Review: no evidence exists that thrombolysis is better than heparin for reducing the risk of recurrent pulmonary embolism and death


In patients with acute pulmonary embolism (PE), is initial thrombolysis more effective than heparin for reducing the risk of recurrent PE and death?

METHODS

Data sources: Medline and EMBASE/Excerpta Medica (1980 to January 2003), Cochrane Library (Issue 1, 2003); and hand searches of reference lists of retrieved articles and abstracts of conference proceedings.

Study selection and assessment: published and unpublished randomised controlled trials (RCTs) with proper randomisation that compared thrombolysis with heparin for initial treatment of patients with objectively diagnosed symptomatic PE, and used objective methods to assess clinical outcomes. 2 independent reviewers assessed the methodological quality of individual trials based on allocation sequence and concealment, blinding, and follow up.

Outcomes: a composite of recurrent PE or death. Secondary outcomes were PE, death, major bleeding, non-major bleeding, and intracranial haemorrhage.

MAIN RESULTS

11 trials (n = 748) met the selection criteria. 3 RCTs used random number tables or programs for generating randomised allocation sequences, 5 had adequate concealment, 3 had blinding of patients and investigators, and none reported the number of patients lost to follow up. All studies included patients with symptomatic PE, and 5 trials also included patients with major PE (haemodynamic instability). Thrombolysis included urokinase, streptokinase, and tPA. Meta-analysis was done using a fixed effects model. Meta-analysis of 11 trials showed that thrombolysis and heparin did not differ for the composite outcome of recurrent PE or death or for individual components of the composite endpoint (table). The thrombolysis and heparin groups did not differ for major bleeding (11 trials) or intracranial haemorrhage (11 trials) (table). However, more patients who received thrombolysis had non-major bleeding than those who received heparin (table).

CONCLUSIONS

No evidence exists that initial thrombolysis is better than heparin for reducing the risk of combined recurrent pulmonary embolism (PE) or death, major bleeding, or intracranial haemorrhage in unselected patients with acute PE. Thrombolysis increases the risk of non-major bleeding.

A modified version of this abstract appears in Evidence-Based Medicine.

Thrombolysis v heparin for recurrent pulmonary embolism (PE)*

<table>
<thead>
<tr>
<th>Outcomes during hospital stay or to 30 days</th>
<th>Thrombolysis</th>
<th>Heparin</th>
<th>RRR (95% CI)</th>
<th>NNT (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrent PE or death</td>
<td>6.7%</td>
<td>9.6%</td>
<td>31% (95% CI)</td>
<td>Not significant</td>
</tr>
<tr>
<td>Recurrent PE</td>
<td>2.7%</td>
<td>4.3%</td>
<td>32% (95% CI)</td>
<td>Not significant</td>
</tr>
<tr>
<td>Death</td>
<td>4.3%</td>
<td>5.9%</td>
<td>29% (95% CI)</td>
<td>Not significant</td>
</tr>
<tr>
<td>Major bleeding</td>
<td>9.1%</td>
<td>6.1%</td>
<td>38% (95% CI)</td>
<td>Not significant</td>
</tr>
<tr>
<td>Non-major bleeding</td>
<td>10.0%</td>
<td>10%</td>
<td>140% (95% CI)</td>
<td>13 (7 to 36)</td>
</tr>
<tr>
<td>Intracranial haemorrhage</td>
<td>0.5%</td>
<td>0.3%</td>
<td>4% (95% CI)</td>
<td>Not significant</td>
</tr>
</tbody>
</table>

*Abbreviations defined in glossary; RRR, RRI, NNT, NNH, and CI calculated from control event rate and odds ratio (with CI) in article using a fixed effects model.
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