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Transparent cap-assisted endoscopic injection sclerotherapy for the treatment of patients with esophageal varices

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Abstract

The aim of this study was to compare the efficacy and safety of cap-assisted endoscopic injection sclerotherapy (EIS) versus direct EIS in the management of esophageal variceal bleeding in patients with cirrhosis.

This retrospective study included patients with cirrhosis and esophageal variceal bleeding who underwent EIS with or without the use of a transparent cap at Shandong Provincial Hospital between December 2014 and April 2017. Patients were divided into two groups: Group A (EIS with transparent cap, n = 50) and Group B (direct EIS, n = 45). Data collected included patients' demographics, procedure details, and rates of variceal eradication, variceal rebleeding, variceal recurrence, and survival during the follow-up period. All data were expressed as mean ± SD. Quantitative variables were compared with Student *t* test; qualitative variables were compared with the Fisher exact test or chi-square test. *P* values less than .05 were considered significant.

The mean follow-up duration was similar in both groups (16.3 ± 10.2 mo in Group A and 15.5 ± 9.5 mo in Group B). The volume of sclerosant (64.86 ± 10.62 vs 104.73 ± 21.25 ml, *P* = .044), mean number of sessions (2.37 ± 1.15 vs 5.70 ± 1.57, *P* = .042), time required to perform endoscopic treatment (6.57 ± 1.50 vs 11.22 ± 2.29 minutes, *P* = .049), and time to initial esophageal varices eradication (5.43 ± 1.38 vs 8.93 ± 1.5 wk, *P* = .041) were significantly smaller in the cap-assisted EIS group than in the direct EIS group. The probability of variceal recurrence and rebleeding was significantly higher in the direct EIS group than in the cap-assisted EIS group (14% versus 35.6% and 20% versus 40%). Only 22 patients (44%) developed complications in the cap-assisted group versus 30 patients (66.7%) in the EIS group (*P* = .039). The probability of survival was similar in both groups (86% versus 75.6%, *P* = .133).

Modified EIS with the use of a transparent cap resulted in lower rates of esophageal variceal recurrence, rebleeding, and complications, compared with direct EIS.

Abbreviations: EIS = endoscopic injection sclerotherapy, EVL = endoscopic variceal ligation.

Keywords: cirrhosis, endoscopic injection sclerotherapy, esophageal varices, transparent cap

1. Introduction

Esophageal variceal bleeding is a major cause of morbidity in patients with cirrhosis. Endoscopic variceal ligation (EVL) and endoscopic injection sclerotherapy (EIS) are widely used to treat esophageal variceal bleeding. Because ligation has lower rebleeding and complication rates than injection, EVL has been recommended as the optimum endoscopic treatment to prevent recurrent bleeding from esophageal varices.[1,2] However, ligation is not without drawbacks, including a higher tendency for variceal recurrence.[3] EIS is superior to EVL in preventing

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variceal recurrence[4] and remains widely used to control acute esophageal variceal bleeding as well as to eradicate varices to prevent recurrent bleeding. The main reason EIS is not generally recommended is its higher rate of complications and lower effect in reducing mortality.[5]

In the 1980s, Kitano et al designed a transparent tube to facilitate accurate sclerosant injection; subsequent studies found that overtube-assisted EIS was easier, safer, and faster for sclerosing esophageal varices than direct EIS and had fewer complications.[6–8] However, in this technique, patients must swallow a 50-cm transparent tube; the method was not widely accepted because of discomfort and pain after the procedure.

EIS includes 2 methods-intravariceal injection and paravariceal injection. It is difficult to perform pure intravariceal injection, especially if the varices are small and in cases of recurrence following EIS or EVL. Therefore, we began to perform intravariceal injection sclerotherapy with a transparent cap (Fig. 1).

The present study was conducted to compare the efficiency and safety of cap-assisted versus direct EIS in the management of esophageal variceal hemorrhage in patients with cirrhosis. To our knowledge, this is the first report in the English literature to compare the 2 procedures in the treatment of esophageal variceal hemorrhage.

2. Materials and methods

2.1. Patients

This retrospective study included patients with cirrhosis suffering from esophageal variceal bleeding who underwent EIS with a transparent cap (Group A) or direct EIS (Group B) at Shandong Provincial Hospital between December 2014 and April 2017. The inclusion criteria were:

(1) patients diagnosed with liver cirrhosis by biopsy or clinical examination and imaging, including ultrasound, computed tomograp, or magnetic resonance imaging;
(2) patients who experienced bleeding within 6 months before admission; and
(3) patients with esophageal varices classified as F2 of F3 on gastroscopy.[9,10]

Patients were excluded if they presented with 1 or more of the following:

(1) hepatocellular carcinoma or other malignancy;
(2) a history of gastric variceal bleeding;
(3) a history of EIS, EVL, or portosystemic anastomosis;
(4) complete obstruction of the portal vein resulting from thrombosis; or
(5) infection.

All procedures were performed by one or two endoscopic experts. Informed written consent was obtained from each patient. Local ethics committee approval was obtained for the chart review.

An indigenously designed transparent cap, a Teflon injector with a 21-gauge needle (Olympus), and a therapeutic gastroscope (Olympus GIF Q260J) were used for intravariceal injection.

2.2. Treatment procedures and follow-up

In Group A, a transparent cap (MAJ-290; Olympus) was fixed to the front of the gastroscope, which allowed accurate injection of

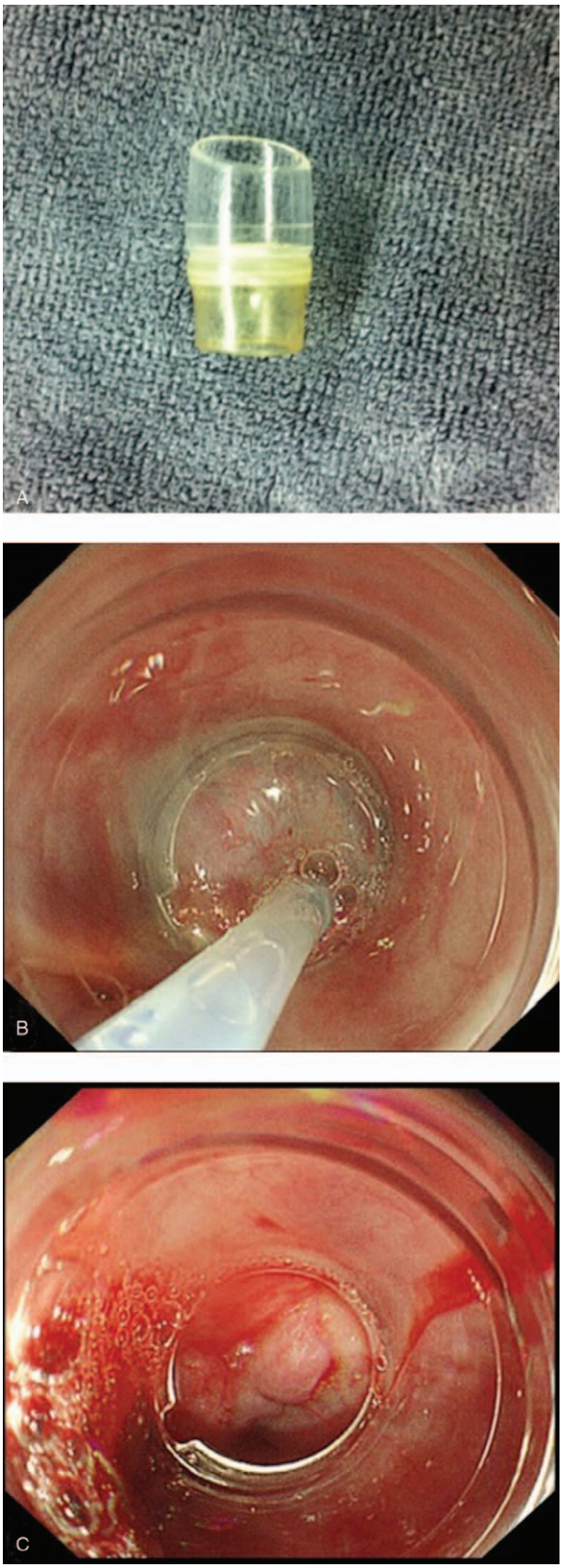

Figure 1. The procedure of cap assisted EIS. A. The transparent cap used in the procedure of EIS; B. Cap assisted intravariceal injection; C. The transparent cap was pressed onto the bleeding point after injection. EIS = endoscopic injection sclerotherapy.

sclerosant into the varices. The injection needle was prefilled with lauromacrogol, which was used as the sclerosant. The procedure started at the lower end of the variceal columns near the cardia; 5 to 7 mL were administered per injection, depending on the diameter of the varices, for a total of less than 40 mL. If bleeding occurred at puncture sites, the transparent cap was pressed onto the bleeding point until the bleeding stopped. In Group B, EIS was performed without the help of a transparent cap, so both intravariceal and paravariceal sclerotherapy were applied. The treatment process was the same in both groups except for the use of the transparent cap.

The endoscope was withdrawn after hemostasis was achieved and the stomach was decompressed. In both groups, sclerotherapy was performed every 2 to 4 weeks until variceal eradication was achieved. Once varices were eradicated, repeat endoscopy was performed at 3- to 6-month intervals to check for recurrent varices. During follow-up, we excluded patients who underwent EVL or transjugular intrahepatic portosystemic shunt placement. All patients were treated with propranolol to reduce portal pressure.

Variceal eradication was defined as the disappearance of varices after treatment, including thrombosed varices (F0, RC0). Variceal recurrence was defined as the reappearance of eradicated varices (F0, RC0) with F and/or RC signs on endoscopy.[11] The final assessment of variceal eradication or recurrence had to be agreed upon by two experienced endoscopists.

Variceal rebleeding was defined according to the Baveno III consensus[12] (ie, at least 2 units of blood transfused within 24 hour; patients were expected to be able to visit the hospital, with a systolic blood pressure < 100 mm Hg or a postural change of > 20 mm Hg and/or pulse rate > 100/min).

Complications were determined with a questionnaire that patients completed before any treatment and after treatment. Complications in both groups were only those symptoms that appeared after the commencement of treatment. Post-treatment esophageal ulcers and stricture were usually diagnosed during endoscopic follow-up.

2.3. Statistical analysis

All data were expressed as mean ± SD. Quantitative variables were compared with Student's t test, and qualitative variables were compared with the Fisher exact test or the chi-square test (with Yates correction), as appropriate. The Kaplan–Meier estimation was used to examine recurrence and rebleeding of esophageal varices and survival rates. Comparisons were performed with the log-rank test. A P value $< .05$ was considered significant. Statistical analyses were performed by use of SPSS 20.0 software.

3. Results

3.1. Demographics

Between December 2014 and March 2017, EIS with transparent cap or direct EIS was performed in a total of 115 cirrhotic patients with a history of esophageal variceal bleeding. Among the 115 patients, six had previously received treatment for esophageal varices with EIS, EVL, or portosystemic anastomosis; 10 had hepatocellular carcinoma; and four had a history of gastric variceal bleeding. These patients were excluded. Among the remaining 95 patients, 50 were treated with cap-assisted EIS (Group A) and 45 were treated with direct EIS (Group B) (Fig. 2). The clinical characteristics of the 95 patients were collected from the computerized database of our hospital and retrospectively reviewed. The severity of liver disease was assessed with the Child–Pugh criteria[13] and the size of esophageal varices was

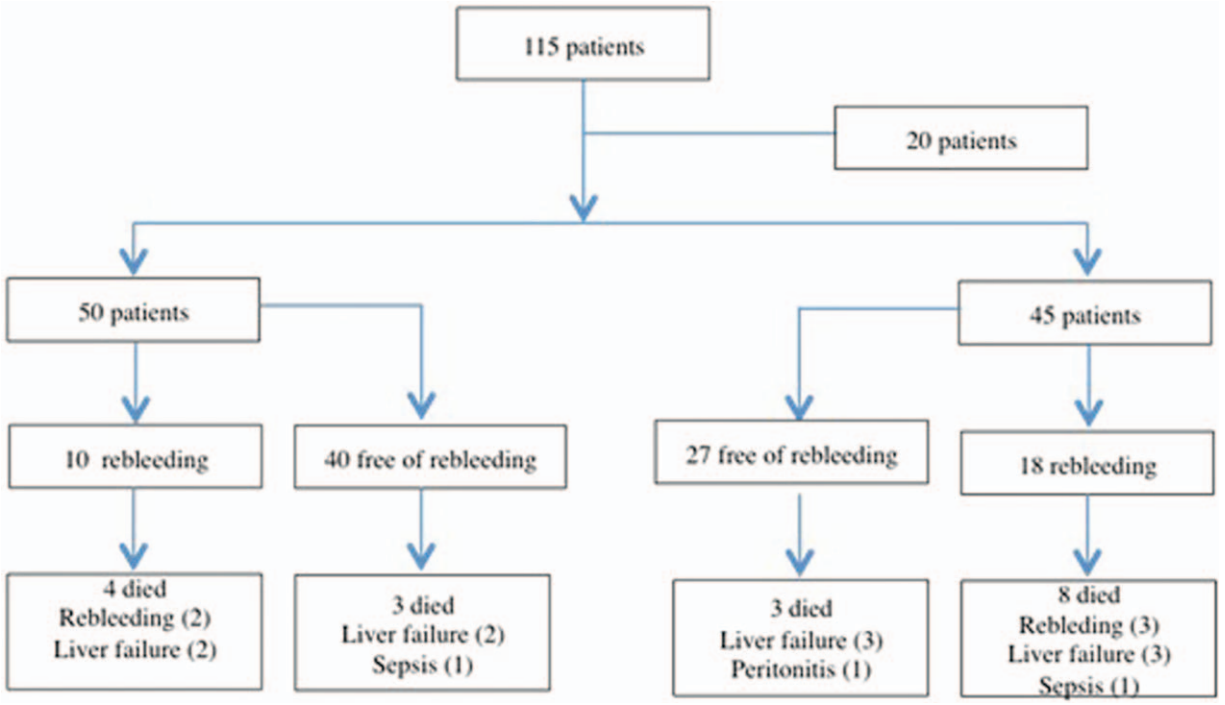

Figure 2. Flow diagram of rebleeding and death after EIS in the 2 groups. EIS = endoscopic injection sclerotherapy.

Table 1

Demographics of the patients included in the 2 groups.

	Group A N=50	Group B N=45	*P* value
Age (yr)	49.23±7.12	53.10±9.05	NS
Male/female	29/21	26/19	NS
Etiology of cirrhosis			NS
Hepatitis	34	28	
Alcohol	12	13	
Others	4	4	
Child-Pugh classification			NS
A	22	24	
B	10	12	
C	13	9	
Variceal size			NS
F2	28	24	
F3	22	21	
Duration of follow-up (mo)	16.3±10.2	15.5±9.5	NS

NS = No significant.

graded according to Beppu's criteria.[10] As shown in Table 1, patients in the two groups were comparable in age, sex, etiology of cirrhosis, Child's grade, and variceal size. The median follow-up period was 15.5±9.5 months in Group A and 16.3±10.2 months in Group B.

3.2. Obliteration and recurrence of esophageal varices

As shown in Table 2, there was no significant difference in initial obliteration of varices between Group A and Group B (44/50 vs 39/45, respectively; $P > .05$). However, the mean time necessary to achieve obliteration was 5.43±1.38 weeks in Group A and 8.93±1.5 weeks in Group B. Furthermore, the probability of variceal recurrence was significantly lower in Group A than in Group B ($P = .014$; Fig. 3). In 17 of the 23 patients with variceal recurrence (five in Group A and 12 in Group B), recurrence presented as an episode of bleeding from ruptured esophageal varices. The other 6 patients (two in Group A and four in Group B) had recurrence diagnosed at routine follow-up examination. Recurrent varices were obliterated with cap-assisted or direct EIS in 10 (43.5%) of the 23 patients and with EVL in 6 (26%). In the remaining patients, recurrent varices were not obliterated because the patient either died (five patients) or was lost to follow-up (2 patients).

Table 2

Results of therapy in the 2 groups.

	Group A N=50	Group B N=45	*P* value
Varices eradication	44/50	39/45	NS
Number of sessions until eradication	2.37±1.15	5.70±1.57	.042
Time for eradication (wk)	5.43±1.38	8.93±1.5	.041
Time for per treatment (min)	6.57±1.50	11.22±2.29	.049
Amount of lauromacrogol (mL)	64.86±10.62	104.73±21.25	.044
Recurrence of varices	7/44	16/39	.014
UGI rebleeding	10	18	.049
Esophageal varices	5	12	.034
Gastric varices	2	2	NS
Esophageal/gastric ulcer	1	2	NS
Portal hypertensive gastropathy	2	1	NS
Undetermined	0	1	NS

UGI = Upper Gastrointestinal.

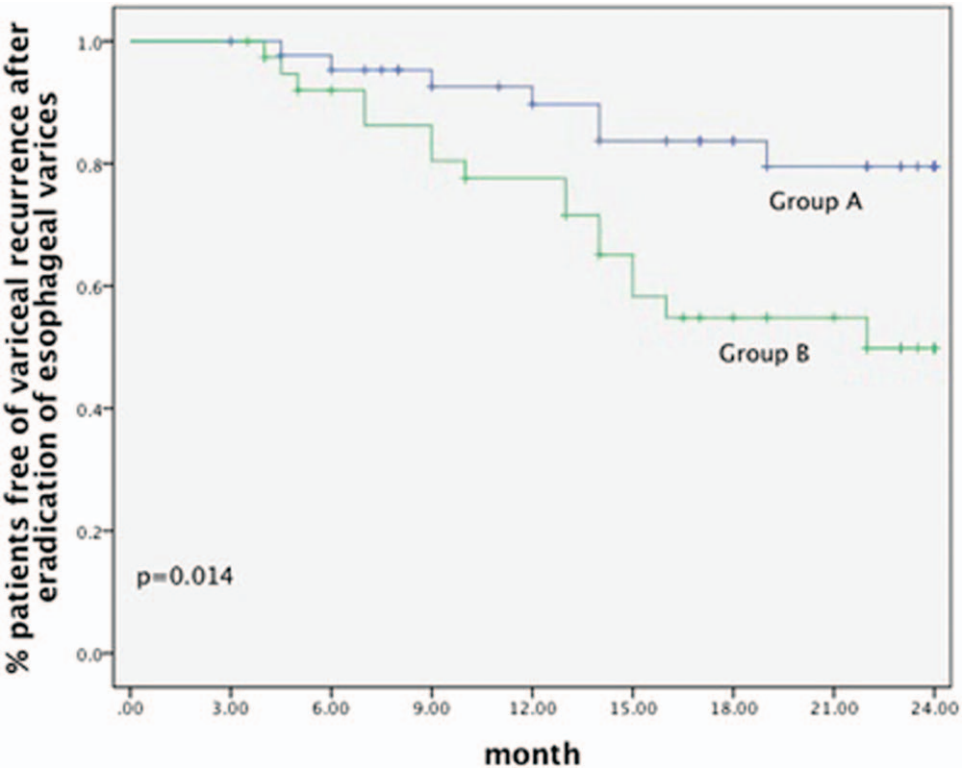

Figure 3. Probability of being free of variceal recurrence after initial esophageal varices eradication in the 2 groups.

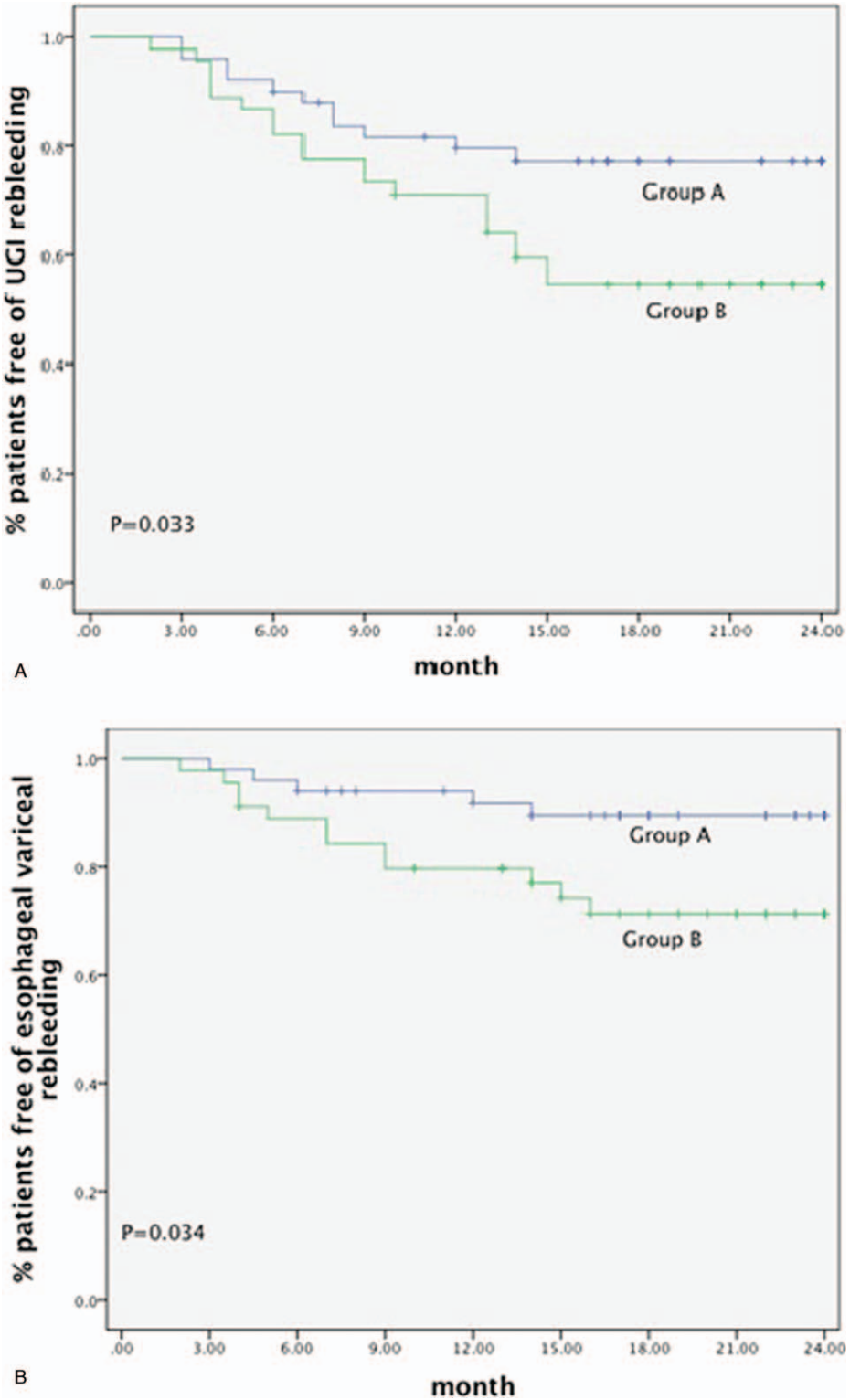

Figure 4. Probability of being free from rebleeding in the two groups. A. Probability of being free from rebleeding from the upper gastrointestinal tract in the 2 groups. B. Probability of being free from esophageal variceal rebleeding in the two groups.

3.3. Rebleeding

Upper gastrointestinal tract rebleeding from all sources occurred in 10 patients (10/50) in Group A and in 18 patients (18/45) in Group B during the follow-up period ($P=.033$; Fig. 4A)). Rebleeding from esophageal varices occurred in five patients in Group A and in 12 in Group B. The probability of rebleeding from esophageal varices was significantly lower in Group A than in Group B ($P=.034$, Fig. 4B). The incidence of bleeding from gastric varices was not significantly different between the 2 groups.

Table 3

Complications in the 2 groups.

	Group A N = 50	Group B N = 45	*P* value
No. of patients with complications	22	30	.039
Fever	7	16	.017
Chest pain	9	15	NS
Ulcer	4	11	.046
Esophageal stricture	3	10	.034

3.4. Complications

The complications in both groups are shown in Table 3. The rate of complications in the cap-assisted EIS group was lower than that in the direct EIS group ($P = .039$). Seven patients in Group A and 16 in Group B developed fever ($P = .017$). Chest pain was encountered in nine patients in Group A and in 16 patients in Group B ($P > .05$). These patients were treated with conventional medical therapy; fever and abdominal pain usually improved within 1 week. Four patients in Group A developed mucosal ulceration at the site of a previous injection. The corresponding number in Group B was 11, and this difference was significant ($P = .046$). Three patients in Group A and in six in Group B who experienced dysphagia after sclerotherapy were diagnosed with esophageal stricture. Most of the procedure-related complications were mild in both groups. There was no complication-related death in either group.

3.5. Survival

There were seven deaths in Group A and 11 in Group B. The causes of death are shown in Fig. 2. The Kaplan–Meier survival curve is shown in Fig. 5. Survival was not significantly different between the groups ($P = .133$, Fig. 5). Two patients in Group A and three in Group B died of variceal bleeding. Four patients in Group A and six in Group B died of hepatic failure.

4. Discussion

Bleeding from esophageal varices is a life-threatening condition with a mortality rate of at least 20% and an incidence of 5% to 15% among patients with liver cirrhosis.[14,15] Treatments for esophageal varices include EIS, EVL, nonselective β-blockers, transjugular intrahepatic portosystemic shunt placement, and shunt surgery.[16–19]

EVL is increasingly used because of its safety and simplicity and because no sclerosant is required. However, EVL achieves only local eradication; it does not completely disrupt the interconnecting perforating and feeder vessels.[20] Accumulating evidence suggests that the patency of feeder vessels of varices, such as paraesophageal and periesophageal varices, predisposes to variceal recurrence.[18,12–23] These feeder vessels are occluded more efficiently by sclerotherapy than ligation, which is usually confined to the mucosal and submucosal collaterals. Hou et al and Shiv et al found that early recurrence and multiple recurrence of esophageal varices were more likely in patients who underwent endoscopic ligation than among those who underwent sclerotherapy.[24,25] Although EVL is widely accepted as the optimum endoscopic treatment for esophageal variceal bleeding,[26] EIS is superior to EVL in preventing esophageal variceal recurrence[4] and is still widely used to control acute esophageal variceal bleeding as well as to eradicate varices to prevent recurrent bleeding. EIS combined with EVL might achieve faster eradication with fewer treatment sessions and fewer bands deployed to

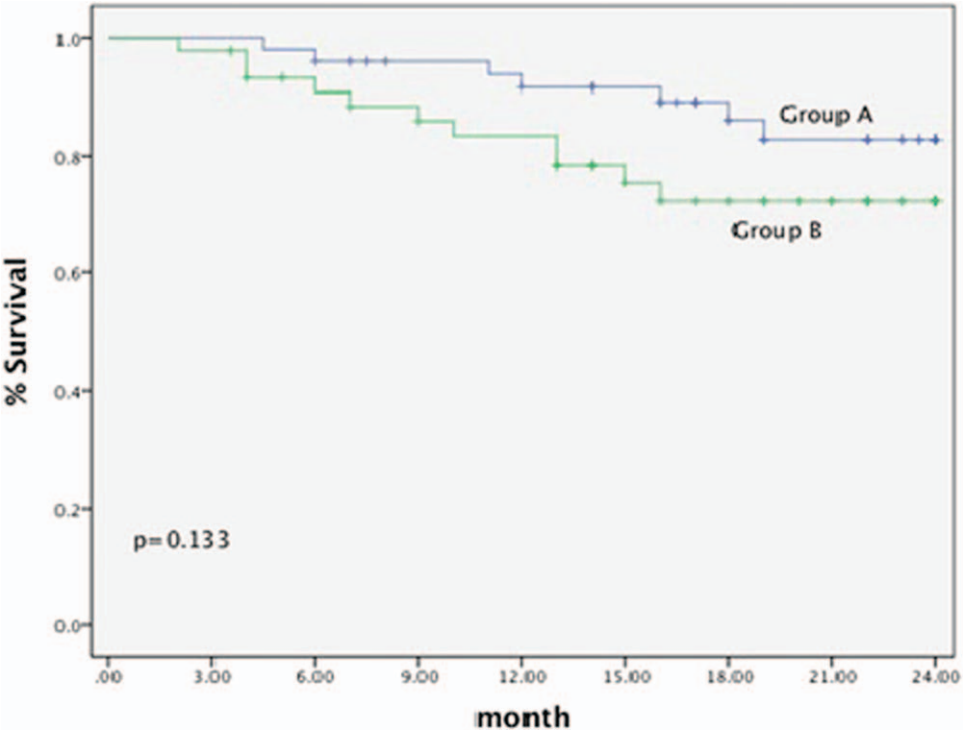

Figure 5. Probability of survival in the 2 groups.

achieve variceal obliteration than band ligation, with comparable cost, adverse events, and recurrence rates.[27,28]

EIS can be either intravariceal or paravariceal. However, as with EVL, paravariceal EIS only achieves local eradication and does not completely disrupt the interconnecting perforating and feeder vessels.[3] Paravariceal injection technique is not effective and early recurrences have been reported.[29]

We observed a lower rate of recurrence of esophageal varices and a lower rebleeding rate in the cap-assisted EIS group than in the direct EIS group. Variceal eradication was achieved significantly sooner with cap-assisted sclerotherapy than with direct EIS. The number of sessions required and the time required for each session were also significantly lower in the cap-assisted group. A smaller volume of sclerosant was required to eradicate esophageal varices in the cap-assisted EIS group than in the direct EIS group.

In the treatment of esophageal varices, intravariceal EIS obliterates both interconnecting perforating veins and feeding veins of esophageal varices. However, EIS is associated with a high incidence of local and systemic complications. Several studies have reported dysphagia and esophageal stricture in up to 59% of patients after EIS.

Our study found a lower incidence of complications in the cap-assisted EIS group than in the direct EIS group ($P = .039$). Four patients in the cap-assisted EIS group developed mucosal ulceration at the site of a previous injection. The corresponding number in the direct EIS group was 11; this difference was significant ($P = .046$). Esophageal stricture was found in three patients in Group A and in 6 in Group B; these patients developed dysphagia after sclerotherapy. The stricture was usually a transient phenomenon and no patient required esophageal dilatation for the relief of symptoms.

The benefits of transparent-cap application in EIS are as follows:

(1) the cap helps maintain a clear field of vision;
(2) the cap compresses and immobilizes the targeted varices, which enables accurate injection of sclerosant and reduces sclerosant leakage at the injection site, reducing complications; and
(3) the cap reduces patient discomfort. There was no significant difference in mortality rates between the 2 groups.

This was a retrospective single-center study that included a limited number of cases. In the future, a prospective, randomized, controlled trial is required to confirm our findings.

In conclusion, transparent cap-assisted EIS had lower rates of esophageal variceal recurrence, rebleeding, and complications than direct EIS. This modification is a promising modality for the treatment of esophageal varices.

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Author contributions

ZSL proposed the study. ZSL, WJ, ZXH performed the research and wrote the first draft. ZSL and WJ collected and analyzed the data. All authors contributed to the design and interpretation of the study and to further drafts. ZSL is the guarantor.

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