Original Article

Efficacy of Endoscopic Variceal Ligation in the Control of Variceal Bleeding: A Real World Setting

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Background: Combined pharmacological and endoscopic therapy, particularly endoscopic variceal ligation (EVL), is the first-line treatment for acute esophageal variceal bleeding (EVB). In patients with rebleeding, the rescue treatment with a transjugular intrahepatic portosystemic shunt (TIPS) is recommended. However, in a real world setting where the accessibility to TIPS is limited, repeated endoscopic therapy is inevitably performed.

Objective: To study the outcomes of EVL on rebleeding and mortality in the resource-limited setting.

Materials and Methods: Patients who underwent EVL during 2017 to 2018 are included. Patients were treated with vasoactive drugs and EVL until the eradication of varices. We focus on the outcome of a second attempt at EVL to control EVB. The rebleeding and mortality rate within 6 months after the combined treatment were collected. Logistic regression analysis was performed to identify risk factors of rebleeding.

Results: There were 339 EVL performed during the 2-year period. Of these procedures, EVL was indicated to control acute EVB in 118 patients. EVB in 98 patients (83%) were successfully controlled in only one session of EVL, while those of 20 patients (17%) required at least 2 sessions to control the recurrent EVB. In the rebleeding group, no patient rebled within 5 days after the first EVL, while 15 patients (75%) rebled within 6 weeks. Once rebled, the second EVL was performed. There were 5 patients (25%) whom the second EVL failed to control the recurrent EVB. Those recurrent EVB were finally controlled by the other endoscopic therapy. The 6-week mortality after rebleeding was 15%. Hepatocellular carcinoma and creatinine are factors associated with recurrent EVB within 6 weeks with odds ratio (OR) 5.96 (95% CI 1.41 to 25.19, $p = 0.02$) and OR 1.47 (95% CI: 1.02 to 2.11, $p = 0.04$), respectively.

Conclusion: The second attempt at endoscopic therapy can be considered to control recurrent EVB after the first EVL with a success rate of 75% in area where an accessibility to a treatment with TIPS is limited.

Keywords: Endoscopic therapy, Outcomes, Real world, Recurrent, Variceal bleeding

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Acute esophageal variceal bleeding (EVB) in cirrhotic patient signifies the decompensation state and leads to death[(1)]. The main underlying mechanism of varices is increase portal pressure which begins in the early state of cirrhosis and relates to other consequences such as ascites and hepatic encephalopathy. Once the hepatic venous pressure gradient (HVPG) reaches 12 mmHg, patient is in decompensation state and variceal bleeding could occur. Patients who have HVPG greater than or equal to 20 mmHg are in deterioration of decompensation leading to recurrent variceal hemorrhage, refractory ascites, bacterial infection and hepatorenal syndrome[(2)].

The main treatments of acute variceal hemorrhage include medication and endoscopic treatment. Non-selective beta-blockers (propranolol, nadolol, and carvedilol) and vasoactive drugs (vasopressin, octreotide, terlipressin and somatostatin) are among common drugs used to control portal pressure, as well as prophylactic antibiotics. Endoscopic treatment includes endoscopic variceal ligation (EVL) and sclerotherapy. In some patients, despite adequate treatment by these two methods, are failed to control the bleeding (persistent bleeding). The next steps of management are polytetrafluoroethylene (PTFE) covered transjugular intrahepatic portosystemic shunt (TIPS) or a second session of endoscopy therapy if the bleeding is not severe. Other bridging therapies to more effective therapy, such as TIPS are balloon tamponade and self-expandable metal stents[(3)]. Patient who have recurrent bleeding within 5 days is also

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managed by second session of endoscopy therapy or TIPS[4,5].

There were several studies exploring the factors associated with recurrent bleeding. A meta-analysis found that beta-blockers and EVL reduced rebleeding in all Child-Pugh classes, with a significant reduction in mortality in Child-Pugh class B/C[6]. A case-control study in 342 patients who receive EVL showed the rebleeding rate of 7.6%. Factors associated with the rebleeding were moderate to excessive ascites, the number of bands placed, the extent of varices and prothrombin time (PT) >18[7].

Early placement of PTFE covered TIPS in cirrhotic patients who are high risk for treatment failure, defined by Child-Pugh class C or those in class B who have persistent bleeding at endoscopy, is associated with significant reductions in treatment failure and in mortality compared to conventional pharmacological and endoscopic treatment[8,9]. However, in resource-limited setting where there is a difficulty assessing to TIPS either by technical proficiency or cost, the mainstays of treatment are pharmacological and endoscopic intervention. Therefore, we aim to assess the real-world outcome of EVL on rebleeding and mortality in the resource-limited setting.

Materials and Methods

The present study was a retrospective study reviewing the medical records and endoscopy results from cirrhotic patients who underwent endoscopic variceal ligation (EVL), approved by the Institutional Review Board of Faculty of Medicine, Chulalongkorn University (IRB number 495/62).

Patient characteristics

Adult subjects, aged 18 or older, who have cirrhosis and underwent EVL at the excellence center of gastrointestinal endoscopy, King Chulalongkorn memorial hospital, Chulalongkorn university, Bangkok, Thailand during 2017 to 2018 were enrolled. We included patients with esophageal varices bleeding requiring EVL to stop bleeding and excluded patients who were done EVL for primary variceal bleeding prophylaxis, patients who bled from gastric varices or other ectopic varices and patients who had transjugular intrahepatic portosystemic shunt. Patients were treated with vasoactive drugs and EVL until the eradication of varices. We focus on the outcome of a second attempt at EVL to control EVB.

Demographic data and clinical characteristics

Collected data included demographics (age and gender), causes of cirrhosis, present of hepatocellular carcinoma (HCC), beta-blockers used, heart rate before and after beta-blocker used, laboratory data (alanine transaminase (ALT), aspartate transaminase (AST), alkaline phosphatase (ALP), total bilirubin (TB), creatinine, albumin, international normalised ratio (INR), hemoglobin, platelets count, white blood cell count), Child-Pugh score and Model for End-stage Liver Disease (MELD) score. The clinical outcomes measured included date of EVL, number of EVL sessions until bleeding was controlled, rebleeding date and death. Decompensation of cirrhosis was defined by Child-Pugh score B and C. Patients were classified into two groups; the non rebleeding group and the rebleeding group. Rebleeding was defined as the date of esophageal varices bleeding which occurred within 6 months after the last EVL session to control bleeding.

Statistical analysis

Baseline characteristics and clinical outcomes were expressed as proportion and mean $\pm$ SD for continuous data. To compare between the two groups, nonparametric test such as χ^2 test or Fisher exact test was used for categorical data and t-test was used to compare the continuous data. The p-value <0.05 was considered as statistical significance. Factors influencing the rebleeding event were analyzed using logistic regression. Statistical analyses were performed using SPSS version 22.0, Chicago, IL, USA.

Results

As shown in Figure 1, there were 339 EVL sessions performed in 224 cirrhotic patients during 2017 to 2018. Of these procedures, EVL was indicated to control acute EVB in 118 patients. EVBs in 98 patients (83%) were successfully controlled in only one session of EVL (non rebleeding group), while those of 20 patients (17%) required at least 2 sessions to control the recurrent EVB within 6 months after the last EVL session to control bleeding (rebleeding group).

Baseline characteristics between the two groups were shown in Table 1. Common causes of cirrhosis are alcohol (30.5%), hepatitis B (18.6%) and hepatitis C (16.1%). Table 2 summarized the causes of cirrhosis among the two groups.

In the rebleeding group, the range of rebleeding occurred between 7 to 98 days with the mean of 33 days and the median of 28 days. There was no patient rebled within five days after the first EVL, while fifteen patients (75%) rebled within 6 weeks. Once rebled, the second EVL was performed. There were five patients (25%) whom the second EVL failed to control the recurrent EVB. Those recurrent EVBs were finally controlled by the other endoscopic therapy. Figure 1 demonstrated the outcome of EVLs in the present study.

There were three patients (15%) in rebleeding group who died within 6 weeks after rebleeding. Causes of death were acute on chronic liver failure in 1 patient and nosocomial infection in 2 patients. No uncontrolled EVB was observed. Multivariate logistic regression identified HCC and creatinine as factors for recurrent EVB within six weeks with OR 5.96, 95% CI: 1.41 to 25.19, $p = 0.02$ and OR 1.47, 95% CI: 1.02 to 2.11, $p = 0.04$, respectively (Table 3).

Discussion

We illustrated our real-world finding on outcome of repeated attempt at endoscopic therapy for recurrent esophageal variceal hemorrhage. Success second EVL sessions were achieved in 15 of 20 patients (75%). After successfully controlled recurrent EVB, there was no rebleeding in the

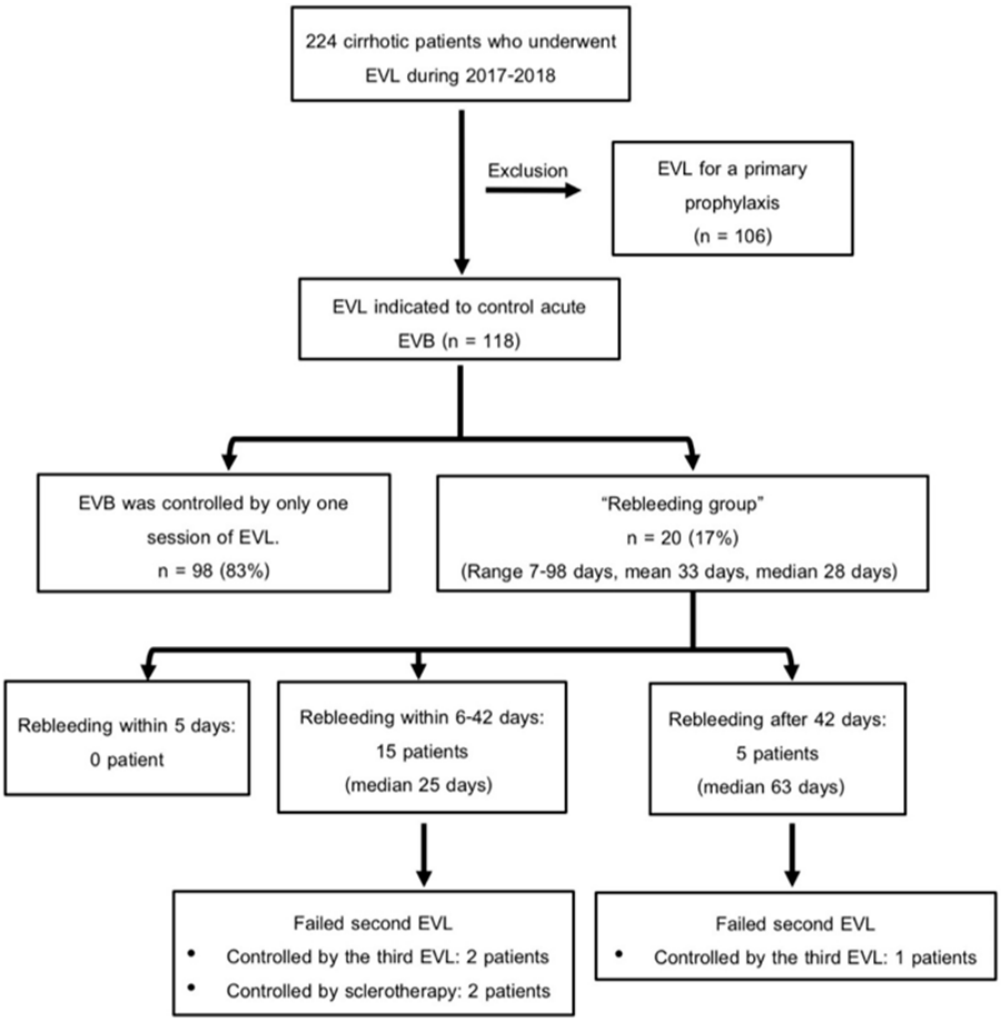

Figure 1. Study flow diagram.

following 6 months in these patients. These data could add on the current guidelines in natural history and management schemes[3,10].

In some patients with EVB, the bleeding could spontaneously stop approximately 40 to 50% as evidenced in a placebo-controlled trials[11]. In these population, the estimated rate of rebleeding was one-third within six weeks (early rebleeding) and in 70 percent over the long-term[12,13]. The risk of rebleeding peaks in the first 5 days in which 40% of all rebleeding occur and slowly decreases afterward. However, there was different outcome reporting from India showing that the success rate of bleeding control was achieved in 100% within 30 days and the rate of recurrent bleeding was 19% within a mean period of about 4 years[14]. The mortality at 6 weeks following variceal bleeding is 10 to 20 percent with current therapy. Treatment with either endoscopic variceal ligation or endoscopic sclerotherapy is associated with decreases in both rebleeding rates and mortality[12,15-17]. Previous study from Nakhon Sawan provincial hospital in Thailand showed that the rebleeding after EVL was 25.8% with subsequent high mortality rate[18]. After EVL, the HVPG returned to baseline. The rebleeding after EVL could occur due to its inability to affect the blood flow through perforators and esophageal collateral veins[19]. Current guidelines recommend the management of recurrent bleeding with PTFE covered TIPS or a second attempt at endoscopic therapy if the bleeding is not severe. Other bridging therapies to more effective therapy, such as TIPS are balloon tamponade and self-expandable metal stents[3,10].

Despite the limitation of TIPS accessibility, repeated endoscopic sessions inevitably have to be performed either by EVL or sclerotherapy to control rebleeding. The exact role and outcome of repeated attempts with endoscopy has not yet been evaluated. Currently, there was only few

Table 1. Baseline characteristics 118 cirrhotic patients who underwent EVL due to acute EVB during 2017 to 2018

Variables	Rebleeding group (n = 20)	Non-rebleeding group (n = 98)	*p*-value
Sex (male:female)	14: 6	64: 24	0.61
Age (years)	57.2 (11.5)	57.0 (13.7)	0.95
HCC	12 (60)	40 (40.8)	0.12
Beta-blockers used before EVB	8 (40)	30 (30.6)	0.41
Heart rate before EVB (beats/min)	79.7 (10.6)	87.79 (18.5)	0.01
Beta-blockers used after EVB	12 (60)	72 (73.5)	0.23
Heart rate after EVB (beats/min)	72.2 (12.3)	74.2 (13.8)	0.57
AST (U/L)	138 (174.5)	134 (185.1)	0.94
ALT (U/L)	66.4 (89.6)	65.5 (96.9)	0.97
ALP (U/L)	154.6 (130.2)	158 (149)	0.92
Total bilirubin (mg/dL)	7 (13.5)	3.7 (4.3)	0.29
Creatinine (mg/dL)	1.7 (2)	1.1 (0.9)	0.16
Albumin (g/dL)	2.6 (0.4)	2.7 (0.6)	0.36
INR	1.5 (0.3)	1.5 (0.4)	0.95
Hemoglobin (g/dL)	8.3 (2.6)	8.5 (2.4)	0.76
Platelets count ($x10^3/\mu L$)	158.8 (739.7)	145.1 (870.7)	0.51
White blood cell count ($x10^3/\mu L$)	10.3 (5.4)	10.4 (8.2)	0.95
Proportion of decompensation	17 (85)	73 (74.5)	0.31
MELD score	19.6 (9.5)	17.2 (6.5)	0.16

Data are expressed as mean (standard deviation) or number (%).
ALT = alanine transaminase; AST = aspartate transaminase; ALP = alkaline phosphatase; EVB = esophageal variceal bleeding; EVL = endoscopic variceal ligation; HCC = hepatocellular carcinoma; INR = international normalised ratio; MELD = Model for End-stage Liver Disease; SD = standard deviation

Table 2. Causes of cirrhosis

Causes, n (%)	Rebleeding group (n = 20)	Non-rebleeding group (n = 98)
Alcohol	6 (30)	30 (30.6)
Hepatitis B	4 (20)	18 (18.4)
Hepatitis C	3 (15)	16 (16.3)
Autoimmune hepatitis	0	4 (4.1)
Nonalcoholic fatty liver disease	0	6 (6.1)
Multiple	1 (5)	12 (12.2)
Others/unknown	6 (30)	12 (12.2)

case report of repeated EVL procedure in patients with recurrent EV bleeding[20].

Our real-world data suggested that rebleeding occurred in 17% of patients and the second attempt endoscopic therapy yield 75% of success in rebleeding group (n = 20). Other failed second endoscopy session patients required third EVL and sclerotherapy. There was no patient required more than 3 sessions of endoscopy and no patient has complication from sclerotherapy. Rebleeding rate evidenced from this study was comparable to previous studies[15-17]. However, there was no rebleeding occurred in the first 5 days.

TIPS was considered as a rescue therapy for uncontrolled EVB (persistent bleeding) and rebleeding[3,10]. Other option is shunt surgery which depends on local expertise and resources[21]. Efficacy of TIPS on technical and

Table 3. Univariate and multivariate logistic regression for recurrent EVB within 6 weeks

	Univariate analysis		Multivariate analysis	
	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
Sex	1.56 (0.49 to 5.00)	0.45	2.36 (0.61 to 9.11)	0.21
Age	1.01 (0.97 to 1.05)	0.62	0.98 (0.93 to 1.03)	0.43
HCC	4.16 (1.24 to 13.95)	0.02	5.96 (1.41 to 25.19)	0.02
Beta-blockers used before EVB	2.03 (0.68 to 6.10)	0.21		
Heart rate before EVB	0.97 (0.94 to 1.01)	0.13		
Beta-blockers used after EVB	0.78 (0.25 to 2.49)	0.68		
Heart rate after EVB	1.00 (0.96 to 1.05)	0.86		
AST	1.00 (1.00 to 1.00)	0.49		
ALT	1.00 (1.00 to 1.00)	0.52		
ALP	1.00 (1.00 to 1.00)	0.49		
Total bilirubin	1.06 (1.00 to 1.12)	0.06		
Creatinine	1.47 (1.03 to 2.10)	0.03	1.47 (1.02 to 2.11)	0.04
Albumin	0.76 (0.28 to 2.04)	0.59		
INR	0.47 (0.07 to 2.92)	0.41		
Hemoglobin	1.06 (0.85 to 1.33)	0.59		
Platelets count	1.00 (1.00 to 1.00)	0.22		
White blood cell count	1.00 (1.00 to 1.00)	0.83		
Decompensation	1.28 (0.34 to 4.91)	0.72		
MELD score	1.04 (0.97 to 1.12)	0.31		

ALT = alanine transaminase; AST = aspartate transaminase; ALP = alkaline phosphatase; EVB = esophageal variceal bleeding; EVL = endoscopic variceal ligation; HCC = hepatocellular carcinoma; INR = international normalised ratio; MELD = Model for End-stage Liver Disease; OR = Odds ratio

clinical success is high (each exceeding 90%). The one month rebleeding rates are 15% or less in the era of covered stent grafts[22,23]. Some causes of TIPS failure are insufficient variceal embolization, TIPS stenosis or occlusion, severe coagulopathy, inadequate portosystemic gradient reduction, and TIPS under-dilation[23].

In center with limited access to TIPS, the referral systems to specialist center with 24 hours emergency TIPS service should be arranged[21]. However, the difficulty to achieve that goal remains the problem due to local availability and competency issues. In the UK, majority of centers provided emergency TIPS service performed 11 to 20 procedures per year. Despite published recommendation on emergency TIPS, there was no clear data of an increases in procedures during 2006 to 2017. This may indicate limitation of clinical comprehension and capacity[24]. To improve the outcome, at least 10 procedures per year should be perform at each unit[25].

From the present study, the mortality at six weeks was 15%. Current data found the decreasing trend of mortality from 42% in the past 30 years to 15% to 24% with current therapies[12,15-17]. The peak onset of death occurred in the first 5 to 10 days and slowly returned to baseline at 6 weeks[12,16]. Main causes of death in patients with EVB are liver failure, infections, and hepatorenal syndrome. While 20 to 40% of death were related to uncontrolled bleeding and exsanguination[17,26]. Our patients showed comparable mortality rate with liver failure and infection as causes of death.

Prognostic factors for recurrent EVB were studied in several studies. These included beta-blockers use, ascites, the number of bands placed, the extent of varices, prothrombin time, active bleeding at endoscopy, platelet count, time to admission, alcohol, heart rate, encephalopathy, HVPG greater than or equal to 20 mmHg, Child-Pugh score, portal vein thrombosis, AST, active bleeding, transfusion volume and MELD greater than or equal to 18[6,7,17,27-30]. Our findings suggested HCC and creatinine as factors for recurrent EVB within six weeks. HCC and Creatinine have also been related to mortality in patients with liver disease[16,17]. However, our limited death numbers restricted the statistical prediction for prognostic factors of mortality.

The present study has several limitations. The retrospective basis of these studies limits the validity of these observations. Our 2-years data from the tertiary care institution showed similar baseline characteristics between

the two groups except baseline heart rate before EVB (p = 0.01) which could vary from multiple conditions including hemodynamic status and beta-blockers compliance. There was no information on HVPG measurement as this was not routinely performed in our center. HVPG measurement is a useful monitor of treatment response. HVPG greater than or equal to 20 mmHg predicts risk of recurrent EVB in patients treated with pharmacologic and endoscopic therapy[30]. There was no TIPS performed for rebleeding in these population, therefore there was no comparative outcome between guideline-based and this real-world practices. However, 75% of our rebleeding patients were successfully controlled by second EVL and the rest were controlled by third endoscopic interventions. There was no more rebleeding during the 6-months follow-up. This could be a bridging management before definite treatment such as TIPS or liver transplantation.

Conclusion

The second attempt at endoscopic therapy can be considered to control recurrent EVB after the first EVL with a success rate of 75% in area where an accessibility to a treatment with TIPS is limited.

What is already known on this topic?

Combined pharmacologic and endoscopic treatment are the main management in EVB. In patient with recurrent hemorrhage, TIPS or repeated endoscopy is considered other rescue options. In a real world setting where the accessibility to TIPS is limited, repeated endoscopic sessions are inevitably performed.

What this study adds?

The outcome of repeated attempt at endoscopic therapy for recurrent esophageal variceal hemorrhage showed satisfied results with 75% success rate. This could be a bridging management before definite treatment such as TIPS or liver transplantation.

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Conflicts of interest

The authors declare no conflict of interest.

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ผลของการรักษาด้วยวิธีส่องกล้องรัดหลอดเลือดดำโป่งพองด้วยยางในการควบคุมภาวะเลือดออกจากหลอดเลือดดำหลอดอาหารโป่งพอง: โลกแห่งความจริง

ภัคพล รัตนชัยสิทธิ์, ปิยะพันธ์ พฤกษพานิช, รุ่งฤดี ชัยธีรกิจ, ปิยะวัฒน์ โกมลมิศร์, สมบัติ ตรีประเสริฐสุข

ภูมิหลัง: การรักษาภาวะเลือดออกจากหลอดเลือดดำหลอดอาหารโป่งพอง ใช้วิธีการรักษาด้วยยา และการส่องกล้องเป็นหลัก โดยเฉพาะการรัดหลอดเลือดดำโป่งพองด้วยยาง ผู้ป่วยที่เกิดภาวะเลือดออกซ้ำ หลังการรักษาด้วยวิธีดังกล่าว ควรรักษาโดยการขยายหลอดเลือดดำที่ตับผ่านทางหลอดเลือดดำที่ต้นคอ อย่างไรก็ตามในโลกแห่งความจริง การเข้าถึงการรักษานี้จำกัด จึงต้องให้การรักษาผู้ป่วยด้วยวิธีการส่องกล้องซ้ำ

วัตถุประสงค์: เพื่อศึกษาผลของการรักษาด้วยวิธีการส่องกล้องซ้ำในผู้ป่วยที่มีภาวะเลือดออกซ้ำจากหลอดเลือดดำหลอดอาหารโป่งพอง

วัสดุและวิธีการ: ผู้ป่วยที่มีภาวะเลือดออกจากหลอดเลือดดำหลอดอาหารโป่งพองที่ได้รับการรักษาด้วยวิธีการส่องกล้องซ้ำในช่วงเดือนมกราคม พ.ศ. 2560 ถึงเดือนธันวาคม พ.ศ. 2561 ประเมินผลการรักษาในแง่อัตราการเกิดเลือดออกซ้ำและอัตราตายร่วมกับปัจจัยเสี่ยงในการเกิดเลือดออกซ้ำ

ผลการศึกษา: ผู้ป่วย 118 รายที่มีภาวะเลือดออกจากหลอดเลือดดำหลอดอาหารโป่งพอง ในช่วงเวลาที่ทำการศึกษา สามารถหยุดเลือดได้ด้วยการส่องกล้องเพียง 1 ครั้ง 98 ราย (ร้อยละ 83) ขณะที่ 20 ราย (ร้อยละ 17) มีเลือดออกซ้ำ ต้องใช้การส่องกล้องตั้งแต่ 2 ครั้งขึ้นไปเพื่อหยุดเลือด ผู้ป่วยที่มีเลือดออกซ้ำ 15 ราย (ร้อยละ 75) มีเลือดออกภายใน 6 สัปดาห์หลังการส่องกล้องครั้งแรก การรักษาด้วยการส่องกล้องครั้งที่สองสามารถหยุดเลือดได้ 15 ราย (ร้อยละ 75) และผู้ป่วยที่เหลือสามารถหยุดเลือดได้ด้วยการส่องครั้งที่สาม อัตราตายที่ 6 สัปดาห์ เท่ากับร้อยละ 15 การมีภาวะตับแข็งและระดับ creatinine เป็นปัจจัยเกี่ยวข้องกับการเกิดเลือดออกซ้ำที่ 6 สัปดาห์ ด้วยความเสี่ยง 5.96 เท่า, ช่วงความเชื่อมั่นร้อยละ 95 ระหว่าง 1.41 ถึง 25.19, ค่าพีเท่ากับ 0.02 และ 1.47 เท่า, ช่วงความเชื่อมั่นร้อยละ 95 ระหว่าง 1.02 ถึง 2.11, ค่าพีเท่ากับ 0.04 ตามลำดับ

สรุป: การรักษาด้วยการส่องกล้องครั้งที่สองสามารถพิจารณาใช้ในผู้ป่วยที่เกิดภาวะเลือดออกซ้ำ หลังการรักษาด้วยวิธีส่องกล้องครั้งแรกโดยมีโอกาสสำเร็จร้อยละ 75 ในกรณีไม่สามารถเข้าถึงการขยายหลอดเลือดดำที่ตับ ผ่านทางหลอดเลือดดำที่ต้นคอได้