Authors' objectives
To assess the efficacy and safety of thrombolytic therapy in pulmonary thromboembolism.

Searching
The authors searched the MEDLINE, EMBASE, Current Contents, HealthSTAR and the Cochrane Library databases (January 1985- November 1997) and also performed a manual search of the references from the retrieved studies for additional relevant studies.

Study selection
Study designs of evaluations included in the review
Randomised clinical trials (RCTs).

Specific interventions included in the review
Thrombolytic agents (streptokinase (UK), urokinase (SK), recombinant- tissue plasminogen activator (rt-PA)) in the intervention group and heparin for the control group. Dosages and route of administration varied between the studies.

Participants included in the review
Pulmonary thromboembolism (PTE) patients whose ages in the studies ranged from a mean of 47 to 65.7 years of age.

Outcomes assessed in the review
Mortality, relapses, and risk of haemorrhage assessed by angiographical, gammagraphical, and/or haemodynamic measures.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the authors performed the selection.

Assessment of study quality
The methodological quality of the clinical trials was appraised according to Jadad's scoring criteria (0-5 points) (see Other Publications of Related Interest no.1). Two evaluators independently assessed the quality of the trials.

Data extraction
Two evaluators independently and blindly extracted the data regarding the characteristics of the studies and their results. Data were extracted for the categories of study identification, treatment groups and numbers of participants, mean age (years), male/female ratio, duration of symptoms prior to randomisation, expected PTE or DVT, basal perfusion deficiency (%), last major surgical trauma or immobilisation, presence of cancer, efficacy measurement and follow-up time, therapies to compare, and schedule of the covered therapies.

Methods of synthesis
How were the studies combined?
Pooled odds ratios (ORs) with 95% confidence intervals (CIs) were calculated using both fixed-effect and random-effects models.

How were differences between studies investigated?
The authors do not state how differences between the studies were investigated.
Results of the review

Eight RCTs were included in the review with 237 participants in the intervention groups and 216 participants in the control groups. Follow-up ranged from 3 days to 12 months.

The average quality score using Jadad’s criteria was 1.87 points, median 2 points, mode 1 point.

In the qualitative synthesis, 7 out of 8 RCTs found no differences in the resolution of the thrombus among both treatment groups 24 hours after the start of therapy. For mortality, no statistical differences were found between mortality rate of patients with PTE treated only with heparin and that of patients treated also with some type of thrombolytic drug. There are no differences either when comparing mortality rate of patients treated with thrombolytics with that of controls (heparin) if those treated with rt-PA and those treated with SK and UK are studied separately.

For relapses, the meta-analytic study of the clinical trials identified has not shown any statistically significant association between the type of therapy received and the presence of not of angiographically and/or gammagrphically confirmed thromboembolic relapses.

For risk of haemorrhage, PTE patients receiving thrombolytic therapy show a 2.5 fold higher risk of suffering some type of haemorrhage than PTE patients not receiving it (OR = 2.6, 95% CI: 1.6, 4.4). The results of the meta-analytic study regarding major bleeding show an OR = 1.87, 95% CI: 0.97, 3.61.

Authors’ conclusions

There is little scientific evidence on the efficacy and effectiveness of thrombolytic therapy in PTE regarding the clinically relevant mid and long-term outcomes, such as mortality, relapses, remaining dyspnea, tolerance to exercise of quality of life, and regarding the efficacy and effectiveness of this therapy in the subpopulation of haemodynamically unstable patients with massive PTE.

CRD commentary

In this brief report, the authors have stated their research question but not the inclusion and exclusion criteria. The literature search appears thorough but the authors do not state their search terms so it is not possible to replicate the review without additional information. Since there is no mention of language restrictions or searching for unpublished material it is possible that additional relevant studies may have been missed. The quality of the included studies was formally assessed but the authors have not reported on how the articles were selected, and they do state how many of the reviewers were involved in the data scoring and extraction.

The data extraction is reported in tables and text. The statistical pooling was appropriate where performed. No tests for homogeneity were reported and there was no discussion of the methodological and data limitations in the review.

The authors conclusions appear to follow from the results but these should be viewed with caution because of the stated methodological limitations of the review.

This review is based on a brief report taken from a full report on the effectiveness of this treatment. That full report (in Spanish) may contain additional information stated as missing in this abstract (See Other Publications of Related Interest no.2 and no.3).

Implications of the review for practice and research

Practice: The authors state that because long-terms effects of this treatment are unknown and it is clearly associated to a higher risk of haemorrhage, its routine use in everyday clinical practice is not advised.

Research: The authors state that further research is needed on the use of thrombolytic agents in PTE to solve the remaining uncertainties of the efficacy of this treatment compared to standard treatment in the target population or subpopulation.
Bibliographic details

Original Paper URL

Other publications of related interest


Indexing Status
Subject indexing assigned by CRD

MeSH
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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.