Comparative Analysis of Early and Late Angiography Post - Fibrinolysis in ST - Segment Elevation Myocardial Infarction Patients

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Abstract: Aims and objectives: To compare the major cardiovascular events (MACE) and other cardiac side effects during in hospital care and to compare clinical outcome profile. To study and compare the complications and functional improvement of heart. Methods: Data collected retrospectively from department records. This study included all patients presented with ST elevation Myocardial infarction who were successfully fibrinolysed. Patients with failed fibrinolysis, unstable angina and elective procedure patients were excluded. They were grouped into early angiography (n=49) and late angiography (n=64) based on time duration after fibrinolysis. Retrospective data analysis done by comparing objectives of the study between both the groups. Results: The mean age of population was 55±6.8. The baseline characteristics like demographics and comorbidities were comparable between both the groups. Physiological status, mechanical and electrical complications of acute myocardial infarction (AMI) at presentation were not significantly different. Laboratory parameters also comparable. Re - infarction occurred in 1 (2%) patient in group A and 2 (3%) patients in group B with P value 0.58. Death occurred in 1 (1.5%) patient in group B and none in group A with p value 0.61. Recurrent MI, readmission and cardiac function status at 30 days period was also statistically insignificant between two groups. Conclusions: In patients presented with STEMI after successful fibrinolysis, both early angiography (with in 24hours) and late angiography has similar incidence of MACE. Improvement in cardiac function and complications during hospitalisation are comparable between late and early angiography following successful lysis.

Keywords: Acute myocardial infarction, Early coronary angiography, Fibrinolysis, Late coronary angiography, ST elevation myocardial infarction

1. Introduction

Acute Myocardial infarction (AMI) is one of the most important cardiovascular events and is responsible for significant mortality and morbidity in India. India has a higher relative incidence of ST - segment elevation myocardial infarction (STEMI) compared to Western countries. The diagnosis of STEMI is based on symptoms, signs and 12 - lead electrocardiogram (ECG). A history of Coronary artery disease and radiating pain in the neck, jaw, or upper arm are the symptoms suggestive of AMI. Atypical symptoms are shortness of breath, nausea/vomiting, weakness, palpitations or fainting. Access to STEMI treatment in India has been delayed by several factors, including a lack of information on PCI facilities [1, 2]. The reperfusion strategies are primary PCI and timely thrombolysis. [2]

Thrombolysis is an effective method of treatment in patients diagnosed with STEMI and unable to undergo PCI on time. According to the latest ESC guidelines, it is recommended to be done within 12 hours of the onset of symptoms. If thrombolysis fails or symptoms persist or there is hemodynamic/electrical weakness, rescue PCI is performed [1]. On the other hand, after successful treatment with fibrinolysis, early PCI within 3 - 24 hours of onset of symptoms is recommended [2].

There are many trials comparing pharmacolysis and primary PCI as primary revascularization strategy [3 - 9]. An ideal time interval from completion of fibrinolysis to PCI has not been established.

A meta - analysis of large trials found a time delay from 1.7 hours to 17 hours. A review of six RCTs found that delay to fibrinolysis was not a predictor of death/re - infarction at one year and recurrent ischemia at 30 days, but latency to symptom onset was death [8, 10 - 12]. In 2017, the European Society of Cardiology (ESC) recommended a delay of 2 - 24 hours from fibrinolysis to angiography [2]. However, in a place like India where there is limited access to medical care and many delays and less number of 24hours working cath lab facility, there is still a need to define the time from completion of fibrinolysis to angiography. There is less research in this area in the Indian subcontinent.

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With this background, we designed a retrospective cross-sectional study to compare routine early angiography (2 - 24 hours) and late angiography (24 - 72 hours).

2. Material and Methods

A retrospective cross-sectional study was conducted among patients who presented in STEMIdo emergency room in a tertiary care hospital in southern part of India during the study period from Jan 2022 to June 2022. Institutional Ethical committee approval obtained.

Enrolment Criteria
Retrospective comparative study
Study period: 6 months (January 2022 to June 2022)
Study place: Department of cardiology, Chengalpattu government medical college
Study population: Patients aged above 18 years who had STEMI
Inclusion criteria:
Following successful fibrinolysis
All consecutive STEMI patients in whom fibrinolysis was successful and undergone angiography.
1) Early angiography group includes those patients who underwent angiography within 3 - 24 hours
2) Late angiography group includes STEMI patients who underwent angiography from 24 - 72 hours

Exclusion criteria:
1) Failed fibrinolysis, unstable angina and elective procedure patients
2) Patient who has not undergone angiography after pharmacolysis

Definitions

STEMI:
1) New onset J - point ST - elevation in two contiguous leads with the cut - point of ≥1 mm in all leads other than V2 – V3.
2) In V2 and V3 cut off point of ≥2 mm in men ≥40 years,
   ≥2.5 mm in men < 40 years, or ≥1.5 mm in women irrespective of age

Presence of LBBB (left bundle branch block): Based on Smith - Sgarbossa criteria
• Concordant ST elevation more than 1 mm in leads with positive QRS complex
• Concordant ST depression more than 1 mm in V1 - V3
• Discordant ST elevation more than 5 mm in leads with negative QRS complex [13]

Sample Size -
Based on a previously published study on timing of coronary angiography (CAG) following successful thrombolysis [14], the sample size was calculated:
\[ N = Z^2 \cdot \frac{p(1-p)}{\text{error}^2} \]
\[ = 1.96^2 \cdot \frac{0.38(1-0.38)}{0.05^2} \]
\[ = 38 + 4 = 42 \]

which yields a sample of 42 which is similar to the past previous year’s admissions in our hospital. Hence we have kept it as a sample for the study.

3. Study Methodology

Data from hospital records of all the patients aged above 18 years who were admitted to our emergency room with STEMI from Jan 2022 to June 2022 and were analyzed retrospectively after obtaining consent and enrolled in the study.

After enrollment, subjects were compared based on time delay from fibrinolysis to angiography as early CAG and late CAG. Primary and secondary objectives were compared between the two groups. Baseline variables were recorded. Primary objectives i.e., major adverse cardiovascular events (MACE) and other cardiac side effects during in hospital care and clinical outcome profile among both groups were compared. Secondary objectives are also compared in the form of re-admission with in 30 days after discharge and improvement in cardiac function during follow up. All outcome measures were entered in the study proforma for all enrolled subjects.

History details, Clinical examination Details, Blood Examination Details, Electrocardiogram, Echocardiography, Coronary angiography, Treatment Details were also recorded.

Each enrolled subject was followed until discharge and were advised about the compliance of medications and were taught to recognize symptoms early. Patients were followed at regular visits at cardiology OPD and enquired regarding any coronary artery disease symptoms. Those who did not come for follow up for 30 days, telephonic call was made, and the details recorded.

Statistical analysis
Microsoft excel spreadsheets for data entry and SPSS version 22 software for statistical analysis. Categorical information is presented in the form of frequency and proportion. Chi-square test or Fischer test (for 2x2 tables only) was used as statistical significance test for qualitative data. Continuous data are presented as mean and standard deviation. Independent t-test or Mann Whitney U-test were used as significance tests, respectively, to determine the difference between two variables in terms of quantity and quality. Graphical presentation by using bar and line charts. A p value of <0.05 (probability of true result) was considered significant after considering all the rules of the test.

Statistical software: MS Excel, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA)

4. Results

A total of 113 patients were included in the study. Among them, there are 49 patients underwent early angiography and 64 patients underwent late angiography.
**Baseline Characteristics**

Median age in both groups was 54 years. Male population constituted 75.51% in early CAG group and 70.31% in late CAG group. All base line characteristics like age, sex distribution, weight, duration of chest pain prior to ER visit, mean needle time (early CAG: 7.51 ± 3.22 h and late CAG: 7 ± 3.01 h; p = 0.38), type of STEMI, number of patients undergone PTCA, complications of MI at presentation and co - morbidity were comparable between both early and late angiography groups with no significant difference statistically (Table 1).

**Comparison of outcome variables**

Major Adverse Cardiovascular Events (MACE) in the form of all - cause mortality (2.08 vs.0; p =0.406), re infarction (4.08% vs.3.13%; p= 0.487), and stroke were compared between both the groups (fig.1). No significant difference noticed between them. Secondary outcome measures like readmission within 30days of discharge (early CAG Group: 2.04% vs.3.13%; late CAG; p =0.48) and left ventricular function (fig 2) at review were also not statistically different. (Table 2).

5. Discussion

Current study showed that following successful fibrinolysis performing CAG within 3 - 24 hours or 24 - 72 hours did not show any difference in the MACE rate and secondary outcome measures. Recent ESC guidelines recommended the time delay of 2 - 24hours for CAG after successful fibrinolysis [2]. In developing nations like India, multiple social factors influence the time delay for treatment of STEMI. S. Guha et al. researched many Indian trials and registries in their latest update [1]. The median time of presentation from symptom onset ranging from 4.5 hours to 13 hours [13 - 19]. In our study mean time of presentation 6.53 ± 3.1 hours. OAT trial revealed comparable long term adverse events of late angiography & PCI from 3 - 28 days and Optimal medical therapy alone in stable patients [20 - 21]. Brave - II study showed PCI from 12 - 48hours decreased infarct size significantly [6]. The recommendation of existing guidelines and previous studies have shown that a good number of patients did not perform CAG within 24 h. Costa C et al. showed coronary intervention done after 24 hours, which was outside the frame of recommended guidelines, did not show increased mortality [24].

NORDISTEMI, GRACIA - 2, TRANSFER - AMI, a few studies focused on pharmaco - invasive therapy compared to standard therapy. In these trials it was proved that transfer for PCI is better than conservative management [9, 10&12]. WEST, FAST - AMI, STREAM trials compared early routine PCI with Primary PCI [8&25 - 26]. However to the best of our knowledge, there is limited research on patients who were presented after 24 hours of fibrinolysis to the PCI facilitated health care unit.

Kilic S et al. in their prospective observational study, feizi B et al. in their cohort study and sharma et al. in their prospective observational studies tried to compare the relation of MACE rate and time delay from fibrinolysis [14, 29].

Our Study compared early angiography and revascularization (3h to 24h) with late angiography and revascularization (24h - 72 h). Time interval groups were comparable to study by sharma et al. even though ours is a retrospective comparative study where as Kilic S et al. grouped the study population into 24 - 72h and >72 h, Feizi et al. grouped the study population into CAG done less than 48h and more than 48hours. Similar to above studies in our study it was found out that time delay more than 24 hours did not result in increased MACE, re hospitalization or decrease in LV systolic function (table.3)

6. Conclusion

Our Study did not show any MACE, increased re - admission with delay of PCI more than 24 hours. We suggest to consider our study as a preliminary observation and supporting the need of conducting more qualitative and quantitative studies to re - define the time targets for routine PCI strategy in Indian population in the following settings as recommended in ESC guidelines in 2017.

1) Patients presenting late after symptom onset (12 - 48 h)
2) Patients presenting after 48 hours
3) Time delay for start of fibrinolysis to angiography

7. Limitations

Our study is a single centered, short duration and a retrospective design with limited supportive evidence

**References**


prospective Myocardial
Ostojic Savonitto Martinoff:


Négri PC, Merwaha R, Paday D. Multicentre HP ACS registry. Indian Heart J.2015; 07–027


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Table 1: Comparison of baseline characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Early CAG (N=49)</th>
<th>Late CAG (N=64)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Mean ± SD)</td>
<td>54.53 ± 8.49</td>
<td>58.44 ± 5.5</td>
<td>0.06</td>
</tr>
<tr>
<td>Male Gender (percentage)</td>
<td>75.15</td>
<td>70.5</td>
<td>0.53</td>
</tr>
<tr>
<td>Duration of chest pain (Mean ± SD)</td>
<td>6.53 ± 3.1</td>
<td>6.27 ± 2.92</td>
<td>0.643</td>
</tr>
<tr>
<td>Time to Fibrinolytic therapy (Mean ± SD)</td>
<td>7.51 ± 3.22</td>
<td>7 ± 3.01</td>
<td>0.388</td>
</tr>
<tr>
<td>Types of STEMI (percentage)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AWMI</td>
<td>61.22</td>
<td>51.56</td>
<td>0.305</td>
</tr>
<tr>
<td>IWMI</td>
<td>38.78</td>
<td>48.44</td>
<td></td>
</tr>
<tr>
<td>Co morbidities (percentage)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>HTN</td>
<td>44.9</td>
<td>31.25</td>
<td>0.317</td>
</tr>
<tr>
<td>T2DM</td>
<td>26.53</td>
<td>31.25</td>
<td></td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>4.08</td>
<td>3.13</td>
<td></td>
</tr>
<tr>
<td>HTN and T2DM</td>
<td>16.33</td>
<td>10.94</td>
<td></td>
</tr>
<tr>
<td>Smoking (percentage)</td>
<td>51.02</td>
<td>42.19</td>
<td>0.351</td>
</tr>
<tr>
<td>Vessel involved</td>
<td></td>
<td></td>
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<tr>
<td>Single Vessel Disease</td>
<td>41</td>
<td>50</td>
<td>0.28</td>
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<tr>
<td>Double vessel disease</td>
<td>2</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Triple vessel disease</td>
<td>6</td>
<td>6</td>
<td></td>
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<tr>
<td>Recanalized Vessel</td>
<td>0</td>
<td>0</td>
<td></td>
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<tr>
<td>PTCA done</td>
<td>81.63</td>
<td>78.13</td>
<td>0.646</td>
</tr>
<tr>
<td>LMCA disease</td>
<td>6.12</td>
<td>9.38</td>
<td>0.527</td>
</tr>
<tr>
<td>Complications of MI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mitral valve rupture</td>
<td>1 (2.04)</td>
<td>3 (4.69)</td>
<td>0.432</td>
</tr>
<tr>
<td>Ventricular Septal rupture</td>
<td>0 (0)</td>
<td>1 (1.56)</td>
<td></td>
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<tr>
<td>Shock</td>
<td>6 (12.24)</td>
<td>7 (10.94)</td>
<td></td>
</tr>
<tr>
<td>Electrical complications</td>
<td>2 (4.08)</td>
<td>1 (1.56)</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Comparison of Outcome variables

<table>
<thead>
<tr>
<th>Variables</th>
<th>Early CAG</th>
<th>Late CAG</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All cause mortality</td>
<td>1 (2.04)</td>
<td>0 (0)</td>
<td>0.406</td>
</tr>
<tr>
<td>Re infarction</td>
<td>2 (4.08)</td>
<td>2 (3.13)</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>0 (0)</td>
<td>2 (3.13)</td>
<td></td>
</tr>
<tr>
<td>EF at follow up</td>
<td>0.489</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Readmission with in 30days</td>
<td>1 (2.04)</td>
<td>2 (3.13)</td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Comparison with previous studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Type of study</th>
<th>Place</th>
<th>Defining time</th>
<th>Outcome variables</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sharma AK, et al. 2018</td>
<td>Prospective observational single center study</td>
<td>UP (India)</td>
<td>24 hours</td>
<td>Allcause mortality Reinfarction Hospitalisation</td>
<td>Statistically insignificant</td>
</tr>
<tr>
<td>Feizi B, et al.2017</td>
<td>Cohort Study</td>
<td>Iran</td>
<td>48 hours</td>
<td>Recurrent MI Mortality Bleeding No reflow phenomenon</td>
<td>Statistically insignificant</td>
</tr>
<tr>
<td>Our study</td>
<td>Retrospective single center study</td>
<td>TN (India)</td>
<td>24 hours</td>
<td>Allcause mortality Mortality cardiac Stroke Re infarction Hospitalization</td>
<td>Statistically insignificant</td>
</tr>
</tbody>
</table>