

**The abstract displayed on this page is for use with the 3 items on the following page.**

**Question**

In patients with cirrhosis and acute bleeding esophageal varices, how do endoscopic sclerotherapy and emergency portacaval shunt compare for control of bleeding and survival?

**Methods**

**Design:** Randomized controlled trial (San Diego Bleeding Esophageal Varices Study). ClinicalTrials.gov NCT00690027.

**Allocation:** Concealed.

**Blinding:** Blinded (gastroenterologist who evaluated patients for portal-systemic encephalopathy).

**Follow-up period:** Up to 17 years.

**Setting:** University of California San Diego Medical Center.

**Patients:** 211 patients (mean age 49 years, 77% men) with acute bleeding esophageal varices resulting from cirrhosis, who required a transfusion of  $\geq 2$  units of blood and, for patients transferred from other hospitals, observation of upper gastrointestinal bleeding within 48 hours of transfer. Exclusion criterion was  $> 1$  previous session of endoscopic sclerotherapy.

**Intervention:** Endoscopic sclerotherapy ( $n = 106$ ) or emergency portacaval shunt ( $n = 105$ ). Emergency portacaval shunt comprised a direct side-to-side or direct end-to-side portacaval shunt done within 8 hours of initial contact.

**Outcomes:** Control of bleeding at  $> 30$  days, survival, readmissions for variceal or nonvariceal bleeding requiring transfusion of packed red blood cells, and recurrent portal-systemic encephalopathy.

**Patient follow-up:** 100% (minimum follow-up until death or 9.4 years).

**Main results**

15-year survival was lower with endoscopic sclerotherapy than with emergency portacaval shunt (10/106 vs 48/105, relative benefit reduction 79%, 95% CI 62 to 89; number needed to harm 3, CI 2 to 4). Other main results are shown in the Table.

**Endoscopic sclerotherapy (EST) vs emergency portacaval shunt (EPCS) in patients with cirrhosis and acute bleeding esophageal varices**

Outcomes	Child-Pugh risk class	EST	EPCS	P value
Control of bleeding at $> 30$ days*		20%	100%	$<.001$
Median survival (years)	A	4.62	10.43	.003
	B	2.61	6.19	$<.001$
	C	0.58	5.30	.005
Mean number of readmissions for variceal bleeding requiring packed red blood cell transfusion		6.8	0.4	$<.001$
Recurrent portal-systemic encephalopathy†		35%	15%	.001

\*Excluding indeterminate deaths at 14 days from nonbleeding causes.  
†In patients who survived 30 days and left hospital.

**Conclusion**

In patients with cirrhosis and acute bleeding esophageal varices, emergency portacaval shunt was better than endoscopic sclerotherapy for control of bleeding, recurrent encephalopathy, and survival.

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**Structured abstract based on:** Orloff MJ, Isenberg JI, Wheeler HO, et al. **Randomized trial of emergency endoscopic sclerotherapy versus emergency portacaval shunt for acutely bleeding esophageal varices in cirrhosis.** J Am Coll Surg. 2009;209:25-40. 19651060

1. A 52-year-old man with hepatic cirrhosis comes to the emergency department because of a 3-hour history of vomiting blood. Esophagogastroduodenoscopy confirms actively bleeding esophageal varices. Based on the abstract shown, the physician is considering an emergency portacaval shunt (EPCS) procedure rather than endoscopic sclerotherapy (EST). According to the results in the abstract, approximately how many patients must be treated with EPCS rather than EST to prevent one case of recurrent portal-systemic encephalopathy?
- (A) 1
  - (B) 3
  - (C) 5
  - (D) 10
  - (E) 16

(Answer: C)

2. Which of the following most strongly limits the generalizability of this study's findings?
- (A) The allocation was concealed
  - (B) EPCS is available only at specialty centers
  - (C) The follow-up period was too short
  - (D) The patients were not blinded
  - (E) Unmeasured confounders were not controlled by the study design

(Answer: B)

3. Which of the following conclusions is most appropriate based on the results presented in the table?
- (A) The 95% confidence interval for the difference in survival between EPCS and EST for Child-Pugh class A patients includes 0 years
  - (B) EPCS is more effective than EST in decreasing hospital readmissions for variceal bleeding requiring transfusion
  - (C) The median survival after EPCS is statistically significantly less for Child-Pugh class C than for Child-Pugh class B
  - (D) The randomization procedure was ineffective in decreasing bias in this study

(Answer: B)