

Safety and Complication of Endoscopic Band Ligation

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Abstract

Original Research Article

Background: Endoscopic band ligation (EBL) is a medical procedure commonly used to treat esophageal varices, which are swollen veins in the lining of the lower esophagus. Esophageal varices can be a serious complication of liver disease, particularly cirrhosis, and they pose a risk of bleeding. **Objectives:** The aim of the study was to evaluate the safety and complication of endoscopic band ligation. **Methods:** This prospective observational study was done in the department of Gastroenterology, Hepatology and Nutrition, BSHI. 60 subjects were included in this study from July 2019 – June 2021. Every case was treated with endoscopic band ligation. Cases were followed up for a minimum period of 1 year after the band ligation. Statistical analyses of the results were obtained by using window-based Microsoft Excel and Statistical Packages for Social Sciences (SPSS-24). **Results:** Age of the children was 3-18 years with mean 7.27 ± 2.21 years and male: female ratio was 2:1. Out of 60 children 34 (56.7%) were extra-hepatic and 26 (46.6%) were hepatic causes of portal hypertension. Maximum patients (46.6%) had grade III varices followed by (30%) patients had grade IV and (23%) patients had grade II with red sign. Most of the patients, (46%) required 2 sessions and (36%) patients required 3 sessions for variceal obliteration in both group and (16%) cases of extra-hepatic children required only 1 session whereas hepatic cases required multiple sessions. Among 60 patients, (83%) patients developed re-bleeding where (40%) patients had early re-bleeding and (43%) had late re-bleeding. No complications were noted except nausea and vomiting. **Conclusion:** It's essential for patients undergoing EBL to discuss the potential risks and benefits with their healthcare provider and to ensure that the procedure is performed by a qualified and experienced medical team. Additionally, patients should follow post-procedure instructions carefully to minimize the risk of complications and promote optimal healing.

Keywords: Endoscopic band ligation (EBL), Esophageal varices, Swollen veins.

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INTRODUCTION

Portal hypertension is a common clinical syndrome defined by an increase in the hepatic venous pressure gradient (HVPG) above 5 mm Hg caused by a combination of two concurrent hemodynamic processes: (1) increased intrahepatic resistance to blood flow through the liver due to cirrhosis and (2) increased splanchnic blood flow due to vasodilation within the splanchnic vascular bed [1]. Many liver and vascular problems produce portal hypertension in children, which can result in serious life-threatening conditions such as esophageal varices, ascites, hepatopulmonary syndrome, portopulmonary hypertension, and hepatic encephalopathy [2].

Esophageal varices are the leading cause of upper gastrointestinal bleeding. In persons with CLD, the incidence of oesophageal varices rises by around 5% per year, with the rate of progression from minor to big varices ranging from 5 to 10% per year [3]. It is typically abrupt and enormous, with a high death rate. The first episode of variceal bleeding is associated with significant mortality and recurrence rate in those who survive [4]. According to one study, around one-third of patients with cirrhosis and esophageal varices experience bleeding during the course of the disease, and nearly 60% of patient's re-bleed following initial bleeding from esophageal varices [5].

Extrahepatic portal hypertension has been identified as the primary cause of upper gastrointestinal bleeding (UGIB) in children [6]. Chronic liver disease (CLD) is prevalent in the pediatric population. A study undertaken by BSMMU's Paediatric Gastroenterology and General Paediatrics departments found that liver ailments accounted for 4% of hospital admissions, with chronic liver diseases accounting for 40% [7]. Esophageal varices impact around 60% of persons with end-stage cirrhosis and 30% of those with compensated cirrhosis [5].

Clinical signs of severe portal hypertension appear when the portal pressure gradient exceeds 10 mmHg [8]. Portal hypertension can lead to gastrointestinal bleeding, splenomegaly, and ascites. As a result, early detection, proper treatment, and continuous follow-up are essential. The gold standard for diagnosing portal hypertension is direct measurement of portal pressure, often known as the hepatic venous pressure gradient [9]. These measurements can only be obtained by intrusive procedures, which are not practical in the majority of the world. The status of oesophageal varices can be assessed indirectly using a barium swallow of the oesophagus, ultrasonography, or upper gastrointestinal endoscopy. Upper gastrointestinal endoscopy is now the most accurate way to diagnose oesophageal varices and thus PHTN [9]. The treatment of portal hypertension has evolved considerably during the last decade. As a result, therapy options with the lowest complication rate and highest long-term success would be best for the children [10].

Endoscopic band ligation includes tying rubber bands around oesophageal varices, followed by necrosis, sloughing, fibrosis, and re-epithelialization. Stiegmann and colleagues first described this method in 1986. The multiband ligator simplified and improved the patient's variceal ligation experience. This method allows for the closure of up to six varices using a single endoscope

insertion [11]. The most effective treatment for variceal bleeding is esophageal variceal band ligation, which is used until liver transplantation or surgical shunting is required owing to recurring bleeding [12]. There is no agreement on the frequency of esophageal variceal band ligation (EVBL) for the excision of esophageal varices.

METHODOLOGY

This Prospective observational study was carried out in the Department of Pediatric Gastroenterology, Hepatology and Nutrition of Bangladesh Shishu (Children) Hospital and Institute during July 2019 to June 2021. A total of 60 children were participated in the study. 3-18 years old children with esophageal varices who were admitted at the department of Paediatric Gastroenterology, Hepatology and Nutrition of BSBI during the study period. After taking consent and matching eligibility criteria, data were collected from patients on variables of interest using the predesigned structured questionnaire by interview, observation. Statistical analyses of the results were obtained by using window-based Microsoft Excel and Statistical Packages for Social Sciences (SPSS-24).

RESULTS

Table-I: Age distribution of the study population

Age (years)	N=60	%
Mean±SD	7.27±2.21	
Min-Max	(4 – 11)	
First variceal bleeding (year)	5.3±1.21	

Table I shows, among 60 study subjects maximum 46.7% patient in between 6-9 years followed by 30% patients age below 5 years and 23.3% patients more than 10 years. The age range of patients were between 4-11 years.

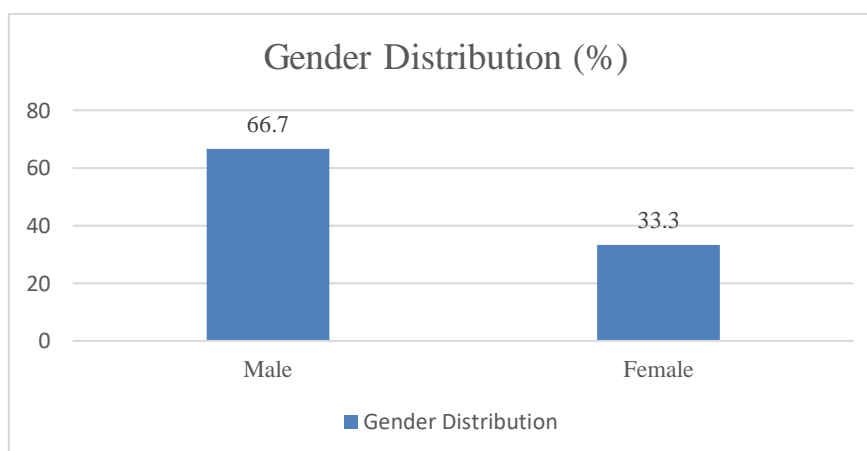


Figure-I: Gender distribution of the subjects

Bar diagram shows that two third 40 (66.7%) patients were male and one third 20 (33.3%) were female.

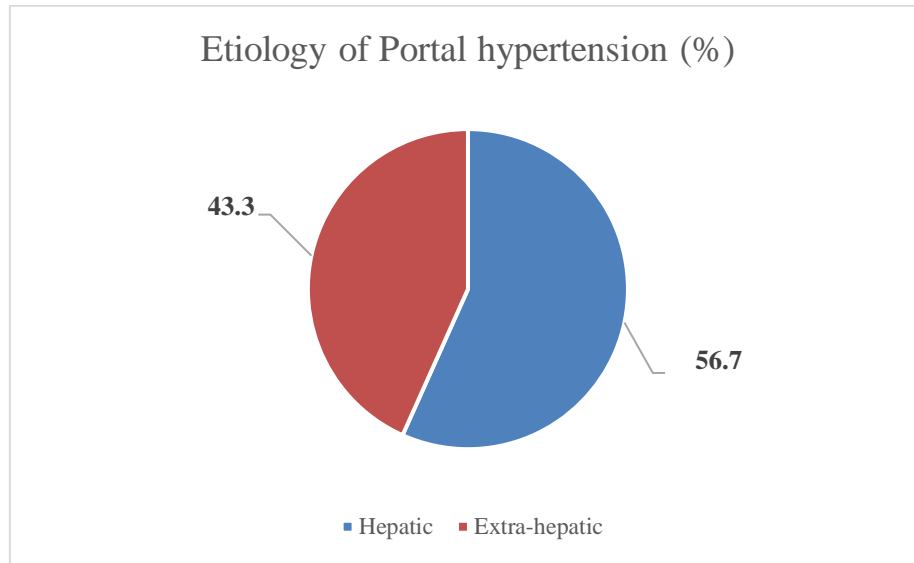


Figure-II: Etiology of portal hypertension (n=60)

Pie diagram shows that, the most common etiology of portal hypertension was extra hepatic

34(56.7%). Hepatic cause of portal hypertension was found 26 (43.3%).

Table II: Etiology of hepatic and extra-hepatic portal hypertension of studied subjects (n=60)

Etiology	Extrahepatic (n=34)	Hepatic (n=26)
Chronic Hepatitis B	0(0.0%)	4(7.7%)
Wilson disease	0(0.0%)	12(46.2%)
Biliary cirrhosis	0(0.0%)	2(7.7%)
Autoimmune hepatitis	0(0.0%)	4(15.4%)
Cystic fibrosis	0(0.0%)	2(7.7%)
Cryptogenic CLD	0(0.0%)	2(15.4%)
Portal vein thrombosis	6(17.6%)	0(0.0%)
Idiopathic cause	28(82.4%)	0(0.0%)
Total	34	26

Table II showing: 34(56.7%) subjects had extra-hepatic portal hypertension, among them portal vein thrombosis 6(17.6%) and idiopathic cause 28(82.4%). Among 26(43.3%) patients in hepatic group

of portal hypertension, maximum was Wilson disease 12(46.2%) followed by autoimmune hepatitis 4(15.4%), cryptogenic CLD 4(15.4%), chronic hepatitis B 2(7.7%), biliary cirrhosis 2(7.7%), cystic fibrosis 2(7.7%).

Table III: History of studied subjects (n=60)

History	Extrahepatic (n=34)	Hepatic (n=26)	P value
H/O hematemesis			
Yes	34(100.0%)	22(84.6%)	0.094 ^{ns}
No	0(0.0%)	4(15.4%)	
H/O melena			
Yes	24(70.6%)	20(76.9%)	0.697 ^{ns}
No	10(29.4%)	6(23.1%)	
H/O jaundice			
Yes	0(0.0%)	26(100.0%)	0.001 ^{ns}
No	34(100.0%)	0(0.0%)	
H/O consanguinity			
Yes	4(11.8%)	6(23.1%)	0.410 ^{ns}

History	Extrahepatic (n=34)	Hepatic (n=26)	P value
No	30(88.2%)	20(76.9%)	
Family history of liver disease			
Yes	0(0.0%)	4(15.4%)	0.094 ^{ns}
No	34(100.0%)	22(84.6%)	
H/O blood and blood product transfusion			
Yes	0(0.0%)	2(7.7%)	0.245 ^{ns}
No	34(100.0%)	24(92.3%)	
H/O umbilical catheterization			
Yes	4(11.8%)	0(0.0%)	0.201 ^{ns}
No	30(88.2%)	26(100.0%)	

Table III shows maximum children of both groups had history of hematemesis and melena. H/O jaundice significantly more in hepatic group. Some children of both groups had H/O consanguinity, few

children of hepatic group had family history of liver disease and H/O blood product transfusion, 2 children of extrahepatic group had H/O umbilical catheterization and there was no significant difference.

Table IV: Comparison of physical examination between two groups (n=60)

Physical examination	Extrahepatic (n=34)	Hepatic (n=26)	P value
Anemia			
Mild	12(35.3%)	6(23.1%)	0.469 ^{ns}
Moderate	22(64.7%)	20(76.9%)	
Jaundice			
Present	0(0.0%)	24(92.3%)	0.001 ^{ns}
Absent	34(100.0%)	2(7.7%)	
Stigmata of CLD			
Present	0(0.0%)	12(46.2%)	0.002 ^{ns}
Absent	34(100.0%)	14(53.8%)	
Hepatomegaly			
Present	2(5.9%)	26(100.0%)	0.001 ^{ns}
Absent	32(94.1%)	0(0.0%)	
Splenomegaly			
Present	34(100.0%)	13(100.0%)	-
Absent	0(0.0%)	0(0.0%)	
Ascites			
Present	3(17.6%)	12(92.3%)	0.001 ^{ns}
Absent	14(82.4%)	1(7.7%)	

Table IV shows, Jaundice, Stigmata of CLD, Hepatomegaly, Ascites were significantly higher in hepatic group (p<0.05).

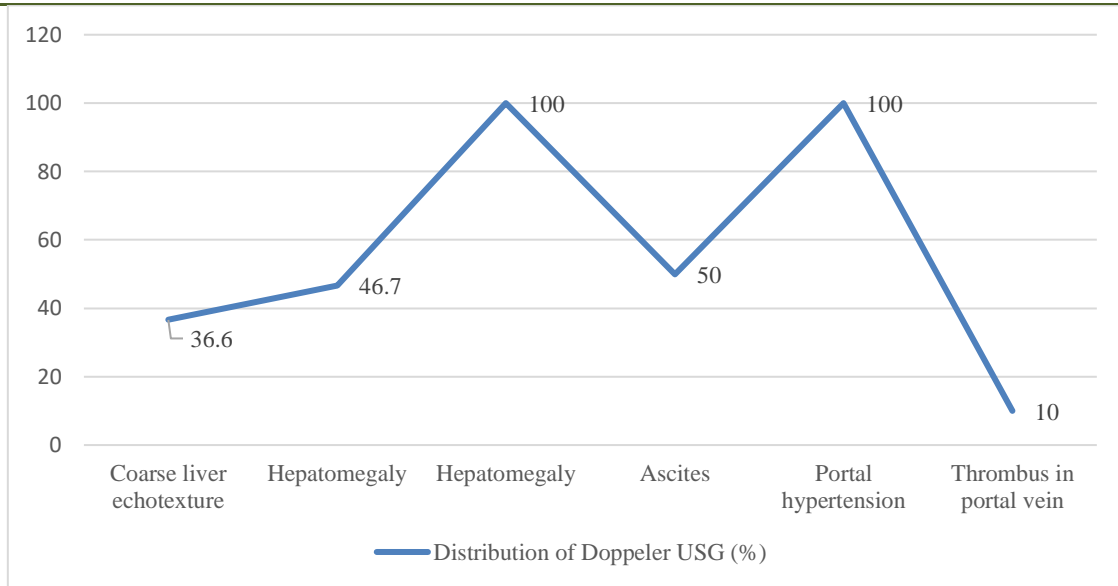


Figure-III: Doppler USG finding in studied population

Figure shows that 100% patient had Portal hypertension was diagnosed by Doppler USG of hepatobiliary system. Others Doppler ultrasound

findings are splenomegaly (100%), hepatomegaly (50%), ascites (50%), coarse liver echotexture (36.6%) and portal vein thrombus (10.0%).

Table V: Grading of esophageal varices in the study subject (n=30)

Grading of esophageal varices	Extrahepatic (n=34)	Hepatic (n=26)	All patients (n=60)	P value
Grade II with red	12(35.3%)	2(7.7%)	14(23.3%)	0.182 ^{ns}
Grade III	14(41.2%)	14(53.8%)	28(46.7%)	0.748 ^{ns}
Grade IV	8(23.5%)	10(38.5%)	18(30.0%)	0.896 ^{ns}
Total	34	26	60	

Table V showing grading of esophageal varices, maximum patients had Grade III varices 46.7.0%, followed by Grade-IV esophageal varices 30% and

Grade II with red sign 23.3%. Severity of grading (grade-III & IV) slightly higher in hepatic cases. No significant difference between groups (p>0.05).

Table VI: Outcome of band ligation (n=30)

Outcome of band ligation	Extrahepatic (n=34)	Hepatic (n=26)	All patients (n=60)	P value
Number of band ligation				
Session 1	10(29.4%)	0(0.0%)	10(16.7%)	0.099 ^{ns}
Session 2	16(47.1%)	12(46.2%)	28(46.7%)	1.000 ^{ns}
Session 3	8(23.5%)	14(53.8%)	22(36.7%)	0.185 ^{ns}
Number of bands required in every session				
Band 1	2(11.8%)	0(0.0%)	4(6.7%)	0.588 ^{ns}
Band 2	10(58.8%)	10(76.9%)	40(66.7%)	0.514 ^{ns}
Band 3	5(29.4%)	3(23.1%)	16(26.7%)	1.000 ^{ns}
Control of bleeding				
Primary hemostasis	34(100.0%)	26(100.0%)	60(100.0%)	
Re bleeding				
Early	10(29.4%)	14(53.8%)	24(40.0%)	0.328 ^{ns}
Late	14(41.2%)	12(46.2%)	26(43.7%)	1.000 ^{ns}
No rebleeding	10(29.4%)	0(0.0%)	10(16.7%)	0.099 ^{ns}

Table VI shows, maximum children of both groups required multiple sessions of band ligation

whereas 5 children of extra-hepatic group required only 1 session. No significant difference found between two

group. All children of both groups required 1-3 bands in each session. Primary hemostasis achieved in all children after endoscopic band ligation. Maximum children 25 (83.3%) developed re-bleeding among them early re-

bleeding found 40.0%% and late re-bleeding 43.7%. No significant difference observed between extrahepatic and hepatic patients.

Table VII: Complication of band ligation of the study subject (n=30)

Outcome of band ligation	Extrahepatic (n=34)	Hepatic (n=26)	P value
Complication			
Nausea + Vomiting	26(76.5%)	22(84.6%)	0.580 ^{ns}
Esophageal ulceration	0(0.0%)	0(0.0%)	-
Esophageal perforation	0(0.0%)	0(0.0%)	-
Aspiration pneumonia	0(0.0%)	0(0.0%)	-
Sepsis	0(0.0%)	0(0.0%)	-

Table VII shows, endoscopic band ligation has less complications. Minor complication like nausea and vomiting observed in 76.5% cases in extrahepatic group and 84.0% in hepatic group, while major complications were not found in both groups.

DISCUSSION

Esophageal varices due to portal hypertension is the most common cause of upper GIT bleeding. It is a life-threatening clinical situation in infants and children. Effective management is needed to treat this condition. There are different types of treatment modalities for esophageal varices. Among them endoscopic band ligation showed safer and more effective in adult practice. There was no previous study regarding use of endoscopic band ligation in children. In this study we evaluate the etiology and outcome of endoscopic band ligation in esophageal varices in Bangladeshi children. This is the first prospective observational study in Bangladesh that carried out in the department of Paediatric Gastroenterology, Hepatology and Nutrition, BSHI during July 2019 to June 2021.

In this study total 60 patients with portal hypertension were included. Their age ranges between 4 to 11 years. The mean (\pm SD) age of the studied patients was 7.27 ± 2.21 years, among them male 66.7% and female 33.3%. Similar results were observed in another study done in Bangladesh by Karim where 31 (56%) were male and 24 (44%) females [13]. A study done by Mahmud *et al.*, (2017) in Dhaka shishu hospital also found patients age group between 2-16 years and 30 (60%) were male and 16 (40%) were female which is similar to this study. In another study done in BSMMU patient's age group was found between 2 to 15 years which was also similar to present study [14].

In this study age of first variceal bleeding were found between 3.5 to 7.5 years. The mean (\pm SD) age at onset of the first variceal bleeding were 5.33 ± 1.21 years. In extra-hepatic cases it was 5.26 ± 1.45 years and

in hepatic cases it was 5.33 ± 1.21 years. So, in extra-hepatic cases first variceal bleeding occurs slightly earlier than hepatic cases. Similar results were found in a study done by Mahmud [11]. They found the mean age at onset of the first variceal bleeding was 5.3 ± 4.5 years. In pre-hepatic cases it was 4.4 ± 3.6 years and in hepatic cases it was 7.6 ± 4.6 years. Similar observation was also reported in North Indian children by Arora [15]. In this present study the most common etiology of portal hypertension was extra-hepatic (56.7%). Among them portal vein thrombosis was (17.6%) and idiopathic cause (82.4%). Mahmud *et al.*, (2015) also found similar results about (80%) due to pre-hepatic causes and (20%) due to hepatic causes. Among them portal vein thrombosis was (62.5%), splenic vein thrombosis (12.5%) and others (25%). Arora and Podder also found similar results in their study [16].

H/O hematemesis and melena found in most of the studied subjects (93%) in this study. Similar results were also found by Shrestha. [9] Regarding hepatic group of portal hypertension jaundice was the most common presenting feature followed by hepatomegaly, ascites and stigmata of CLD. This parameter was significantly different between hepatic and extrahepatic portal hypertension. In this study, regarding liver function test serum bilirubin, serum ALT and serum albumin was significantly altered in cases of hepatic group. Whereas in extra-hepatic portal hypertension liver function test was normal which is similar to a study done by Chaudhary [17].

In present study portal hypertension of all children was diagnosed by Doppler USG of hepatobiliary system where portal hypertension and splenomegaly found in 100% cases which is similar to a study done by Lafortuneet [18]. Here, considering grading of esophageal varices, maximum patients (46.6%) had grade III varices followed by (30%) patients had grade IV and 7 (23%) patients had grade II with red sign which is similar to Khattak and Ray studies. [19, 20] Number of endoscopic band ligation session showed that most of the patients (46%) required 2 sessions and (36%) patients required 3 sessions for variceal obliteration in

both group and (16%) cases of extra-hepatic children required only 1 session whereas in hepatic children required multiple sessions which is similar to study done by Mahmud [11]. Shrestha B found that most variceal eradication was achieved after second session of endoscopic band ligation (68.2%) which is similar to present study [9].

In present study all children achieved primary hemostasis after endoscopic band ligation. Among total cases about (83%) patients developed re-bleeding where (40%) patients had early re-bleeding and (43%) had late re-bleeding. There was no significant difference of re-bleeding between hepatic and extra-hepatic patients. Mahmud did same type of study where he found initial variceal obliteration was achieved in all (100%) cases and recurrence of bleeding was observed in 50% cases of pre-hepatic and all cases of hepatic children [11]. Early re-bleeding was more common in hepatic (75%) cases and late re-bleeding was common in both pre-hepatic and hepatic cases. Khattak also found similar results as shown in present study [19].

Endoscopic band ligation eradicates esophageal varices with less complications. Minor complication like nausea and vomiting were observed in maximum children of both hepatic and extra-hepatic cases and no major complications was observed in present study which is similar to study done by Mahmud [11]. Khattak found no major complication during the study and follow up period except development of post band ulcer in 3 patients out of 113 [19].

Limitations of the study

The present study was conducted in a very short period due to time constraints and funding limitations. The small sample size was also a limitation of the present study.

CONCLUSION

The study concluded that extra-hepatic portal hypertension was the most common etiology in children, and that endoscopic band ligation was both effective and safer for treating esophageal varices grade II and above.

RECOMMENDATION

This study can serve as a pilot to much larger research involving multiple centers that can provide a nationwide picture, validate regression models proposed in this study for future use and emphasize points to ensure better management and adherence.

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The wide range of disciplines involved safety and complication of endoscopic band ligation research

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