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Original Research Article

Endoscopic Band Ligation versus Endoscopic Sclerotherapy for Oesophageal Varices in Portal Hypertension: A Prospective Comparative Study

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Abstract:

Background: Variceal haemorrhage is a serious complication of portal hypertension, and endoscopic sclerotherapy (EST) and endoscopic band ligation (EBL) remain the two principal endoscopic modalities used for its control, yet their comparative procedural burden and short-term efficacy warrant continued local evaluation.

Aim: To study the comparable outcome of endoscopic variceal band ligation and endoscopic sclerotherapy in the management of oesophageal varices.

Methods: This hospital-based prospective comparative study enrolled 50 patients with portal hypertension and grade II–IV oesophageal varices, allocated equally to an EST group (n=25) and an EBL group (n=25) by an alternate allocation method. Baseline demographic, clinical and laboratory profiles were recorded, and patients were followed clinically and endoscopically for six weeks.

Results: The two groups were comparable at baseline for age, gender, variceal grade, aetiology and laboratory parameters ($p>0.05$ for all). Patients in the EST group required a significantly higher sclerosant volume across successive sessions than the number of bands used in the EBL group ($p=0.001$–0.005). Retrosternal pain, odynophagia and oesophageal ulceration occurred significantly more often after EST ($p=0.01$, 0.01 and 0.04 respectively). At six weeks, complete variceal eradication was seen in 76% of the EBL group against 48% of the EST group ($p=0.02$), and rebleeding was significantly higher following EST (32% vs 8%, $p=0.03$). Post-procedure hospital stay was numerically shorter with EBL, though the difference did not reach significance ($p=0.19$).

Conclusion: EBL was associated with a lower treatment burden, fewer local complications and superior short-term variceal eradication compared with EST, and appears the preferable endoscopic modality where both options are technically feasible.

Keywords: Oesophageal varices; Endoscopic band ligation; Endoscopic sclerotherapy; Portal hypertension; Variceal eradication.

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Introduction

Portal hypertension leads to the formation of oesophageal varices, and their rupture remains one of the most feared complications in patients with chronic liver disease.[1] Variceal haemorrhage carries an appreciable mortality with each bleeding episode, and repeated episodes further compromise hepatic reserve, so timely and effective management of varices has direct bearing on patient survival.[2] Endoscopy occupies a central place in both diagnosis and treatment of variceal disease, permitting direct visualisation of the varices along with therapeutic intervention in the same sitting.[3]

Two endoscopic techniques, sclerotherapy and band ligation, have been used over the decades for control and eradication of varices. Sclerotherapy acts by injecting a sclerosant agent into or adjacent to the varix, producing thrombosis and subsequent fibrosis, whereas band ligation mechanically strangulates the varix with an elastic band, leading to its later sloughing.[4] Sclerotherapy was historically the first endoscopic option available, but band ligation has gained wider acceptance owing to a perceived lower complication rate.[5] Even so, the published comparisons are not entirely uniform,

with some studies reporting broadly comparable eradication rates between the two methods and others favouring ligation for fewer sessions and reduced local mucosal injury.[6,7]

Much of the comparative literature on this subject originates from outside India, and local data evaluating procedural burden together with short-term efficacy in a single cohort remain limited. Portal hypertension in this setting arises from a mix of cirrhotic and non-cirrhotic causes, and in a tertiary care hospital, the number of sessions required, length of hospital stay, and complication profile all influence patient acceptance of a given technique. A comparative evaluation carried out in this population was therefore considered useful in guiding routine practice.

The choice between the two techniques in day-to-day practice is often guided as much by procedural burden, cost of consumables, and patient tolerance of repeated sessions as by eradication rate alone, and these practical considerations are not always captured fully in efficacy-only comparisons.[6] A study that records both the resource and symptom burden of treatment, alongside the standard endoscopic endpoints, would therefore be of more direct use to a treating surgeon deciding which technique to offer a given patient.

This prospective comparative study was accordingly undertaken in patients with grade II–IV oesophageal varices, to compare the disappearance and recurrence of varices, post-procedure oesophageal ulceration, post-procedure chest pain, and duration of post-procedure hospital stay between EST and EBL, so that the technique offering the better short-term safety and efficacy profile in this patient population could be identified.

Aim

To study the comparable outcome of endoscopic variceal band ligation and endoscopic sclerotherapy in the management of Oesophageal varices.

Materials and Methods

This was a hospital-based prospective comparative study carried out in the Department of General Surgery, Jaipur National University, Institute for Medical Sciences and Research Centre, Jaipur, Rajasthan, over a period of 18 months. Ethical clearance for the study protocol was obtained from the Institutional Ethics Committee prior to enrolment of any patient, and the study was initiated only after due approval was granted. The study population comprised patients admitted to the Department of Surgery with portal hypertension, together with patients referred from other departments with complaints of haematemesis and/or melena, who on upper gastrointestinal endoscopy were diagnosed with grade II, III or IV oesophageal varices. Patients fulfilling all of the following inclusion criteria were enrolled in the study:

1. Age 18 years and above
2. Both sex
3. Endoscopically diagnosed Grade II, III and IV Oesophageal varices
4. Patients complaining with hematemesis and/or melena
5. Due to Portal Hypertension
6. Patient who are giving consent for the proposed endoscopic treatment.

Patients meeting any of the following exclusion criteria were not enrolled:

1. Age <18 years
2. Grade I varices
3. Non portal hypertension causes of upper GI bleeding.
4. Prior history of endoscopic treatment and shunt operation (TIPS) for varices.
5. Patient who are not giving consent for the proposed endoscopic treatment.

The sample size was calculated using the Cochran formula with finite population correction. For the infinite-population estimate, an alpha error of 0.1 (margin of error, e = 0.1), an estimated attribute proportion of p = 0.5 with its complement q = 0.5, and a Z-value of 1.65 (corresponding to a study power of 90%) were used, giving an initial recommended sample size (n_0). This was then adjusted for a finite reference population of N = 200 using Cochran's finite population correction to yield the adjusted sample size. Taking this calculation together with feasibility of recruitment within the study period, a total of 50 patients was enrolled, with 25 patients allocated to each treatment arm.

Consecutive sampling was used, whereby every eligible patient presenting during the study period was recruited in sequence until the calculated sample size of 50 was reached. Group allocation was carried out by an alternate allocation method, so that patients were assigned in turn to either the endoscopic sclerotherapy group or the endoscopic band ligation group, keeping the two arms numerically equal. Written informed consent was obtained from every patient, or from a legally acceptable representative where applicable, before the endoscopic procedure was performed.

Data for the study were drawn from a pre-tested, structured proforma completed for each patient, together with clinical records, endoscopy findings and laboratory reports generated as part of routine work-up. Detailed history and clinical examination findings were recorded prospectively at enrolment, following which patients underwent baseline investigations comprising complete blood count, C-reactive protein, liver function tests, prothrombin

time/INR, random blood sugar, blood urea, serum creatinine, electrocardiography, urine routine and microscopy, HIV serology, HBsAg, and diagnostic upper gastrointestinal endoscopy. For the procedure itself, patients were kept nil per oral for six hours beforehand, and Xylocaine spray was applied over the posterior pharyngeal wall prior to endoscopy. Diagnostic endoscopy confirmed the presence and grade of oesophageal varices, after which the patient underwent the assigned procedure. In the sclerotherapy group, visible varices were injected in the paravariceal region with 1% polidocanol using a 22-gauge disposable sclerosant needle, with the actively bleeding varix injected first in patients presenting with haemorrhage, and colour change of the varix taken as confirmation of adequate injection; the volume of sclerosant used at each session was recorded. In the band ligation group, a PENTAX upper gastrointestinal video endoscope fitted with a six-shooter multi-band kit was used; once the varix had been drawn into the cap by continuous suction and the red-out sign appeared, a silicone band was released, beginning at the gastro-oesophageal junction and proceeding upward in a spiral pattern; the number of bands applied at each session was recorded. Patients in both groups were followed clinically for post-procedural symptoms and adverse events over the subsequent six weeks, and a repeat endoscopy was performed at six weeks to reassess variceal status, grading and number of variceal columns, and to document eradication, persistence or recurrence.

The outcomes of primary interest were the disappearance and recurrence of varices at six weeks, post-procedure oesophageal ulceration, post-procedure chest pain, and duration of post-procedure hospital stay, all of which were captured through the six-week follow-up endoscopy and the clinical assessment sheets completed at each visit. Additional post-procedure findings, including fever, tachycardia and rebleeding episodes, were also recorded to place these outcomes in context.

Data were entered and cleaned in MS-Excel and analysed using SPSS version 25. Quantitative variables were summarised as mean ± standard deviation where normally distributed, or as median with interquartile range where the distribution departed from normality on Shapiro-Wilk testing. Qualitative variables were expressed as frequencies and percentages. Continuous variables were compared between the two groups using the Student's t-test for normally distributed data and the Mann-Whitney U test for non-normally distributed data, while categorical variables were compared using the Chi-square test or Fisher's exact test where expected cell counts were small. A p-value of less than 0.05 was taken as statistically significant throughout.

Results

A total of 50 patients with oesophageal varices fulfilling the inclusion and exclusion criteria were studied, 25 managed with endoscopic sclerotherapy (EST) and 25 with endoscopic band ligation (EBL).

Table 1: Characteristics of Participants

Characteristic	EST (n=25)	EBL (n=25)	p-value
Male, n (%)	16 (64)	17 (68)	0.76
Female, n (%)	9 (36)	8 (32)	
Age, years (mean ± SD)	47.64 ± 13.02	44.40 ± 15.50	0.43
Grade II varices, n (%)	7 (28)	9 (36)	0.53
Grade III varices, n (%)	15 (60)	15 (60)	
Grade IV varices, n (%)	3 (12)	1 (4)	
Cirrhosis, n (%)	14 (56)	19 (76)	0.14
NCPF, n (%)	9 (36)	3 (12)	
EHPVO, n (%)	2 (8)	3 (12)	
Child–Pugh A, n (%)	8 (32)	6 (24)	0.45
Child–Pugh B, n (%)	15 (60)	14 (56)	
Child–Pugh C, n (%)	2 (8)	5 (20)	
Haemoglobin, g/dl (mean ± SD)	8.54 ± 2.82	7.91 ± 2.59	0.42

Table 1 shows the baseline characteristics of participants. The two groups were comparable with respect to gender, age, grading of varices, aetiology of portal hypertension, Child–Pugh class and baseline haemoglobin, with no statistically significant difference for any of these variables ($p>0.05$).

Table 2: Comparison of Variceal Status and Recurrence at 6 Weeks (Objective 1)

Outcome at 6 weeks	EST (n=25)	EBL (n=25)	p-value
Complete eradication, n (%)	12 (48)	19 (76)	0.04
Persistent varices, n (%)	6 (24)	0 (0)	0.02
Reduced varices, n (%)	7 (28)	6 (24)	
Rebleeding, n (%)	8 (32)	2 (8)	0.03
Recurrence, n (%)	0 (0)	0 (0)	1.00

Table 2 shows the comparison of groups according to variceal disappearance and recurrence at six weeks. Complete eradication of varices was achieved in a significantly higher proportion of the EBL group than the EST group (76% vs 48%, p=0.04), while persistent varices were seen only in the EST group (24%, p=0.02). Rebleeding was significantly more common after EST (32% vs 8%, p=0.03), and no patient in either group showed recurrence of varices during the follow-up period.

Table 3: Comparison of Post-procedure Oesophageal Ulceration (Objective 2)

Oesophageal ulcer	EST (n=25)	EBL (n=25)	p-value
Yes, n (%)	14 (56)	7 (28)	0.04
No, n (%)	11 (44)	18 (72)	

Table 3 shows the comparison of groups according to post-procedure oesophageal ulceration. Ulceration was observed in a significantly higher proportion of patients treated with EST than EBL (56% vs 28%, p=0.04).

Table 4: Comparison of Post-procedure Chest Pain (Objective 3)

Retrosternal chest pain	EST (n=25)	EBL (n=25)	p-value
Yes, n (%)	12 (48)	4 (16)	0.01
No, n (%)	13 (52)	21 (84)	

Table 4 shows the comparison of groups according to post-procedure chest pain. Retrosternal chest pain was significantly more frequent following EST than EBL (48% vs 16%, p=0.01).

Table 5: Comparison of Post-procedure Hospital Stay (Objective 4)

Variable	EST (n=25)	EBL (n=25)	p-value
Hospital stay, days (median, IQR)	3.00 (3.00)	2.00 (2.50)	0.19

Table 5 shows the comparison of groups according to duration of post-procedure hospital stay. The median hospital stay was numerically shorter in the EBL group than the EST group (2.00 vs 3.00 days), though the difference did not reach statistical significance (p=0.19).

Discussion

Complete variceal eradication at six weeks was achieved in significantly more patients in the EBL group than the EST group (76% vs 48%, p=0.04), and persistent varices at follow-up occurred only in the EST group. This finding is broadly in keeping with several comparative series. Bhuiyan et al reported that the mean time to complete variceal eradication was significantly shorter with band ligation than with sclerotherapy (35 ± 4.1 days vs 75 ± 6.5 days, p<0.001).[14] Sakthivel et al similarly found a shorter duration to eradication with ligation compared with sclerotherapy (78.6 days vs 134.6 days, p<0.05), and required fewer sessions to achieve it.[10] Zargar et al found comparable overall eradication rates between the two techniques (94.6% vs 91.7%) but noted that ligation achieved this more efficiently, with fewer sessions and a shorter interval to eradication.[16] Not every series agrees on the direction of this advantage: Hou et al found the two methods comparable for overall eradication, with no statistically significant difference between them,[18] and Ali et al likewise found no significant difference in eradication rates between sclerotherapy and ligation.[11] Rebleeding in the present study was significantly higher after EST (32% vs 8%, p=0.03), a pattern also seen by Bhuiyan et al, where rebleeding was significantly more frequent with sclerotherapy,[14] and by Hou et al, where the total number of rebleeding episodes was higher in the sclerotherapy group (p=0.009).[18] Other studies, such as that by Luz et al, found no significant difference in early or late rebleeding between the two arms,[13] and Yue et al reported the opposite pattern, with more rebleeding after ligation alone compared with combined ligation and sclerotherapy.[9] Neither group in the present study showed recurrence of varices by six weeks, a short interval over which recurrence is in any case uncommon; longer series, such as that of Mansour et

al, only begin to show measurable recurrence from three months onward.[8]

Oesophageal ulceration was significantly more common after EST than EBL in this study (56% vs 28%, p=0.04). This is consistent with the underlying mechanism of sclerotherapy, in which chemical injury from the sclerosant produces mucosal injury at the injection site, whereas band ligation causes more localised, mechanical strangulation of the varix. Sakthivel et al reported a similar pattern, with superficial oesophageal ulcers seen in only one patient after ligation as against nine patients after sclerotherapy, a statistically significant difference.[10] Bhuiyan et al likewise found procedure-related complications such as oesophageal ulceration and ulcer-related bleeding to be more frequent with sclerotherapy.[14] Saeed et al, comparing ligation with combined ligation-sclerotherapy, found deep oesophageal ulcers were significantly more common with the combination approach than with ligation alone (65% vs 20%, p<0.05), reinforcing that the sclerosant component of treatment is the principal driver of mucosal injury.[15] These findings taken together support the safety advantage of ligation over sclerotherapy with regard to local mucosal complications.

Retrosternal chest pain was significantly more frequent after EST than EBL in this study (48% vs 16%, p=0.01). Mansour et al similarly found post-procedure pain to be significantly more common in the scleroligation group than in the ligation-alone group (13.3% vs 3.3%, p=0.04).[8] Sakthivel et al reported retrosternal pain in ten patients after sclerotherapy compared with only three after ligation, a significant difference.[10] Yue et al reported chest pain in a somewhat higher proportion of patients after ligation alone compared with combined ligation-sclerotherapy, although this difference did not reach statistical significance in their series.[9] The consistency of a higher chest pain burden with sclerotherapy across most of these comparative studies mirrors the greater degree of chemically induced mucosal irritation associated with sclerosant injection, as against the more limited, band-confined tissue effect of ligation.

The median post-procedure hospital stay in this study was shorter with EBL than EST (2.00 vs 3.00 days), although the difference fell short of statistical significance (p=0.19), likely reflecting the modest sample size available to detect a difference in this outcome. Bhuiyan et al reported a similar direction of effect, with patients in the band ligation group having a shorter hospital stay than those receiving sclerotherapy, which they attributed to improved resource utilisation and faster recovery with ligation.[14] Taken together with the lower complication burden associated with EBL in the present cohort, a shorter or at least non-inferior hospital stay with ligation would be the expected clinical outcome, even where statistical significance is not reached in a modestly sized comparative study such as this one.

Taken together: EBL reduced the immediate treatment burden per session, produced fewer local mucosal complications, and achieved a higher rate of complete variceal eradication with less rebleeding by six weeks, without any offsetting disadvantage in hospital stay. This pattern mirrors the mechanistic difference between the two techniques, mechanical strangulation of the varix with EBL versus chemically induced mucosal injury with EST, and is broadly consistent with the direction, if not always the statistical significance, of findings from comparable trials conducted elsewhere.[8,10,14,16,18] Where both techniques are locally available and the endoscopist is equally trained in each, the present findings would favour EBL as the first-line endoscopic approach to oesophageal varices, reserving sclerotherapy for settings such as small-calibre varices or difficult anatomical access where band placement is technically constrained.

Conclusion

In this prospective comparative study, endoscopic band ligation showed a lower treatment burden, fewer post-procedure complications, including chest pain and oesophageal ulceration, and significantly better short-term variceal eradication with lower rebleeding than endoscopic sclerotherapy, while hospital stay was numerically shorter though not significantly different. EBL therefore appears the preferable endoscopic modality for management of oesophageal varices where both techniques are feasible.

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Conflict of Interest: The authors declare no conflict of interest.

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