MATERIAL
&
METHODS
MATERIAL AND METHODS

This study was conducted prospectively over a period of 16 months from August 2002 to November 2003 in the Department Of Medicine, Maharani Laxmi Bai Medical College, Jhansi.

Subject: - This was a randomized single blind study. 60 patients of recent ischemic stroke were included for the study. 6 patients were lost on follow up. All the patients were followed for one year. Subjects were evaluated initially for signs, symptoms & risk factors and followed up according to a predesigned & pretested working Proforma shown in Annexure-1.

Subject selection: - it was done for the study among the patients of recent ischemic stroke who attended the –

➢ General Medicine O.P.D
➢ Emergency Department

Eligible patients were determined by diagnosis of ischemic stroke by the detailed history about onset and progression of symptoms and
neurological examination for the site and cause and confirmation by CT scan head.

**Inclusion criterion-** A) Ischemic stroke with onset >1 week, but <6 months prior to randomization, B) Hemorrhage ruled out by CT, C) Persistent neurological signs (> 1 wk), D) Non cardio embolic stroke.

**Exclusion criterion-** A) Severe cerebral deficit likely to leave the patient Bedridden or Demented, B) Uncontrolled hypertension, C) Scheduled for major surgery, D) Severe renal or hepatic insufficiency, E) History of a haemostatic disorder or systemic bleeding, F) History of hematological abnormalities, G) Contraindication to clopidogrel or aspirin, H) Severe co morbidity with life expectancy < 3 yrs.

Patients were randomly separated into two-treatment groups, with Group-A received aspirin 325 mg./day and the group B received clopidogrel 75 mg./day. Mean follow up time was one year.

**Techniques for diagnosis and follow up:-**

- Initially the diagnosis of acute ischemic stroke was made by history, clinical examination and confirmed by non-contrast head CT scan.
Patients were followed up for one year at regular intervals to see any deterioration in neurological signs or new focal neurological signs, recurrent stroke \{confirmed by CT-scan\}, myocardial infarction \{Diagnosis based on the presence of 2
of the three elements; a) chest discomfort, b) ECG changes of ischemia, c) a rise and fall in serum cardiac markers}, peripheral vascular disease, bleeding tendencies, gastric discomfort and/or peptic ulcer (peptic ulcer diagnosed by upper GI endoscopy), rashes, neutropenia or thrombocytopenia {diagnosed by CBC } or any adverse effect mentioned earlier.

The data was compiled and assessment of outcome of the study was done by standard statistical methods in terms of –

a) Positive results: that was, benefits of both the drugs such as reduction of combined risk of recurrent ischemic stroke, MI and other vascular events causing mortality and morbidity in patients of acute ischemic stroke.

b) Negative results: that was, severity and frequency of side effects & complications.

The incidences of positive & negative results were compared in both the groups, & the differences, were tested for statistical significance\(^6\).
The patients of recent ischemic stroke who attended the General Medicine O.P.D. And Emergency Department of MLB Medical College, Jhansi.

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**Randomisation done in 2 groups**

GROUP-A given 325 mg/d of aspirin

GROUP-B given 75mg/d of Clopidogrel

**Follow up for 1 yr to see primary & adverse outcome**

**Primary outcome**- Occurrence of ischemic stroke, MI, or vascular death.

**Adverse outcomes**, which were looked for, were intracranial and extra cranial hemorrhage, any abnormal bleeding, upper and lower gastrointestinal disturbances, neutropenia, thrombocytopenia, and skin...

**Assessment & analysis of positive & negative results**