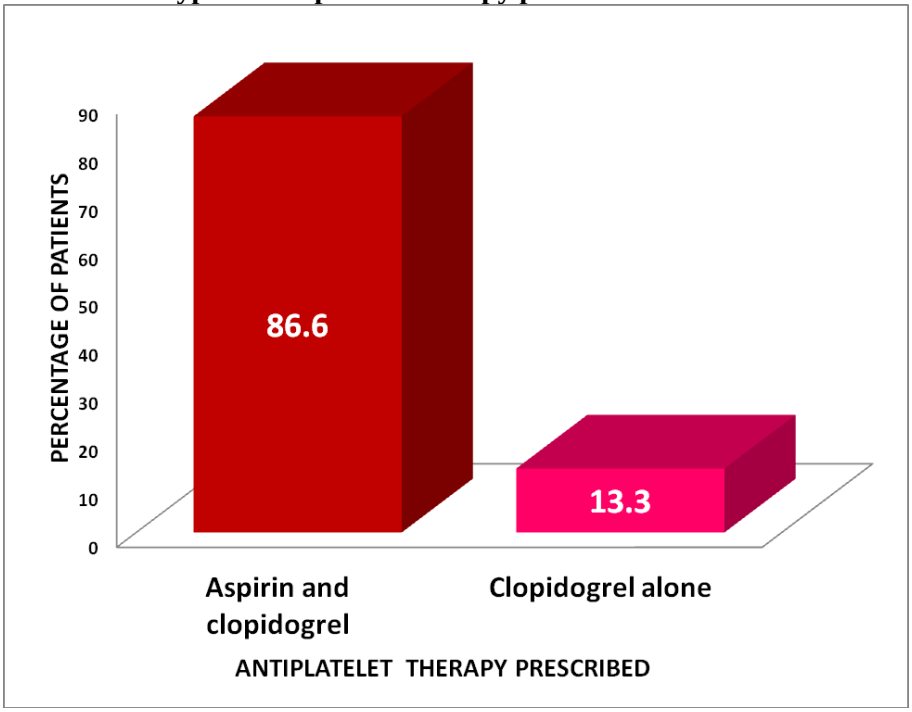


TABLE 4: Type of Antiplatelet therapy prescribed in female patients.

FEMALE

Sl.No	Antiplatelet therapy prescribed	Percentage of patients
1.	DUAL	87.5
2.	MONO	12.5

Dual: Aspirin + Clopidogrel Mono: Clopidogrel

FIGURE 4: Type of Antiplatelet prescribed

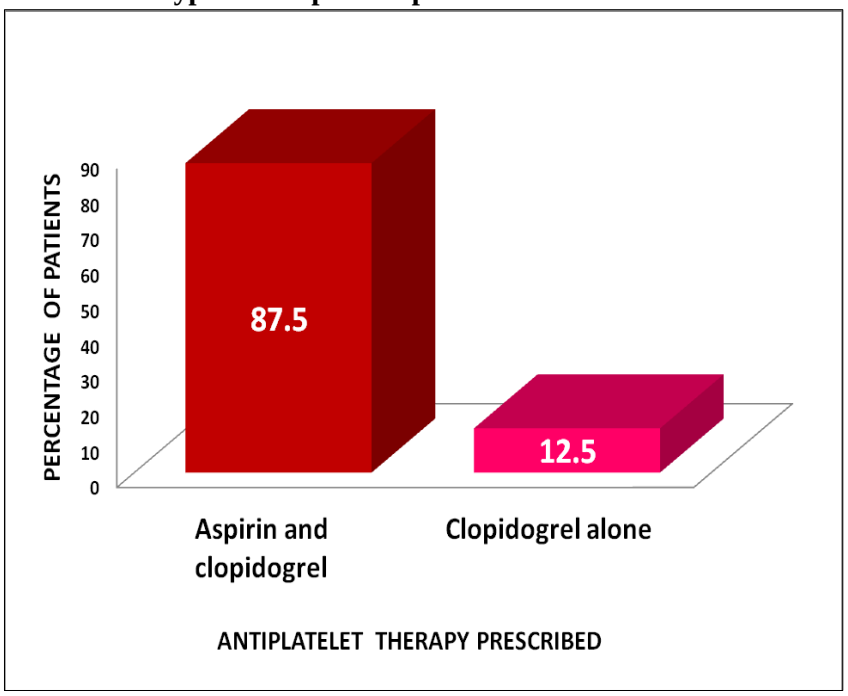


TABLE 5: Risk factors and medical history of the study population

Sl.No	Risk factors	percentage of patients
1.	Hypertension	86.8
2.	Diabetes	52.6
3.	Previous ischemic stroke (beforequalifying event)	28.9
4.	Hypercholesterolemia	60.5
5.	Smoking	10.5

FIGURE 5: Risk factors and medical history of the study population

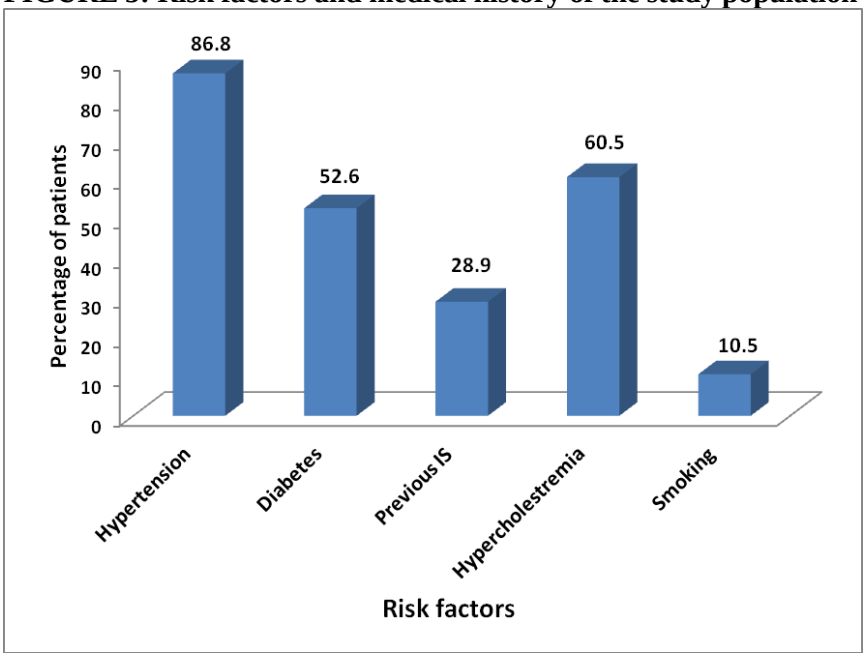


TABLE 6: Baseline characteristics of the study population
Data are expressed as number (%) or mean ± SD

	DUAL (n=33)	MONO (n=5)
MEAN AGE (years ± S.D)	60.93 ± 11.45	64.2 ± 20.64
QUALIFYING EVENT		
IS	31(93.9)	5(1)
TIA	2(6)	0
TOAST CLASSIFICATION		
Cardioembolism	2(6)	1(20)
Large-artery atherosclerosis	20(60.6)	0
Small-vessel occlusion	12(36.3)	3(60)
Stroke of other determinedcause	-	-
Undetermined cause	-	-
RISK FACTORS ANDMEDICAL HISTORY		
Previous IS (before qualifying event)	12(36.3)	1(20)
Hypertension	30(90.9)	3(60)
Diabetes	16(48.4)	4(80)
Hypercholesterolaemia	19(57.5)	4(80)
Past or current smoker	11(33.3)	2(40)

TOAST CLASSIFICATION

FIGURE 7: Characterization of the study population based on Risk factors and medical history

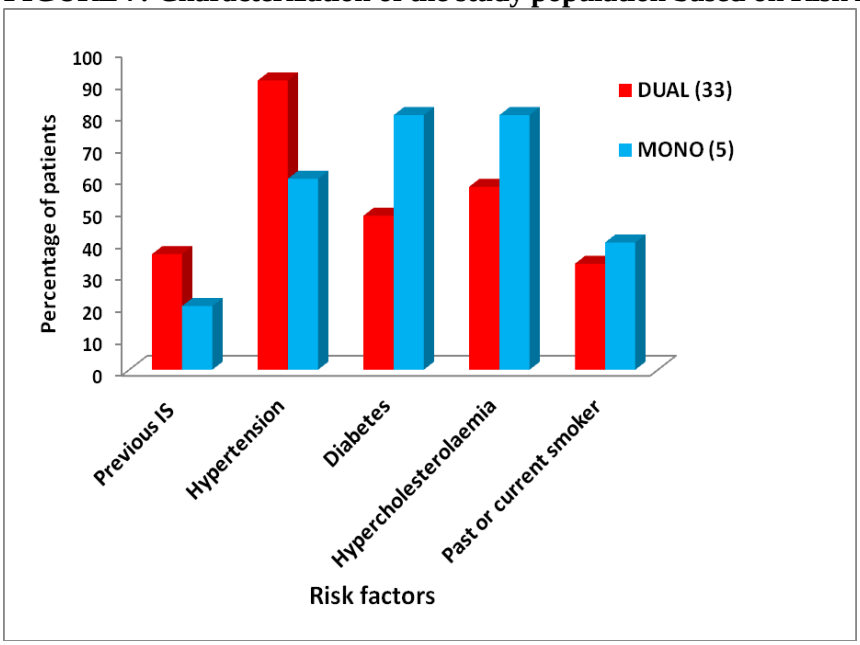
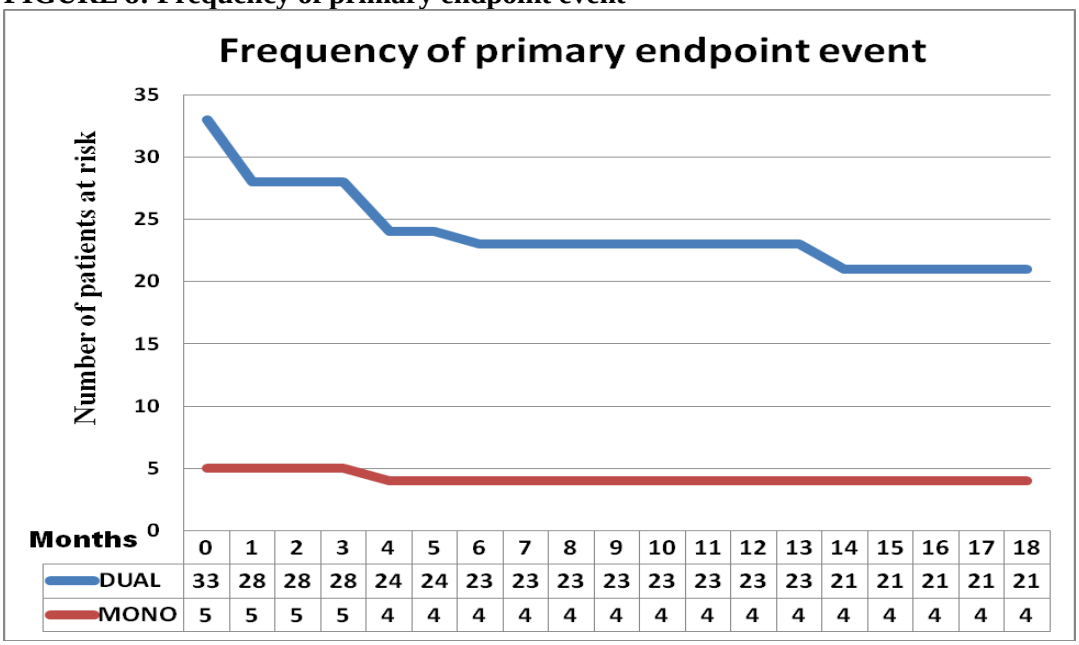


FIGURE 8: Frequency of primary endpoint event



Months	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
DUAL	33	28	28	28	24	24	23	23	23	23	23	23	23	23	21	21	21	21	21
MONO	5	5	5	5	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4

TABLE 7: Rates of primary endpoint event in specified subgroups

Subgroup			EVENT RATE (%)	
		number(n)	DUAL	MONO
Qualifying event	IS	36	35.48	0.2
	TIA	2	0.5	0
Age(years)	<61	18	31.2	0
	≥61	20	41.1	33.3
Sex	Female	8	14.2	0
	Male	30	42.3	0.25
Hypertension	No	5	0	0
	Yes	33	0.4	33.3
Diabetes	No	18	47	0
	Yes	20	0.25	0.25
Previous IS	No	25	0	0
	Yes	13	1	1

TABLE 8: Univariate analysis of factors affecting primary event

Subgroup		Recurrence	Non recurrence	P value
Age < 61		8	15	< 0.20
Age ≥ 61		5	10	
Male		12	18	< 0.01
Female		1	7	
Hypertension	YES	13	20	< 0.01
	NO	0	5	
Previous IS	YES	13	0	< 0.01
	NO	0	25	
Diabetes	YES	5	11	< 0.7
	NO	8	10	
Therapy	MONO	1	4	< 0.01
	DUAL	12	21	

TABLE 9: Relative risk of primary endpoint in different subgroups on dual and mono antiplatelet therapy

Subgroup	Relative risk	95% CI	P value
Ischaemic stroke	1.7742	0.2886 -10.9086	0.5361
TIA	1.0000	0.104 - 9.6139	1.0000
Age < 61	1.9412	0.141 - 26.7183	0.6200
Age ≥ 61	1.2353	0.2261 - 6.7498	0.8073
Male	1.6923	0.2924 - 9.7948	0.5570
Female	0.7500	0.04558 - 12.3407	0.8404
Hypertension	0.9744	0.41 - 2.3153	0.9531
Previous IS	1.2821	0.5717 - 2.8748	0.5465

DISCUSSION

Stroke is an enormous and serious public health problem. Not only is it a common cause of death but also it is a major cause of disability among adults. Approximately, 20 million people suffer from stroke each year and out of these 5 million do not survive. Developing countries account for 85% of global deaths from stroke. Stroke causes functional impairments; 20% survivors require institutional care after 3 months and disability occurs in 15-30%**.** Ischemic stroke is found to be the principal universal cause of disability in the developed world, and the third leading cause of mortality. It is expected that 8–12% of individuals are found to die within the first 30 days of their initial stroke, and patients who survive the initial attack face an enlarged risk of successive vascular events and stroke, as approximately one-quarter of all strokes occurring each year are found to be recurrent. 21.5% of patients are found to be experiencing either a recurrent stroke or a transient ischemic attack (TIA) within the first year following the initial attack**.** Our results showed that out of the total patients, 34.2% had recurrence of vascular events.
Official census data from the United Kingdom in 1981, 1991, and 2001 have persistently shown inequalities in ischemic stroke mortality among the South Asian population. According to the 3 cross-sectional studies based on the national census data in the United Kingdom, the average standard mortality ratios (SMR) in South Asians were 55% and 41% higher in males and females, respectively when compared with the white population**.**
In a Prospective Community-Based Study of Stroke in Kolkata, India **(**, Out of the screened population of 52 377 (27 626 men, 24 751 women), the age standardized prevalence rate of stroke to world standard population was 545.10 (95% CI, 479.86 to 617.05) per 100 000 persons. The age standardized average annual incidence rate to world standard population of first-ever-in-a-lifetime stroke was 145.30 (95% CI, 120.39 to 174.74) per 100 000 persons per year. Thirty-day case fatality rate was 41.08% (95% CI, 30.66 to 53.80). Women had higher incidence and case fatality rates.

In our study the age of the study population varied from 41 to 90 years and the mean age of the study population was found to be 61.36 years. In the population identified, the number of male patients were found to be 78.94% and female patients were 21 %.
A randomized, double-blind, placebo-controlled trial revealed that the most prevalent risk factors at randomization were hypertension (78%), diabetes mellitus (68%) and hypercholesterolemia (56%). 26% of patients had previous ischemic stroke and 19% had transient ischemic attack. Most patients had one additional risk factor, as defined in the inclusion criteria at study entry, and 20% had two or more. In our total study population, 86.8 % were having hypertension as the risk factor, 52.6% patients were identified to be having diabetes and 34.2 % of patients had a previous history of stroke. Previous ischemic stroke, hypertension, diabetes, hypercholesterolemia was found to be the most common risk factors in the population studied. Previous ischemic stroke was reported in12 % of dual therapy group and 1% in the mono group. Hypertension was found in 30 % of dual group and 3 % of mono group. Diabetes was found to be a risk factor in 16% of dual therapy patients and 4% in mono group. Hypercholesterolemia was identified as risk factor in 19% of dual group and 4 % of mono group.11% of dual therapy patients and 2 % of mono therapy patients were smokers.
The only South Asian studies that classified their stroke population according to the TOAST taxonomy found a higher prevalence of lacunar strokes (42.7% and 68%) compared with large vessel infarctions (26% and 10%). In our study, according to TOAST classification, majority of the patients were found to have large artery atherothrombosis.
Of the 700,000 strokes that occur yearly in the United States, 200,000 are recurrent events. The risk of recurrent stroke has been reported as 11.5% at 7 days, 6% to 15% at 30 days, and 18.5% at 3 months. Following a transient ischemic attack (TIA), the estimated risk of recurrent stroke was 8% at 7 days, 11.5% at 1 month, and 17.3% at 3 months. However, in our study, out of the total study population, 36 patients had ischemic stroke as the qualifying event and 2 patients were having Transient Ischemic Attack. The event rate for ischemic stroke in dual therapy group was found to be 35.48 % and 0.2% for TIA. The event rate for TIA was found to be 0.5 % in dual group.

In a MATCH trial conducted in 507 centers, the event rates for the primary endpoint in different predefined patient subgroups indicated a slight favour for adding aspirin to clopidogrel compared with placebo to

clopidogrel in most subgroups. No interactions were reported between covariates and treatment effect, apart from patient age and treatment effect. In our study, the relative risk for recurrence were obtained from the study population and our results indicate a favour for monotherapy (clopidogrel alone) compared to dual (clopidogrel + aspirin). In patients having ischemic stroke the relative risk of dual therapy was found to be 1.7742 times than that of dual therapy. The relative risk was found to be the same for both mono and dual therapy in patients having TIA. Relative risk with dual therapy was 0.9412 times than dual therapy in patients of age < 61years and 1.2353 times in age ≥ 61 years. In male patients, relative risk with dual therapy was 1.6923 times thanthat with mono therapy and in females it was found to be 0.7500 times that of mono. Patients with hypertension had 0.9744 times the risk and those with previous ischemic stroke had 1.2821 times risk than with mono therapy. The relative risk in patients having diabetes was found to equal in both dual and mono therapy.

CONCLUSION

The aim of the study was to determine whether addition of aspirin to clopidogrel could have a greater benefit than clopidogrel alone in the prevention of secondary vascular events in patients after TIA or ischemic stroke. Out of the total patients, 34.2 % of patients had recurrence of vascular events. 36.3 % patients reached the primary endpoint in the group receiving dual therapy compared to 20% in the monotherapy group. 31% in dual therapy group had Ischemic stroke as qualifying event compared to 5 % in monotherapy.

Our study focused on the prevalence of risk factors in patients with recurrence of vascular events. Risk factors found were previous ischemic stroke in 12 % of dual therapy group and 1% in mono group. Hypertension was found in 30 % of dual group and 3 % of mono group. Diabetes was risk factor in 16% of dual therapy patients and 4% in mono group hypercholesterolemia was found in 19% of dual group and 4 % of mono group11% of dual therapy patients and 2 % of mono therapy patients were smokers.

In our study, we also observed the prescribing trends in patients, and noted that dual therapy was found to be more prominent than monotherapy. Dual therapy did not appear to have any added advantage over monotherapy as the event rate of recurrence of vascular eventwere more in patients under dual therapy. The primary events were found to have a significant association with gender, risk factors and therapy. No bleeding complications were observed in the study population.

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