N-2-butyl-cyanoacrylate for bleeding gastric varices: a United States pilot study and cost analysis


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Patients with active or recent gastric variceal bleeding were given N-butyl-2-cyanoacrylate (cyanoacrylate) by injection (up to six injections) until the gastric varices were occluded. Coexisting oesophageal varices were treated with endoscopic variceal injection or sclerotherapy, using conventional sclerosants at the same session if they were of Grade II (do not collapse with insufflation) or larger, or if markings indicating a high risk were present. The comparator group of patients were of similar age and had similar symptoms, but were not treated with cyanoacrylate. The treatments used were transjugular intrahepatic portosystemic shunting (TIPS), surgical splenorenal shunts, endoscopic management, and a Sengstaken-Blakemore tube. One patient refused all treatment apart from beta-blockers.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients were included in the study if they had actively bleeding gastric varices or gastric varices with high-risk markings (red wale marks, white plug in varix, adherent clot to varix) with evidence of recent upper gastrointestinal (GI) bleeding with no other obvious cause. Patients were excluded if they had proven hepato-cellular carcinoma, pulmonary arteriovenous malformations, or an allergy to cyanoacrylate, ethiodol, or iodine. They were also excluded if there was uncertainty as to the cause of GI bleeding, or if they were pregnant or had known hepatopulmonary syndrome.

Setting
The setting was secondary care. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness evidence for the study patients related to 1997 to 2001; the years for the comparator group were not reported. The dates for the cost evidence were not given, but they can be assumed to have been the same as those for the effectiveness evidence. No price year was reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out retrospectively on a sub-set of the patients who provided the effectiveness data.
Study sample
No power calculations were reported. All of the patients who met the inclusion criteria were recruited to receive cyanoacrylate therapy. There were 44 patients in the intervention group and 11 patients in the comparator group.

Study design
This was a single-centre, non-randomised study in which patients were allocated to the comparator group if they were similar to those in the intervention group.

Analysis of effectiveness
The analysis was conducted on an intention to treat basis. The health outcome used to assess the patients was rebleeding at 72 hours, 6 weeks and 1 year. Survival was assessed at 3 months and 1 year. The patients in the two groups were similar in terms of age, Child-Turcotte-Pugh class (which measures the severity of liver disease), type and shape of varix, and underlying aetiology of portal hypertension.

Effectiveness results
Among the patients receiving cyanoacrylate, 37 suffered from cirrhosis and 7 from non-cirrhotic portal hypertension. Among the cirrhotic patients, 2 patients suffered rebleeding before 72 hours, and one suffered rebleeding between 72 hours and 6 weeks.

Among the non-cirrhotic patients 2 suffered from rebleeding before 72 hours, one suffered from rebleeding between 72 hours and 6 weeks, and 6 patients suffered from rebleeding between 3 and 12 months.

All of the non-cirrhotic patients survived. Twenty-nine of the cirrhotic patients survived up to 12 months.

In the comparator group, 3 patients suffered from rebleeding at 72 hours but none suffered from rebleeding at 6 weeks.

Five patients survived 3 months and at 12 months one patient was lost to follow-up. Thus, only 4 patients were known to have survived to 12 months.

Clinical conclusions
The authors concluded that the health outcomes of the patients receiving cyanoacrylate therapy were better, in terms of rebleeding and survival, than those who had not been offered it.

Measure of benefits used in the economic analysis
The reduction in the probability of death was used to measure benefit.

Direct costs
Discounting was not carried out, but it was not necessary as the costs were incurred during less than 2 years. The costs were derived from actual data and were obtained from hospital charge data. The total hospital charges from the time of the index bleed were used. These costs were not broken down into their components. There was no breakdown of the costs into prices and quantities. The price year was not reported.

Statistical analysis of costs
No statistical analysis of the costs was carried out.

Indirect Costs
The indirect costs were not calculated.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
The odds of death were 7-fold greater in the non-cyanoacrylate group than in the cyanoacrylate group (95% confidence interval, CI: 1.18 - 41.36; p=0.0318).

**Cost results**
At 12 months the total charges were $46,729 (+/- 44,316) for the cyanoacrylate group (n=17) and $85,215 (+/- 56,105) for the comparator group (n=11).

**Synthesis of costs and benefits**
The cyanoacrylate treatment was dominant. However, the authors also presented a cost-effectiveness ratio of $108,237 per death averted (95% CI: 10,970 - 528,370) for treatment with cyanoacrylate. This can be interpreted as a cost-saving of $108,237 per death averted. This figure is not, therefore, an incremental cost-effectiveness ratio.

**Authors’ conclusions**
The use of cyanoacrylate for bleeding gastric varices was a dominant treatment, as it cost less and produced better health outcomes for the patients.

**CRD COMMENTARY - Selection of comparators**
The choice of the comparator, a variety of treatments available for bleeding gastric varices, was justified as it represented current practice in the authors’ setting. You should decide if the comparator represents current practice in your own setting.

**Validity of estimate of measure of effectiveness**
The source of the effectiveness data was a single study. The study design was based on the non-random allocation of patients to the comparator and the intervention. The authors tried to match the comparator patients (from an earlier historical period) to the intervention patients, but there was a big disparity between the numbers in the two groups (11 in the comparator group and 44 in the intervention group). All of the patients who met the inclusion criteria were eligible to belong to the intervention group. An examination of the inclusion criteria will determine whether or not the patients were typical of those suffering from bleeding gastric varices. Although the authors reported that the two groups were comparable, some of the patients who belonged to the comparator group were treated at the same time as those in the intervention group and, therefore, must have missed the inclusion criteria for being in the intervention group. The analysis of effectiveness was not handled in a very clear way: sometimes the authors used data from 17 of the intervention group, as these were the patients for whom they had cost data, and sometimes they used data from all 44 patients. Also, the comparator group of patients was treated in a range of ways, thus one cannot ascribe the results to any particular treatment.

**Validity of estimate of measure of benefit**
The authors used a valid measure of benefit, the reduction in the probability of death.
Validity of estimate of costs

The authors included all those costs relevant to their analysis, which were hospital costs. However, the costs and the quantities were not reported separately. The resource use quantities were taken from a single study, while the prices were taken from the authors' setting. No other source was used for quantities. No statistical, sensitivity or any other kind of analysis was carried out on either the quantities or prices. The price year was not reported. The authors used hospital charges to represent costs, which means that the cost data do not reflect opportunity costs. Although the study found increased effectiveness and lower costs for the intervention (therefore dominant) the authors reported a cost-effectiveness ratio. This would only normally be done where the costs are greater, in which case an incremental cost-effectiveness ratio would be relevant.

Other issues

The authors made appropriate comparisons of their results with those from other studies. The issue of generalisability to other settings was not addressed. The authors did not present their results selectively. The authors' conclusions seem stronger than is warranted by their analysis.

Implications of the study

In terms of clinical practice, the study's findings (in terms of effectiveness and cost) supported the use of cyanoacrylate. However, the authors proposed a controlled trial in which cyanoacrylate would be compared with TIPS.

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