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Original Research Article

Endoscopic Variceal Ligation in Primary and Secondary Prevention of Variceal Bleeding: A Retrospective Study in Tertiary Care Center, Sitapur, UP, India.

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Abstract:
Background: Endoscopic variceal ligation (EVL) is a crucial procedure for the primary and secondary prevention of variceal bleeding. The objective of this study was to evaluate the efficacy and tolerability of EVL in the prevention of variceal bleeding.
Methods: This was a retrospective, single-center study from March 2023 to December 2024, including all patients who came for EVL in primary or secondary prevention.
Results: A total of 100 patients (male/female: 72/28) were included. The mean age of the patients was 39.00±7.14 years (range: 18–70). Portal hypertension was secondary to cirrhosis in 22 patients (22%) and to a non-cirrhotic cause in 78 patients (88%). EVL was indicated for primary and secondary prevention in 5% and 95%, respectively. All patients had received propranolol with a mean daily dose of 108.07±38.52 mg (extremes: 80–160). Eradication of varices was achieved in 58 patients (58%) with an average of 2.02±0.50 sessions (extremes: 1–4) and an average duration of 9.12±1.23 months (extremes: 1–18). Eighteen patients (18%) had variceal bleeding. There was no significant difference between patients with cirrhotic and non-cirrhotic portal hypertension in terms of varices eradication, variceal bleeding. Dysphagia (74%) and retrosternal pain (79%) were the main adverse events after ligation.
Conclusion: EVL is an efficient technique to eradicate varices. Its tolerance is good with post-ligation signs that are rapidly regressive.
Keywords: Endoscopic variceal ligation, variceal bleeding, Liver cirrhosis, Portal Hypertension, Efficacy, Safety.

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Introduction

Liver cirrhosis is a chronic disease with significant prevalence worldwide, associated with high morbidity and mortality. Upper gastrointestinal (GI) bleeding following variceal rupture is a leading cause of death in liver cirrhosis patients with portal hypertension [1]. Traditional esophageal variceal ligation (EVL) introduced in 1986 is now advocated as a safe procedure for the treatment of esophageal variceal bleeding via mechanical blockade of variceal fow [2,3].

EVL has been accepted as the preferred endoscopic treatment for prevention of variceal rebleeding and achieving adequate hemostasis, with a lower rate of rebleeding, mortality, and complications than sclerotherapy [4]. However, EVL has been associated with a wide range of complications such as substernal pain, esophageal ulceration, stricture, perforation, and even death. Complications can occur in up to 40% of patients, while incidence of treatment-related death is 1% to 2% [5,6]. Currently, much controversy surrounds EVL induced altered esophageal motor function such as changes in motility, described in some reports as transient and persistent in others [8,9].

Esophagogastric variceal bleeding (EVB) is one of the most serious and aggressive complications of portal hypertension in liver cirrhosis, and is the leading cause of death in patients with cirrhosis [10]. Esophagogastric varices are present in 52% of patients with cirrhosis, and varices are present in 50–60% of patients with compensated cirrhosis and up to 85% of patients with decompensated cirrhosis. The rate of variceal bleeding is 5–15% per year, and the mortality rate after 6 weeks of variceal bleeding is as high as 15–25% [11]. EVL is a first-line treatment method for preventing first EVB (primary prophylaxis), controlling acute esophagealgastric variceal bleeding, and preventing second EVB (secondary prophylaxis). Notably, EVL is recommended by numerous national and regional gastroenterology and hepatology society guidelines, including those in Europe and America [12].

The EVL is influenced by numerous factors, including an esophageal varices (EV) diameter that is too large to be completely ligated. For complete ligation, and to ensure that the surface mucosa of the target vessel, including the proximal and contralateral walls of the vessel, are completely absorbed into the ligator, EVL is only used for varices of a medium diameter. Moreover, the ligation ring may detach following EVL and fatal rebleeding may occur. Thus, the Chinese Guidelines for Liver Cirrhosis [8] state that an EV diameter of >2.0 cm is a contraindication for EVL, and results of a previous study suggested that an EV diameter >1.0 cm should be included as a contraindication for EVL [8].

Endoscopic Variceal Ligation: In 1989, Stiegmann and Goff introduced the application of endoscopic variceal ligation (EVL) to treat esophageal varices. In contrast to the use of chemical action induced by EST, EVL obliterates varices by causing mechanical strangulation with rubber bands. The technique is an adaptation of that applied to banding ligation of internal hemorrhoids. Owing to its action on the suctioned, entrapped varices, the main reaction is usually limited over the superficial esophageal mucosa. EVL consists of the placement of rubber rings on variceal columns which are sucked into a plastic hollow cylinder attached to the tip of the endoscope [12,13]. Multiples hot devices have largely replaced the original single-shot ligators, since the procedure is much simpler and faster with multishot devices, and an overtube is not required, thus avoiding the severe complications related to its use.

Furthermore, new transparent caps are available which improve the visibility (visibility with the old caps may be reduced by 30%)[14]. Several commercial multiband devices are available for EBL. Eradication of varices usually requires two to four EVL sessions [15]. Variceal eradication is obtained in about 90% of patients, although recurrence is not uncommon [16,17]. The main disadvantage of EVL is possibly a higher frequency of recurrent varices [17]. EBL was developed as an alternative, with fewer complications than EST, for the treatment of esophageal varices. The complications of EVL include esophageal laceration or perforation (mostly due to trauma of the overtube), transient dysphagia, retrosternal pain, esophageal stricture, transient accentuation of portal hypertensive gastropathy, ulcer bleeding, and bacteremia [15].

The incidence of bacteremia and infectious sequelae after EIS was 5-10 times higher than after EVL [16].The aim of this study was to evaluate the efficacy and safety of EVL in rural patients who had benefited from this procedure in primary and secondary prevention.

Materials and Methods

Study Site: Tertiary Care Center, Department of Surgery, HIMS, Ataria, Sitapur, UP, India.

Study Design: Retrospective and single-center study.

Study Period: 18th Months, March 2023 to December 2024

Sample Size: 100, both sexes (male/female: 62/28).

We included all patients treated EVL in primary or secondary prevention.

Patients who had stopped after a single session of EVL without endoscopic control were excluded.

The parameters studied were as follows: gender, age, comorbidities, previous bleeding, jaundice, ascites, splenomegaly, grade of varices, red signs, Child–Pugh class, propranolol dose, number of sessions, interval between sessions, follow-up time, varices eradication, bleeding rate during the procedure, mortality, and adverse events.

Endpoints

The primary endpoints were varices eradication rate, variceal bleeding rate. Safety was judged on the occurrence of immediate post ligation adverse events.

Definitions

A diagnosis of cirrhosis was based on the results of noninvasive liver examination (clinical, biological, hepatobiliary ultrasound, and degree of fibrosis).

Alcoholic etiology of cirrhosis was retained on the basis of an alcohol consumption of more than 20 g/day in women and 40 g/day in men for at least 6 years and without any other etiologies found. Viral and autoimmune etiology of cirrhosis was retained in view of the positivity of viral markers and anti-tissue auto antibodies. The diagnosis of portal thrombosis was made by hepatic Doppler ultrasound and/or abdominal CT scan. Variceal bleeding was retained by the association of several criteria: evidence of PH and the presence of esophageal varices with red signs or recent bleeding (hematemesis and/or melena). Eradication of varices was defined by the disappearance of esophageal varices or the existence of grade 1 fibrous varices.

Description of EVL and management of variceal bleeding: EVL consisted of the placement of rubber rings on variceal columns, which are sucked into a plastic hollow cylinder attached to the tip of the endoscope by an experienced senior endoscopist. Ligation was started at the lower end of the esophagus and proceeded upwards in a spiral fashion.

The average number of rubber bands was five (extremes 2–4). Olympus: Q160 video endoscope and a rechargeable multiband system (Euroligator) were used. EVL sessions were performed under general anesthesia with propofol administered intravenously in a patient fasting for at least 6 h.

Induction dose was 2.5 to 3 mg/kg. The maintenance dose was done by a bolus of propofol of 25, 50, or 100 mg, intermittently as judged by the anesthesiologist, depending on the clinical (hemodynamic parameters) and sedation level of the patient. After the ligation, the patients were kept in hospital for 24-h monitoring and systematically put on nefopam infusion and paracetamol every 8 h associated with a proton pump inhibitor. Patients with variceal hemorrhage between EVL sessions were hospitalized and supportively cared according to a standardized protocol of the gastroenterology unit. Propranolol was continued in all patients during hospitalization, maintaining the dose before bleeding. EVL was continued at discharge in all patients until eradication of esophageal varices.

Statistical Analysis: Statistical analyses were performed using SPSS (Inc., Chicago, IL, USA version 26.1). Quantitative variables were expressed as mean and standard deviation (SD), while qualitative variables were expressed as frequency and percentage. Te chi-square ($\chi 2$) test or Fisher's exact test, when appropriate, was used for the comparison of qualitative variables between cirrhotic PH and noncirrhotic PH. Continuous variables in both groups were compared using the paired t-test. In case of a skewed distribution, the Mann-Whitney U-test was used for the comparison of continuous variables. The accumulative probability of patients who experienced bleeding was assessed by Kaplan-Meier curves. Multivariate Cox proportional hazard models were used to detect independent predictors of variceal bleeding. All p-values were two-sided, with values<0.05 considered statistically significant.

Results

A total of 100 patients (male/female: 72/28) were included. The mean age of the patients was 39.00±7.14 years (range: 18–70). Portal hypertension was secondary to cirrhosis in 22 patients (22%) and to a non-cirrhotic cause in 78 patients (88%) in Table-1.

Table 1: Baseline clinical and endoscopic characteristics of the enrolled patients

Sl.no	Variables	Total (N=100)	Cirrhotic PH (N=22)	Non-cirrhotic PH (N=78)	P-value
1	Gender, male, n (%)	72	22 (22%)	78 (78%)	0.05
2	Mean age ± SD (years)	39.00±7.14	46.3±7.43	38.26±6.14	0.05
3	Hypertension, yes/no	32/68	12/10	20/58	0.05
4	Diabetes, yes/no	13/87	6/16	7/71	0.05
5	Number of previous bleeds, mean±SD	3.86±1.50	3.23±2.00	2.88±1.56	0.58
6	1/2/≥2	14/31/21	0/7/8	9/24/36	0.05
7	Jaundice, yes/no	27/73	10/12	17/61	<0.01
8	Splenomegaly, yes/no	67/33	13/9	54/24	0.02
9	Stage 1/2/3/4/5	7/33/21/9/15	16/8/0/0/0	0/29/21/17/15	0.05
10	Ascites, yes/no	34/66	14/8	20/58	0.19
11	Grade 1/2/3	5/13/16	2/8/4	1/10/9	0.02
12	Causes of cirrhotic PH, n (%)				
13	Alcohol	12	12 (54.54%)	-	-
14	Hepatitis B virus	7 (7%)	7 (31.81%)	-	-
15	Hepatitis C virus	(2%)	2 (9.09%)	-	-
16	Alcohol/hepatitis B virus	2 (2%)	2 (9.09%)	-	-
17	Autoimmune hepatitis	4 (4%)	4 (18.18%)	-	-
	Causes of non-cirrhotic PH, n (%)				
18	Portal thrombosis	7 (7%)	-	7 (8.97%)	-
19	Grade of esophageal varix III/II	76/24	20/2	56/22	0.05
20	Red signs, yes/no	49/51	8/14	41/ 37	0.05

21	Child–Pugh score, mean±SD	11.38±3.29	11.38±3.29	-	-
22	Child–Pugh class, A/B/C	13/28/122	13/28/12	-	-
23	Dose de propranolol (mg/jour), mean±SD	108.07±38.52	86.15±22.19	114.55±40.0	0.02
24	Propranolol dose (mg/day), 80/160	67/33	18/4	49/29	0.02
	Indication for EVL, n (%)				
25	Primary prevention	8 (8%)	1 (1%)	7 (7%)	0.33
26	Secondary prevention	92 (92%)	22 (100%)	70 (89.74%)	
27	Number of sessions, mean±SD	3.10±2.03	2.61±2.03	3.43±2.04	0.05
28	Time between EVL sessions (months), mean±SD	1.60±0.46	1.41±0.48	1.60±0.46	0.05
29	Follow-up time (months), mean±SD	6.28±6.54	7.69±7.27	5.86±6.33	0.05

PH Portal hypertension, EVL Endoscopic variceal ligation, SD Standard deviation

The mean age was significantly lower in patients with non-cirrhotic PH compared with those with cirrhosis (38.26 vs 46.7, $p<0.05$). Alcohol (12 (54.54%) and hepatitis B virus (7 (31.81%) were the main etiologies of cirrhosis. Grade III varices occupied the 76% of patients (n=76), and 49% (n=49) had red signs. For patients with cirrhosis, the mean Child–Pugh score was 11.38±3.29. All patients were on beta-blocker (propranolol) before EVL (mean dose: 108.07±38.52 mg/day) including 67 patients (67%) on 80 mg/day and 33 (33%) on 160 mg/day. EVL was indicated for primary prevention in 8% of patients and secondary prevention in 92% of cases.

The overall mean number of EVL sessions was 3.10±2.03 (range 1–4). The mean interval between EVL sessions and the mean duration of follow-up were 1.60±0.46 months (range 1–2) and 6.28±6.54 months (range 1–18), respectively. There was no significant difference between the characteristics of cirrhotic and noncirrhotic patients, except for age, the presence of jaundice and splenomegaly, and daily dose of propranolol. The clinical and endoscopic characteristics of the patients are shown in Table-1.

Efficacy and safety of EVL: Eradication of esophageal varices was achieved in 59 patients (59%). The average number of sessions and the average duration to achieve eradication were 3.46±1.30 sessions (extremes: 1–4) and 10.88±5.32 months (extremes: 1–18), respectively. Eighteen patients (18%) had variceal bleeding during the follow-up period.

There was no significant difference between cirrhotic and non-cirrhotic patients in terms of eradication rate, variceal bleeding rate (Table-2, Figure-1). The number of EVL sessions was significantly higher in patients with variceal bleeding compared with those without bleeding (3.30±0.82 vs 2.21±0.98; $p=0.002$).

The probability of variceal bleeding was determined using Kaplan-Meier survival curves (Figure-2). Male gender (HR: 39.00±7.14; CI: 3.16–501.40; $p=0.009$) and number of previous bleeds (HR: 1.34; CI: 1.01–1.80; $p=0.041$) were independent predictors of variceal bleeding during EVL (Table-3). Dysphagia 82 (82%) and retrosternal pain 79 (79%) were the main adverse events after ligation that resolved very quickly.

Table 2: Efficacy and tolerance of EVL in our patients

	Variables	Total (N=100)	Cirrhotic PH (N=22)	Non-cirrhotic PH (N=78)	P value
1	Varices eradication, n (%)	59 (59%)	15 (68.18%)	44 (56.41%)	0.05
2	Number of sessions for eradication, mean±SD	3.46±1.30	3.10±0.34	3.28±1.36	0.7
3	Time for eradication, mean±SD	9.12±5.21	10.88±5.32	8.76±6.23	0.05
4	Variceal bleeding, n (%)	18 (18%)	6 (27.27%)	12 (15.38%)	0.05
5	Death, n (%)	0	0	0	0
6	Tolerance				
7	Dysphagia, n (%)	82 (82%)	22 (100%)	60 (76.92%)	0.01
8	Retrosternal pain, n (%)	79 (79%)	22 (100%)	57 (73.07%)	0.05
9	Perforation, n (%)	3 (3%)	1 (4.54%)	2 (2.56%)	0.05

Figure 1: Endoscopic Image of bleeding of Esophageal Varix

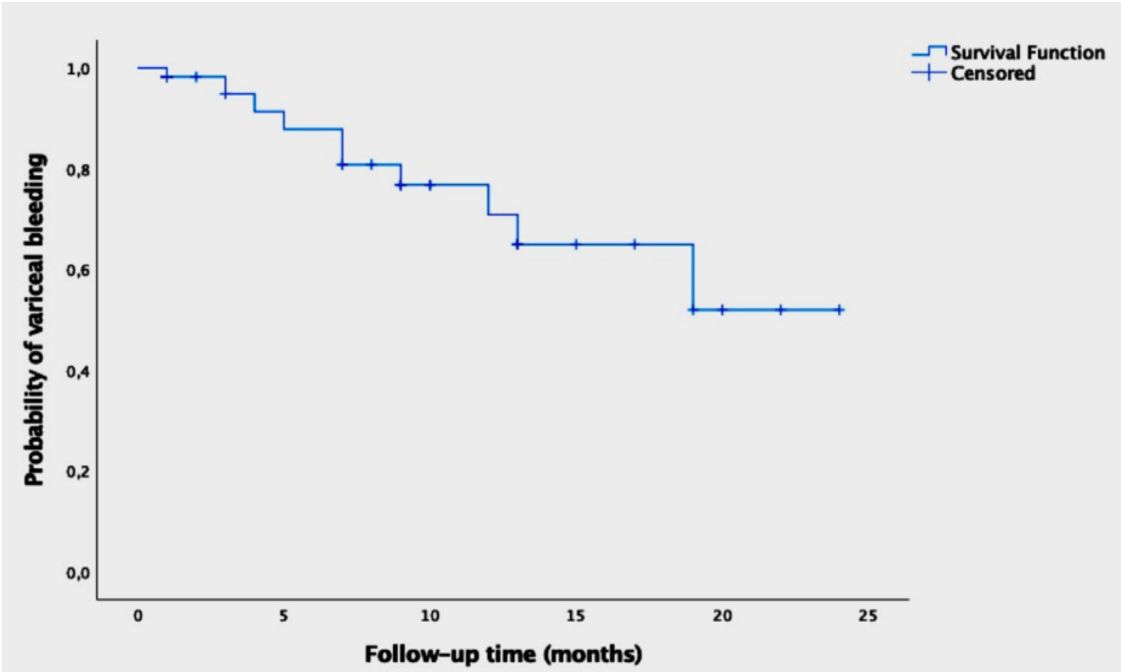

Figure 2: Probability of variceal bleeding was determined using Kaplan-Meier survival curves

Table 3: Predictive factors of variceal bleeding during EVL:

Sl. No	Variables	Multivariate		
		HR	CI (95%)	p-value
	Age (years) (<35 vs≥35)	1.62	0.14–18.4	0.05
	Gender (male vs female)	39.00±7.14	3.16–501.40	0.009
	Number of previous bleeds	21.14	2.01–2.70	0.05
	Splenomegaly (yes vs no)	0.99	1.13–7.80	0.01
	Ascites (yes vs no)	1.76	1.08–6.20	0.05
	Jaundice (yes vs no)	0.62	1.03–3.10	0.05
	Red signs (yes vs no)	1.16	1.02–2.60	0.05
	Cirrhosis vs non-cirrhosis	6.18	2.17–71.20	0.05
	Number of EVL sessions (<3 vs≥3)	1.07	1.0001–220	0.05
	Interval between EVL sessions (months) (1 vs 2)	2.14	1.72–6.81	0.05

EVL= Endoscopic variceal ligation, HR= Hazard ratio, CI= Confidence interval

Discussion

Esophageal variceal bleeding is one of the most important causes of morbidity and mortality in patients with parenchymal liver disease and portal hypertension. Endoscopic treatment is one of the recommended therapeutic armamentariums for primary prevention of variceal bleeding in patients at high risk of bleeding and has become the gold standard for the management of bleeding esophageal varices. Once the initial bleeding episode is controlled by endoscopic treatment, there is a significant risk of rebleeding. Patients who survive the bleeding episode require repeated endoscopic treatments until the varices are obliterated to prevent recurrence [4,6].

This retrospective study evaluated the efficacy of EVL in patients with cirrhotic or non-cirrhotic PH in primary and secondary prevention followed in the Department of Surgery, Hind Institute of Medical Sciences, Ataria, Sitapur, UP, India. This study remained fundamental because it allowed us to determine the eradication rate, the number of sessions for varices eradication, and the rate of variceal bleeding in our Tertiary Care Center.

Nevertheless, this study had several limitations. The retrospective, monocentric nature, and the relatively small size of our sample constituted these main limitations.

The study population consisted mainly of 78% noncirrhotic PH patients. Age has been considered an important risk factor for varicose rebleeding [9]. In the present study, the overall mean age was 39.00±7.14 years. This mean age was significantly higher in the cirrhotic PH group compared to those in the non-cirrhotic PH group.

In this study, secondary prevention of variceal bleeding occupied the totality of the indication for EVL (92%). This finding can be explained by two reasons. The first reason was that the technical platform did not allow us to perform EVL in the context of acute variceal hemorrhage, unlike in other countries [3,7,8,13]. The second reason was that patients came to hospital in the majority of cases only after an episode of hemorrhage, and the diagnosis of PH is often made at this time. Several studies had shown that EVL is effective and safe, requires few sessions to eradicate varicose veins, and significantly reduces the rate of recurrent bleeding. Varices eradication in this study was achieved in 59% of patients with an average of 3.46±1.30 endoscopy sessions.

There was no significant deference in patients with cirrhotic and non-cirrhotic PH. Our eradication rate was similar to those reported in the previous studies [7, 8]. However, this eradication rate remains largely inferior to those of the studies where eradication varies from 79 to 100 [3, 9, 13–15,18]. This difference can be explained by our technical platform. In this study and the other studies, the re-usable ligation kit was used, allowing only a maximum of 5 elastics to be dropped, whereas in Western countries, they use precise and efficient kits (Multiple Band Ligator) allowing a maximum of 8 elastics to be dropped. In addition, the average number of elastic bands recommended is 5 to 8 bands per session, whereas it was 2 to 5 per session in our study [1,14].

In this study, patients required an average of 3 endoscopy sessions with an interval of 3 to 6 weeks to achieve eradication of varicose veins. Several authors had reported the same results [13]. It has been observed that the majority of these patients obtained complete eradication after 3 sessions of ligation [13].

A similar study had reported obliteration of varices in 89.6% of patients with 3 ± 1.99 sessions of ligation [3]. A report also advocated that the required an average of 3.3 sessions at 3–4-week intervals to achieve varices obliteration [12]. In another study mentioned, required a median of 2 sessions using 2-week intervals, while in other study mentioned, required an average of 3.2 sessions with 1-week intervals [9,11]. There are varying views regarding the timing of EVL sessions. We have followed a flexible 3- to 6-week interval for our EVL sessions, whereas some preferred a weekly or biweekly schedule and others a bimonthly schedule [6,7].

In our study, 18 patients (18%) had experienced variceal bleeding. The rate of bleeding was higher in patients with cirrhosis (6 /27.27%) compared with patients with noncirrhotic PH (12/15.38%), it was also found statistically significant. A study had reported a bleeding rate of 15%, similar to our study [13]. Nevertheless, the rate of variceal bleeding is variable in the literature, ranging from 5 to 29% [7, 8, 14,16].

A study had observed that variceal rebleeding was significantly higher in patients who received endoscopic sessions>3 times compared with those who received sessions≤3 times (61.5% vs 17.5%, $p<0.001$) [9]. This finding was verified in our patients where the number of EVL sessions was significantly higher in patients with variceal bleeding compared with those without bleeding (3.30±0.82 vs 2.21±0.98; $p=0.05$). In this study, male gender (HR: 39.00±7.14; CI: 3.16–501.40; $p=0.009$) and number of previous bleeding (HR: 21.14; CI: 2.01–2.70; $p=0.05$) were independent predictors of variceal bleeding during EVL. We found that the predictive factors were different in each of the studies [9–11,18]. The population was different in each study explaining this finding. EVL is an effective treatment option for the prevention of recurrent variceal bleeding. However, the efficacy of elastic ligation is significantly increased by the addition of β-blocker therapy [5, 15]. Other treatment modalities such as splenectomy/EVL or EVL/ sclerotherapy could also be considered in selected clinical scenarios [2, 9]. As in our study, other authors had also reported the adverse effects after ligation, such as dysphagia and retrosternal pain [1, 7, 8, 17].

Conclusion

This study demonstrates the feasibility and efficacy of EVL to eradicate esophageal varices and reduce variceal rebleeding. Its tolerance is good even if there are post-ligature signs which are rapidly regressive. The improvement of the technical platforms remains at least necessary to improve our results.

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