Authors' objectives
To determine the efficacy of established therapeutic regimens in ongoing variceal bleeding at the time of initial endoscopy.

Searching
MEDLINE was searched from 1964 to February 2000; the keywords and combinations used were reported in the paper. Additional studies were identified by examining the reference lists of all available review articles and the primary studies. Articles published in any language were considered.

Study selection
Only randomised controlled trials (RCTs) were eligible for inclusion.

Specific interventions included in the review
Studies using ligation, sclerotherapy or medical treatment were eligible for inclusion. Studies were excluded if they compared combined treatments, e.g. endoscopic treatment after administration of vasoactive drugs, or dealt with preventive endoscopic treatments.

Four of the included studies compared two medical regimens with each other; 6 compared sclerotherapy with ligation; 2 compared medical and endoscopic regimens; and one study compared vasopressin with oesophageal tamponade. The time until endoscopy, where reported, ranged from emergency (immediate) to within 24 hours.

Participants included in the review
Patients with acute variceal bleeding. Studies were eligible for inclusion if ongoing bleeding was clearly defined (e.g. oozing or spurting) and all patients were bleeding at the time of initial endoscopy, or if the data were reported for the subgroup of patients with ongoing bleeding. The mean age of the participants in the included studies ranged from 35 to 61 years. Studies of gastroenterological bleeding other than oesophageal variceal bleeding were excluded.

Outcomes assessed in the review
The outcome assessed was initial control of bleeding, as defined by the included studies. Trials without a clear definition of control of bleeding were excluded.

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 reviewers performed the selection.

Assessment of study quality
The authors used a modified quality scoring system to assess validity. This quality scoring system used criteria derived from Nicolucci et al. (see Other Publications of Related Interest no.1) and Pagliaro et al. (see Other Publications of Related Interest no.2) to address the following: randomisation, efficacy of randomisation, sample size, and external validity. The maximum possible score was 24. All RCTs considered for inclusion were analysed independently by three observers.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction.
Data were extracted for the following categories: setting, i.e. single- or multicentre; therapeutic arm; the number of patients with ongoing bleeding; time until endoscopy; the duration of follow-up; previous sclerotherapy exclusion criteria (yes, no, not reported); the patients’ characteristics, such as mean age, male-to-female ratio, alcoholic liver cirrhosis, Child class of cirrhosis, and variceal size; the definition of initial control of bleeding and treatment failure; drug dosage and duration of administration.

To quantify the efficacy of the various therapeutic regimens, the initial control of the ongoing bleeding was calculated on the basis of the data reported in the studies (percentage of patients in whom control of bleeding was achieved). The data were analysed on an intention-to-treat basis. The 95% confidence interval (CI) for the success rate (initial control of bleeding) was calculated for each study.

Methods of synthesis
How were the studies combined?
The success rates for the pooled data were compared in three ways. First, chi-squared values were calculated for the absolute number of patients in whom control of bleeding was achieved, or for whom there was treatment failure. Second, the 95% CI was calculated for the success rate from the pooled data of trials evaluating the same therapy. Third, the estimated true effect of any therapy was calculated using a fixed-effect model (see Other Publications of Related Interest nos.3-4).

How were differences between studies investigated?
Homogeneity was tested for using the Q statistic (see Other Publications of Related Interest no.3). Studies with the same therapeutic regimen were only pooled if the Q test verified that the clinical outcomes were not heterogeneous.

Results of the review
A total of 13 prospective RCTs were eligible for inclusion.

The total quality scores ranged from 12 to 22 out of a maximum of 24.

The authors did not appear to use an appropriate method to pool the studies; the results of the pooled success rates will not, therefore, be reported in this abstract.

Authors’ conclusions
Ligation is the most effective treatment option. No significant difference was found between the efficacy of sclerotherapy and treatment with somatostatin and octreotide.

CRD commentary
The review addressed a clear question, and the criteria for inclusion and exclusion were reported. The search was not very wide-ranging, i.e. only one database was searched, and, therefore, a number of important studies may have been missed. The authors undertook an appropriate validity assessment, but the results did not appear to be taken into account in the analysis. The details of the included studies were well presented in tabular format. The method of pooling chosen by the authors did not seem to be appropriate for a meta-analysis.

The conclusions drawn by the authors are unreliable and should be approached with caution.

Implications of the review for practice and research
Practice: The authors state that in the emergency situation, administration of somatostatin or octreotide may be recommended as first-line therapy if ligation is not immediately available.

Research: The authors did not report any implications for research.
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Other publications of related interest

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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.