Clinical Value of 12-Lead Electrocardiography to Predict the Long-Term Prognosis of GISSI-1 Patients

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OBJECTIVES We evaluated the prognostic relevance of the extent of myocardial injury, as measured by a standard electrocardiographic (ECG) method, on the patients’ long-term prognosis, its time dependence and its relation to fibrinolytic therapy efficacy.

BACKGROUND Many clinical and instrumental variables influence the short- and long-term prognoses of patients with acute myocardial infarction (MI). The extent of myocardial injury is relevant to predict both the short-term prognosis and the benefit of fibrinolytic treatment.

METHODS In 8,731 patients with MI enrolled in the Gruppo Italiano per lo Studio della Sopravvivenza nell’Infarto (GISSI-1) study, the number of ECG leads with ST-segment elevation was used to define the extent of myocardial injury and four different severity groups: A, B, C and D, with ST-segment elevation in two or three leads, four or five leads, six or seven leads and more than eight leads, respectively.

RESULTS At 10 years, the mortality rates were 36.6%, 41.0%, 47.9% and 51.2% in groups A, B, C and D, respectively. At 30 days, according to the extent of myocardial injury, the relative risk (RR) of death was significantly higher for groups B, C and D, compared with group A (RR 1.19 and 95% confidence interval [CI] 1.06 to 1.34 for group B; RR 1.54 and 95% CI 1.31 to 1.80 for group C; RR 2.01 and 95% CI 1.69 to 2.39 for group D). At one-year follow-up, the RR of death remained higher for groups C and D, whereas, subsequently, the extent of myocardial injury did not influence the RR of death. At 10 years, the differences in fibrinolytic treatment benefit between the four groups were similar to those at hospital discharge.

CONCLUSIONS At 10 years, the survival rate appears to be related to the extent of myocardial injury, as evaluated by ST-segment elevation on the admission ECG. (J Am Coll Cardiol 2002;39:1594–600) © 2002 by the American College of Cardiology Foundation

The substantial advances in the treatment of acute myocardial infarction (MI) achieved in the last two decades can be attributed mainly to a prompt and early recovery of optimal infarct-related coronary artery flow by pharmacologic therapy and/or mechanical intervention.

An early definition of the short-term prognosis is an important step in the decision-making process of selecting the best therapy. Lee et al. (1) have recently stated that the prognosis of individual patients can be accurately estimated through consideration of various characteristics, including age, a medical history, the pathophysiologic presentation of the infarction and medical treatment at hospital admission. However, there is a lack of detailed measures of ST-segment elevation and left ventricular function.

Among the many demographic, clinical and instrumental variables that influence the short- and long-term prognoses of acute MI, the extent of injury and left ventricular function have significant relevance. The extent of injury can be measured by different techniques, but standard electrocardiography (ECG) is the most widely available and the most easily and promptly achievable method (2,3).

A method to assess the short-term prognostic significance of the extent of myocardial injury, evaluated by standard ECG at admission for acute MI, has been developed from the Gruppo Italiano per lo Studio della Sopravvivenza nell’Infarto (GISSI-1) study (4). This large, randomized trial, including 11,712 patients with acute MI within 12 h from the onset of symptoms, conducted between February 1984 and June 1985, showed the efficacy of streptokinase versus standard therapy in reducing in-hospital mortality, and thus began the thrombolytic era (5). The GISSI-1 study even showed that the extent of myocardial injury, assessed as the number of standard ECG leads with ST-segment elevation, was more relevant than the site in determining in-hospital mortality and the efficacy of thrombolytic therapy (4).

The aim of the present study is to evaluate the time dependence and long-term prognostic significance of the same index of extent of myocardial injury and its correlation with the benefit of thrombolytic therapy after 10 years.

METHODS

Study group. The GISSI-1 protocol has been fully described elsewhere (5). In brief, 11,712 patients with MI who...
were admitted to the 176 participating coronary care units were randomized to streptokinase (SK) or control within 12 h from the onset of symptoms.

The results of in-hospital mortality and one-year survival have been previously published (5,6). The 10-year follow-up results have also been published, tracing the vital status for all randomized patients through the census of their towns of residence by means of prepaid return-mail questionnaires. Information on death from any cause at the 10-year follow-up was available for 10,889 (93%) of the 11,712 patients originally randomized, with no significant differences between SK-treated patients and control subjects (7).

For each patient, a standard ECG was obtained before randomization and centrally analyzed. For the purpose of the present study, all patients with a previous MI, bundle branch block and an unconfirmed diagnosis were excluded from the analysis. Using these criteria, 8,731 patients were selected: 6,976 (79.9%) were male; 5,789 (52.5%) were 65–75 years of age; 885 (10.1%) were >75 years old; 4,372 (50.07%) were assigned to routine treatment; and 4,359 (49.93%) were treated with 1.5 million units of SK. The demographic characteristics were similar to those of the whole population enrolled in the GISSI-1 trial.

**ECG analysis.** All ECGs were reviewed centrally by two clinicians who had no knowledge of the randomized treatment or the patients’ outcome, and the following information was gathered: the presence of ST-segment elevation, ST-segment depression and Q-waves ≥0.03 s in each lead, the presence of major conduction disturbances and the infarct site.

The criteria to classify the different infarct locations have been previously described (4): anterior MI represents Q-waves and/or ST-segment elevation ≥2 mm in leads V1 through V6, I and aVL; inferior and/or posterior MI represents Q-waves ≥0.030 s and voltage ≥1/4 of the R-wave in lead aVF and/or 1-mm ST-segment elevation in leads II, III and aVF; R > S in lead V1 or V2, compared with a previous ECG, or with a lower voltage in the precordial leads that followed; lateral MI represents Q-waves >0.030 s and voltage ≥1/4 of the R-wave in isolated leads I and aVL and/or isolated leads V5 and V6, and multiple sites represent concomitant signs of anterior or lateral plus inferior MI. The criteria to define the different myocardial injury sizes, according to the presence of ST-segment elevation ≥1 mm in the limb leads and ≥2 mm in the precordial leads, have been previously reported. In the presence of inferior MI, any precordial ST-segment depression was considered as indicative of myocardial injury at the opposite location and counted as ST-segment elevation if ≥2 mm. The number of leads with ST-segment elevation was used to classify four groups: patients in group A (small myocardial injury) had ST-segment elevation in 2 to 3 leads; patients with ST-segment elevation in 4 or 5 leads comprised group B (modest injury); those with ST-segment elevation in 6 or 7 leads comprised group C (large injury); and those with ≥8 leads with ST-segment elevation comprised group D (extensive injury).

**Statistical analysis.** PROGNOSTIC SIGNIFICANCE OF THE EXTENT OF MYOCARDIAL INJURY. The association between the extent of myocardial injury and other baseline characteristics was analyzed by using the chi-square test. For survival analysis, the Kaplan-Meier method was used, and

<table>
<thead>
<tr>
<th>Demographic and Clinical Variables</th>
<th>Group A (n = 3,539)</th>
<th>Group B (n = 2,198)</th>
<th>Group C (n = 1,631)</th>
<th>Group D (n = 1,363)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (male)</td>
<td>2,885 (81.5)</td>
<td>1,729 (78.7)</td>
<td>1,256 (77.1)</td>
<td>1,106 (81.1)</td>
<td>0.001</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65</td>
<td>2,450 (69.2)</td>
<td>1,445 (65.7)</td>
<td>1,027 (63.0)</td>
<td>867 (63.6)</td>
<td>0.001</td>
</tr>
<tr>
<td>65–75</td>
<td>783 (22.1)</td>
<td>517 (23.5)</td>
<td>414 (25.4)</td>
<td>341 (25.0)</td>
<td></td>
</tr>
<tr>
<td>&gt;75</td>
<td>305 (8.6)</td>
<td>236 (10.7)</td>
<td>190 (11.6)</td>
<td>154 (11.3)</td>
<td></td>
</tr>
<tr>
<td>Delay from onset of symptoms (h)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–3</td>
<td>1,899 (53.7)</td>
<td>1,111 (50.5)</td>
<td>835 (51.2)</td>
<td>736 (54.0)</td>
<td>0.08</td>
</tr>
<tr>
<td>3–6</td>
<td>1,074 (30.5)</td>
<td>715 (32.5)</td>
<td>501 (30.7)</td>
<td>431 (15.8)</td>
<td></td>
</tr>
<tr>
<td>&gt;6–9</td>
<td>388 (10.9)</td>
<td>257 (11.7)</td>
<td>197 (12.1)</td>
<td>144 (10.6)</td>
<td></td>
</tr>
<tr>
<td>&gt;9–12</td>
<td>176 (5.0)</td>
<td>111 (5.0)</td>
<td>93 (5.7)</td>
<td>50 (3.7)</td>
<td></td>
</tr>
<tr>
<td>Killip class</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>2,749 (77.7)</td>
<td>1,599 (72.7)</td>
<td>1,082 (66.3)</td>
<td>830 (60.9)</td>
<td>0.001</td>
</tr>
<tr>
<td>II</td>
<td>642 (18.1)</td>
<td>480 (21.8)</td>
<td>420 (25.7)</td>
<td>419 (30.7)</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>73 (2.1)</td>
<td>67 (3.1)</td>
<td>83 (5.1)</td>
<td>60 (4.4)</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>62 (1.7)</td>
<td>42 (1.9)</td>
<td>40 (2.4)</td>
<td>51 (3.7)</td>
<td></td>
</tr>
<tr>
<td>Control subjects</td>
<td>1,780 (50.3)</td>
<td>1,100 (50.0)</td>
<td>807 (49.5)</td>
<td>685 (50.3)</td>
<td>0.96</td>
</tr>
<tr>
<td>Streptokinase-treated patients</td>
<td>1,759 (49.7)</td>
<td>1,098 (50.0)</td>
<td>824 (50.5)</td>
<td>678 (49.7)</td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as the number (%) of patients.
the p value was determined by the log-rank test (8). Multivariate analysis, according to the Cox model, was used to estimate the relative risk (RR) and the 95% confidence interval (CI); all variables with a statistically significant difference on the univariate analysis were included in the model. Data were analyzed according to the intention-to-treat principle. All p values are double-sided; values of $p < 0.05$ were considered as conventionally significant.

To test the time dependence of the RR for the extent of myocardial injury over the 10-year period, a test for the proportional hazards assumption was performed by using multivariate analysis according to the Cox model and including the extent of myocardial injury as the time-dependent covariate (9). Such analysis was also adjusted for confounding variables (e.g., age, gender, time from onset of symptoms, Killip class, systolic blood pressure, randomized treatment).

**EFFECT OF THROMBOLYTIC TREATMENT AMONG THE GROUPS WITH DIFFERENT EXTENTS OF MYOCARDIAL INJURY.** The modified Mantel-Haenszel method (10,11) was used to calculate univariate estimates of the proportional treatment effects among the four different groups of the extent of myocardial injury.

To ascertain the heterogeneity of the effect of thrombolytic treatment after 10 years among the groups with different extents of myocardial injury, the Cox regression model, including age, gender, time from symptom onset, Killip class and systolic blood pressure, was used. The improvement, in terms of the goodness-of-fit obtained by comparing a model including only the main effects with a model also including interaction variables, was measured by means of the likelihood ratio test, which has an asymptotic chi-square distribution. To make some allowance for the effects of multiple comparisons, values of $p < 0.01$ were considered as conventionally significant for this analysis.

**RESULTS**

Among the 8,731 patients evaluated in this study, information on vital status after 10 years was obtained for 8,093 patients (92.6%); this figure is similar to that observed for the whole population of the GISSI-1 trial (93%), and, like the main trial, a loss of information was equally distributed among the four groups with different extents of myocardial injury (6.8% of patients in group A; 7.4% in group B; 7.8% in group C; and 7.4% in group D).

The distribution of demographic characteristics and the delays from the onset of symptoms were not balanced among the four different groups. Patients in groups C and D were older, with a higher Killip class, whereas groups B and C had more females (Table 1).

Of the 8,731 patients, 7,759 (88.9%) were discharged alive from the hospital. The in-hospital mortality was slightly lower than that of the whole population of the GISSI-1 trial, as patients with left bundle branch block and with ST-segment depression, which are associated with a significantly worse prognosis, were excluded from the present study (12,13).

**Survival according to the extent of myocardial injury.** As previously described (4), in-hospital mortality was significantly different among the four groups with myocardial injury: 6.5% in group A; 9.6% in group B; 14.3% in group C and 21.7% in group D. The mortality rate was slightly higher after 30 days and was still significantly different.
among the groups. At 10 years, the estimated mortality rates, as evaluated by survival curves, were 36.6% in group A, 41.0% in group B, 47.9% in group C and 51.2% in group D (Fig. 1). The curves indicate that the difference in survival of the four different groups of patients is still significant at 10 years ($p < 0.0001$ by the log-rank test).

Influence of the extent of myocardial injury on long-term prognosis. As described in the Methods section, one of the aims of this study was to test the time dependence of the RR of death, according to the extent of myocardial injury during the 10 years after the MI. The test for the proportional hazards assumption ($p < 0.0001$) suggests that the RR of death for the extent of myocardial injury is not constant but varies over time. For this reason, we calculated the adjusted RR of death at 30 days after MI and for each year of the subsequent 10 years (based on the number of survivors at each previous year) for the four groups, taking patients with small extent of myocardial injury as the reference group and considering the extent of myocardial injury as the time-dependent variable. At 30 days after the index event, the risk of death was significantly higher in groups B (RR 1.19, 95% CI 1.06 to 1.34), C (RR 1.54, 95% CI 1.31 to 1.80) and D (RR 2.01, 95% CI 1.69 to 2.39), compared with group A. At one year, the risk of death was significantly higher in groups C and D (1.25 and 1.32, respectively), although slightly different when compared with that at 30 days. After the first year from the index event, the extent of myocardial injury did not seem to further influence the long-term prognosis, as no significant differences in the risk of death at 5 and 10 years were observed between the four groups. Figure 2 shows the adjusted RRs of death at 30 days and 1, 5 and 10 years after MI. A different representation of the same results is provided in Table 2, which shows the mortality rates of the four groups, calculated for survivors at each of the follow-up periods.

Effect of fibrinolysis in the groups with different extents of myocardial injury. The difference in survival achieved by in-hospital SK treatment was still significant at the 10-year follow-up ($p = 0.02$ by the log-rank test). The estimated cumulative 10-year mortality rate was 45.0% for the 5,860 patients allocated to thrombolytic therapy and 46.9% for the 5,852 allocated to the control group, corresponding to an absolute benefit of 19 lives saved for every 1,000 patients treated with fibrinolytic therapy (7). As for the benefit distribution among the groups with different extents of injury, long-term survival data are symmetrical with those observed at hospital discharge (Fig. 3). The chi-square test for heterogeneity on 3 degrees of freedom was 6.99 ($p = 0.03$), suggesting the presence of a qualitative interaction between the effect of fibrinolytic treatment and the different extents of myocardial injury. In other words, the direction of the effect is maintained in all the four groups, but the size of the effect remains statistically significant only in those with a larger extent of injury. At hospital discharge, the difference in favor of SK was present in all the subgroups, but reached statistical significance only in patients with modest (group B), large (group C) or extensive (group D) myocardial injury. The lack of a significant benefit observed at hospital discharge for group A, with small infarcts, did not change (Table 3) at 10 years.

![Figure 2. Plots of relative risk (RR) for the three groups with larger extents of myocardial injury versus the group with the smaller extent of injury over the different periods of follow-up.](image)

### Table 2. Mortality Rates for Study Patients at the Different Periods of Follow-Up

<table>
<thead>
<tr>
<th></th>
<th>30 Days (Number of Patients)</th>
<th>1 Year (Number of Patients)</th>
<th>5 Years (Number of Patients)</th>
<th>10 Years (Number of Patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group B</strong></td>
<td>216/2,198 (9.83) [8]</td>
<td>94/1,974 (4.76) [14]</td>
<td>234/1,866 (12.54) [140]</td>
<td>307/1491 (20.59) [2]</td>
</tr>
<tr>
<td><strong>Group C</strong></td>
<td>242/1,631 (14.84) [6]</td>
<td>85/1,383 (6.15) [12]</td>
<td>184/1,286 (14.31) [110]</td>
<td>227/992 (22.88) [—]</td>
</tr>
</tbody>
</table>

Data are presented as the number of deaths per total number of patients in the group (percentage of patients) (number of patients lost at follow-up).
**DISCUSSION**

Our study shows that the simple method of standard ECG allows a good evaluation of the extent of myocardial injury, providing a good prognostic index for patients with acute MI in the short- and long-term periods. Accordingly, a concise reflection on some points appears appropriate.

**Influence of the extent of myocardial injury on long-term prognosis.** First of all, the remarkable advances in the quality and efficacy of the recent methods of pharmacologic coronary reperfusion have improved the short-term prognosis of patients with acute MI (14). However, the mortality rate remains high, as the expected mortality rate per year for patients between 51 and 59 years old, with no signs of ischemic heart disease, is 2.93% (95% CI 2.05 to 4.18), according to Rosengren et al. (15), whereas the mortality rate for the whole GISSI-1 population mortality is 7.3% in the first year after hospital discharge and 4.1% per year from the second to the tenth year of follow-up. However, it is well known that the risk of death varies among patients with different demographic and clinical data or instrumental features and is related to the effectiveness and early administration of therapy. Then, it is crucial to identify at hospital discharge.

![Figure 3](image_url). Survival curves for patients included in the four groups with different extents of myocardial injury and different treatments. C = control; SK = streptokinase.

**Table 3.** Estimated Mortality and Absolute Benefit of Streptokinase Treatment According to Extent of Infarct

<table>
<thead>
<tr>
<th>Infarct extent</th>
<th>Randomized Patients (n)</th>
<th>Mortality (%)</th>
<th>p Value</th>
<th>Absolute Benefit per 1,000 (95% CI)</th>
<th>Estimated Mortality (%)</th>
<th>p Value†</th>
<th>Absolute Benefit per 1,000 (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>4,359</td>
<td>9.7</td>
<td>12.5</td>
<td>0.005</td>
<td>40.9</td>
<td>0.011</td>
<td>24 (11)</td>
</tr>
<tr>
<td>2 or 3 leads</td>
<td>1,759</td>
<td>6.1</td>
<td>6.9</td>
<td>NS</td>
<td>36.5</td>
<td>NS</td>
<td>4 (17)</td>
</tr>
<tr>
<td>4 or 5 leads</td>
<td>1,098</td>
<td>7.7</td>
<td>11.5</td>
<td>0.005</td>
<td>37 (12-62)</td>
<td>NS</td>
<td>7 (22)</td>
</tr>
<tr>
<td>6 or 7 leads</td>
<td>802</td>
<td>12.1</td>
<td>16.6</td>
<td>0.01</td>
<td>45 (11-79)</td>
<td>NS</td>
<td>46 (26)</td>
</tr>
<tr>
<td>8 or 9 leads</td>
<td>678</td>
<td>19.5</td>
<td>23.9</td>
<td>0.05</td>
<td>45 (1-88)</td>
<td>0.004</td>
<td>78 (28)</td>
</tr>
</tbody>
</table>

*The 10-year estimated mortality values are derived from the life-tables. †By the log-rank test.

C = control subjects; CI = confidence interval; NS = not significant; SD = standard deviation; SK = streptokinase.
admission those at higher risk of death, in order to select the best strategy (fibrinolysis or percutaneous transluminal coronary angioplasty, or both) to achieve the optimal myocardial salvage in the shortest time.

Lee et al. (1) have defined an accurate formula based on the demographic and clinical data observed at hospital admission, in order to calculate the probability of death within 30 days. They advocate the importance of the availability of a simple method to define the extent of the ischemic injury in progress.

The prognostic relevance of the extent of myocardial injury, as evaluated by the number of standard ECG leads with ST-segment elevation, has been previously emphasized for the in-hospital period by our group (4) and other investigators (16,17). Subsequently Hathaway et al. (18) defined the relationship between ST-segment deviation, in whichever direction, and mortality. More recently, Morrow et al. (19) have included the anterior location of ST-segment elevation among the 10 most important variables useful to build up a convenient bedside clinical score for MI risk assessment at presentation. The information is perfectly consistent with our previously reported results (4): the anterior MI site is usually associated with a larger extent of injury, as evaluated by standard ECG. In our previous study, we showed that in the group with anterior infarcts, there was a confluence of patients with very different extents of myocardial injury. The extent of injury varied from 2 or 3 leads in 4.6% of patients to 8 or 9 leads in ~30% of patients. The mortality rate of patients with a smaller anterior MI similar to that observed in patients with 2 or 3 leads in the inferior site, validating the hypothesis that the size of myocardial injury is more relevant than its site in predicting the in-hospital outcome. The present study indicates that the extent of myocardial tissue under jeopardy at hospital admission also influences the long-term prognosis.

The second remarkable point is derived from the observation that the four survival curves mainly diverge in the first period of observation, and the survival difference is sustained up to 10 years (Fig. 1). In addition, Figure 4, showing the four survival curves for patients discharged alive from hospital, clearly shows that there is a divergence during the first year, and then the slopes become similar. The RR plot in Figure 2 confirms that at one year, the RR of death from MI is significantly higher for patients with a larger extent of myocardial injury. As the first month and, at the most, the first year are the critical periods, it is clinically important to have available an index of the extent of injury that can be easily derivable from the standard ECG and widely and promptly usable not only in the coronary care unit but also in the mobile unit assisting the patient at the very first contact (e.g., at home, in the office or even on the road). The availability of information on the extent of myocardial injury could allow us to triage patients to the most appropriate level of care in hospitals with different therapeutic facilities.

Effect of fibrinolysis in the groups with different extents of myocardial injury. The third point hinges on the fact that, once again, the results of this study prove that the larger the extent of myocardial injury, the better is the benefit from thrombolytic therapy in terms of long-term survival. Rentrop et al. (20) proposed, for the first time, the hypothesis that the benefit of fibrinolytic therapy depends

![Figure 4. Survival curves for patients with different extents of myocardial injury and discharged alive from the hospital.](image_url)
on the extent of jeopardized myocardium and on the delay between the onset of symptoms and drug administration. Their hypothesis concerned the final extent of myocardial infarct. Many studies have subsequently confirmed the consistency of this hypothesis, which can be demonstrated by the mortality rate, starting from the in-hospital period up to 10 years, as well as the survival rate of patients with a larger myocardial injury size, as seen in the present study. The observation can be assumed as an incentive to increase the efforts to achieve in the shortest possible time the best reperfusion therapeutic approach in these patients at high risk, not as an indication to select patients for thrombolytic therapy, given the fact that in terms of myocardial salvage, a positive effect can be achieved in smaller infarcts as well.

**Study limitations.** The proposed method of evaluation does not seem to be as precise as the one evaluated by Aldrich et al. (16), which is nevertheless more elaborate, suggesting a different approach for anterior and inferior myocardial sites, and it requires the application of a mathematical formula, so without a calculator, which is not always at hand, it may be difficult to use.

Moreover, the method proposed cannot be applied to one-fourth of the whole population of patients with acute MI with ST-segment depression, left bundle branch block and a previous MI (21), nor probably to patients admitted after 12 h, due to the spontaneous regression of ST-segment elevation, especially when spontaneous reperfusion occurs.

Finally, the different results observed after thrombolytic treatment must be considered as a result of subgroup analysis, with all of the consequent limitations. They cannot be considered as criteria for not treating patients with smaller infarcts. The only real and important conclusion that can be drawn from the evaluation reported here is that patients with a larger extent of myocardial injury must be treated with the most effective and quickest reperfusion method to achieve survival.

**Conclusions.** Among the many demographic and clinical variables that influence the prognosis of patients with MI, from the decision-making point of view, only a few can be useful to define the best therapeutic strategy that can significantly improve the patient’s prognosis. The extent of myocardial injury is probably the most important; this can be immediately and simply established by standard ECG, which has a valid albeit not anatomically precise prognostic value.

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**REFERENCES**


