Percutaneous clot removal devices in acute ischemic stroke: a systematic review and meta-analysis

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CRD summary
The authors concluded that percutaneous mechanical embolectomy to treat acute ischaemic stroke was feasible and may be an option for some patients, but that randomised controlled trials were required. The very poor quality of evidence currently available suggests that these tentative conclusions are justified.

Authors' objectives
To evaluate the use of percutaneous clot removal devices for acute ischaemic stroke.

Searching
MEDLINE and EMBASE were searched without language restriction from 2000 to March 2006. Abstracts from the International Stroke Conference (2000 to 2006) were handsearched, as were the reference lists of articles retrieved. Device manufacturers were contacted.

Study selection
Studies of percutaneous clot removal after acute ischaemic stroke were eligible for inclusion. Acute ischaemic stroke was defined as symptoms resulting from arterial occlusion, with onset preceding treatment by less than 24 hours. Outcomes of interest were technical success, functional outcome and survival. Technical success was defined as restoration of flow, demonstrated by a Thrombosis in Myocardial Infarction (TIMI) flow grade of 3. A good functional outcome was defined as a modified Rankin score of 2 or less.

The mean age of participants in the included studies was 63 years. About 60 per cent of participants were male. The mean pre-embolectomy National Institutes of Health Stroke Survey (NIHSS) score was 20.5 (range 6 to 41). The most frequently occluded vessels were the posterior circulation and the middle cerebral and carotid arteries. The mean time to intervention was 10.6 hours (range one to 216 hours). Mechanical embolectomy was performed using a snare, laser or ultrasonographic device or a clot retrieval device or clot disruption/aspiration device. More than half the participants in the review received thrombolysis concurrent with the intervention. Clinical outcomes were compared within the included study population (procedure group) between participants in whom the procedure restored arterial flow (the clot was accessed by the device and flow was restored) and those in whom this was not achieved. Clinical outcomes were also compared between the procedure group and a historically concurrent registry cohort who had had stroke or transient ischaemic attack and were matched for age, sex and NIHSS score. Other outcomes reported in the review included rates/grades of clot accessibility, postoperative flow and haemorrhage. For comparative outcomes, studies were included only if individual patient data were available.

Two reviewers independently selected studies for inclusion.

Assessment of study quality
Study validity was measured with the Newcastle-Ottawa Scale, which assesses study design, patient selection, length of follow up and blinding of outcomes assessment. Up to four points were allocated for compliance with quality criteria. The authors did not state how the assessment was performed.

Data extraction
The authors apparently extracted individual patient data from the primary studies, including both data on the procedure and on subsequent clinical outcomes. Findings were classified into two groups according to whether the procedure completely restored flow. Unpublished data were sought from primary study authors as required. The authors stated neither how the data were extracted for the review nor how many reviewers performed the data extraction.

Methods of synthesis
An odds ratio (OR) was calculated from the odds of clinical events in each group, with 95% confidence intervals (CIs). Subgroup analyses were conducted to examine whether effects differed according to the device used or other clinical variables. The Chi² test or Wilcoxon rank sum test were used to assess the significance of any associations. The pooled population was also compared with a matched registry cohort (where sufficient data were available) by calculating ORs and 95% CIs from the event rates in the two populations. Multivariate logistic regression was used to adjust for age, sex and NIHSS score.

Results of the review
The review included 22 studies (n=147): 14 case series (n=139, sample size range two to 34) and eight single-case reports. Out of a maximum of 4 points for quality, 13 studies scored 1 point, four scored 2 points, three scored 3 points and two scored 4 points. Among the case series, five studies enrolled consecutive patients, eight studies based patient selection on a priori criteria and four studies conducted blinded outcomes assessment. All studies had an adequate duration of follow-up.

Outcomes within procedure group: The odds of death were significantly higher among patients in whom the procedure did not restore arterial flow than among those in whom it did (OR 2.4, 95% CI: 1.14, 5.03, p=0.02). The odds of a good functional outcome were significantly higher in the latter group (OR 3.94, 95% CI: 1.90, 8.17, p=0.002) and this finding remained statistically significant after adjustment for initial NIHSS score.

Other findings were also reported in the review, including the results of subgroup analyses.

Outcomes in procedure group versus matched cohort: A good functional outcome was significantly more likely in the procedure group (n=84) than in the matched cohort (n=84) (unadjusted OR 4.4, 95% CI: 1.9, 10.00, p<0.001; adjusted OR 14.9, 95% CI: 4.4, 50.0, p<0.001). There was a non-significant trend for 90-day mortality to be higher in the matched cohort (n=70) than in the procedure group (n=116) (adjusted OR 2.2, 95% CI: 0.98, 5.1, p=0.06).

Authors’ conclusions
Percutaneous mechanical embolectomy for acute ischaemic stroke was feasible and may be an option for some patients, but randomised controlled trials (RCTs) were required.

CRD commentary
The objectives and inclusion criteria of the review were clear. Relevant sources were searched without language restriction for both published and unpublished studies. No search terms were reported. Steps were taken to minimise the risk of bias and error in study selection by having more than one reviewer make decisions independently, but it was not clear whether this also applied to data extraction and validity assessment. Authors of primary studies were contacted for additional information as required. It was uncertain whether the pooling of individual patient data was appropriate, in view of the uncontrolled design and strong potential for selection bias and confounding and/or publication biases in the primary studies. For the same reasons, the results of comparison with a matched cohort were difficult to interpret. Overall the clinical import of the review findings was unclear. The very poor quality of evidence currently available suggests that the authors’ tentative conclusions are justified.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that RCTs were needed to evaluate the short- and long-term outcomes of percutaneous mechanical embolectomy to treat acute ischaemic stroke.

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