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Original Research Article

Combined endoscopic intervention (ligation+sclerotherapy) compared with TIPS for prevention of bleeding from gastro-esophageal varices in patients with liver cirrhosis

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ABSTRACT

Background: Liver cirrhosis (LC) and portal hypertension (PH) is one of the most serious problems of modern surgical hepatology. The most common complication of liver cirrhosis is bleeding from varicose veins of esophagus and stomach. Today experts have several ways to prevent rebleeding from varices: pharmacotherapy, endoscopic intervention, transjugular intrahepatic portosystemic shunt (TIPS), a surgical portocaval bypass. Purpose of this study was to compare effectiveness of transjugular intrahepatic portosystemic shunts (TIPS) and combined endoscopic therapy the management of bleeding in cirrhotic patients.
Methods: We observed 96 consecutive patients with portal hypertension who were treated in 2nd clinic of Tashkent Medical Academy (2014-2015). Bleeding was in history of 17 (17.7%) patients. The duration of the bleeding averaged 9.7±4.3 hours. Ascites was observed in 54.5 % of patients. Patients were divided two major groups. First group included 72 patients who was performed endoscopic intervention. Second group consisted of 24 patients who underwent TIPS in emergency cases.
Results: Seventy-two patients were assigned to variceal ligation and Sclerotherapy, other 24 patients to TIPS. In the ligation combined Sclerotherapy group, a second treatment was performed 8–10 days after the initial endoscopy. Deterioration of portal gastropathy was observed in 9 (9.4%) cases after EL and 24 (25.0%) after ES ($p < 0.05$). The mean portal system pressure prior to TIPS placement was 53.67±4.21 mm Hg, which decreased to 25.10±4.06 mmHg after the first shunt tract was established ($P < 0.001$). The mean portal system pressure prior to the second TIPS was 43.68±3.98 mm Hg and decreased to 25.14±4.67 mm Hg after the procedures ($P < 0.001$).
Conclusions: TIPS can become dysfunctional if stenosis develops in the shunt or the hepatic vein above the shunt. Screening allows detection of stenosis before portal hypertensive–related complications recur. Revision of stenotic shunts can be easily accomplished in most cases. Techniques for screening and revision will be discussed. This is one of the most effective methods to control patients with liver cirrhosis.

Keywords: Bleeding, Endoscopic ligation, Liver cirrhosis, Portal hypertension, Sclerotherapy, TIPS, Varicose veins

INTRODUCTION

Portal hypertension is a progressive complication of liver cirrhosis. Therefore, the management of patient with cirrhosis and hypertensive gastrointestinal bleeding depends on the phase of portal hypertension, which the patient is situated, from the patient with liver cirrhosis (LC) and portal hypertension (PH) who has not yet developed varices to the patient with acute variceal hemorrhage for whom the objective is to control the

active episode and prevent rebleeding.[1,3] Liver cirrhosis (LC) and portal hypertension (PH) is one of the most serious problems of modern surgical hepatology. The most common complication of liver cirrhosis - bleeding from varicose veins of esophagus and stomach - the main cause of deaths in the surgery, and complications such as ascites, hepatic encephalopathy and hepatorenal syndrome - disability of patients.[2-5] Annually, bleeding from the esophagus and stomach varices occur in 4-15% of patients with PH. Fatal outcome in first episode of bleeding occurs in 30% of patients. More than 60% of those survivors of the first episode of bleeding during the period from 3 to 6 months, have a high risk of rebleeding and in others it arises during the year. Therefore, all patients who have had a first episode of bleeding should receive treatment to prevent recurrence of varicose veins.[6,7]

Today experts have several ways to prevent rebleeding from varices: pharmacotherapy, endoscopic intervention, transjugular intrahepatic portosystemic shunt (TIPS), a surgical portocaval bypass. Endoscopic interventions for eradication of varices are the "gold standard" of treatment for patients with bleeding.[8] However, this intervention did not reduce portal pressure, so varices after endoscopic treatment may recur. Such patients need to be dynamic endoscopic control or hold decompression angiographic interventions.[9]

With experience of endoscopic interventions in patients with PH there is a need to systematize the errors and dangers in their carrying out, to clarify the pathogenesis of complications arise, develop tactics and medical indications for endoscopic sclerotherapy (ES) and endoscopic ligation (EL) for the prevention and treatment of esophageal-gastric bleeding in PH.[10]

Endoscopic sclerotherapy is currently not recommended as a prophylactic therapy for oesophageal varices because of conflicting results in earlier studies. Endoscopic variceal ligation is more effective and safer than sclerotherapy and decreases the risk of initial bleeding and the risk of death due to varices as compared with no treatment.[11] On the basis of these results, we conducted a prospective, randomised, controlled trial to compare the efficacy and safety of variceal combined ligation and sclerotherapy with TIPS for the primary prevention of variceal bleeding in patients with oesophageal varices that were at high-risk for bleeding.[12,13]

The purpose of this study was to compare effectiveness of transjugular intrahepatic portosystemic shunts (TIPS) and combined endoscopic therapy the management of bleeding in cirrhotic patients.

METHODS

We observed 96 consecutive patients with portal hypertension who were treated in 2nd clinic of Tashkent Medical Academy (2014-2015). The average age was 48.2±11.3 years. Among them, 74 patients (77%) were males. Bleeding was in history of 17 (17.7%) patients. The duration of the bleeding averaged 9.7±4.3 hours. Ascites was observed in 54.5% of patients, some of them had resistant character of ascites. Eligible patients included those with large, grade 2, 3 or 4 varices as independently evaluated by three endoscopists and no history of haematemesis or melaena. The size of the varices was graded according to criteria published by Conn.[14]

The risk of bleeding in large varices (>5 mm) was assessed by searching for the presence of at least one "red sign", such as a cherry-red spot, a red wale, or a haematocystic spot. The rate of agreement between two observers with regard to red signs on endoscopy was 72%. For the same observer, the rate of agreement between two readings was 76%. LC was diagnosed on the basis of clinical, biochemical, histologic, or ultrasonographic examination. Non-cirrhotic portal fibrosis was diagnosed when varices were present and there were no signs of thrombosis in the splenoportal axis on ultrasonography and no evidence of cirrhosis on liver biopsy. Extrahepatic obstruction of the portal vein was diagnosed when the portal cavernoma was detected by ultrasonography, and there were no signs of cirrhosis. For all the patients, information on alcohol abuse was obtained, and tests for hepatitis B and C viruses and autoimmune markers in the serum were carried out. The severity of liver disease (LD) was classified according to Child-Pugh classification's criteria.

Patients were excluded if they were receiving antiviral therapy or if they had concomitant hepatoma or another tumor, severe cardio-pulmonary or renal disease, bradycardia (basal heart rate <60 beats per minute), bronchial asthma, diabetes mellitus, heart failure, peripheral vascular disease, a psychiatric disorder, glaucoma, or prostatic hypertrophy. Written and informed consent was obtained from the patients according to the guidelines of the 1975 declaration of Helsinki.

Table 1: Distribution of patients according to the class of liver failure and the extent of varices of the esophagus and the stomach, n=96, absolute (%).

Clinical index	First group, n=72	Second group, n=24
Liver failure by Child – Pugh		
Class A	13 (18.05)	4 (16.7)
Class B	44 (61.1)	13 (54.2)
Class C	15 (20.8)	7 (29.2)
The degree of varices of the esophagus and the stomach		
II	18 (25.0)	7 (29.2)
III	46 (63.9)	13 (54.2)
III with transition into the stomach	8 (11.1)	4 (16.7)

Patients were divided two major groups. First group included 72 patients who was performed endoscopic intervention. Second group consisted of 24 patients who underwent TIPS in emergency cases.

Endoscopic procedures were performed in an emergency, and in a planned manner. In 29 patients at admission to temporarily stop the bleeding and stabilize the hemodynamic parameters was used Blackmore tube. Afterwards, for them was performed ES or EL. The study excluded patients with esophageal varices with gastric bleeding, concomitant cancer, renal failure, or other competing diseases previously undergone sclerotherapy or any endovascular intervention. During the examination, patients did not take β-blockers.

Technique of endoscopic intervention

Endoscopic intervention was performed in the endoscopy room using a fiber-optic endoscopy, endoscopic instruments of firm Olympus (GIF-10), endoscopic injector. Emergency ES was carried out after a gastric lavage, delayed - after stopping the bleeding by Blackmore tube. We used intravasal and paravasal sclerotherapy by 10% lidocain solution. During one session of ES administered 5-8 ml 3% sclerosant into two or three varicose veins below the bleeding. Reintroducing of sclerosants to other varicose veins of the esophagus was performed at intervals of 3-4 days.

EL was performed on an empty stomach with a device consist of from 6 or 10 rings of firm Wilson-CookMed Ine. Ligation was started with the cardio-esophageal region and continued cardioesophageal above staggered helix. Given that, EL was performed using multiligating apparatus in one session made "circular" ligation of all varicose veins of the esophagus, since the level of the gastro-esophageal junction. If necessary, re-ligation of varices was carried out a month later.

TIPS placement technique

TIPS procedure was carried out in the Interventional Radiology Suite (TSF-35-180, Cook Medical) under local anesthesia. The Graft Transjugular Liver Access Set (GORE Viatorr® Endoprosthesis, USA) was used for every patient. Right jugular venous access was established with a 10-F sheath. A 5-F multipurpose catheter was used to engage the right hepatic vein and perform angiography, and a curved cannula was then advanced with the guide wire into the right hepatic vein.

A sheathed needle was advanced into the portal vein through the liver parenchyma and the guide wire was placed into the portal vein through the sheath. Portal vein angiography was performed with a 5-F pigtail catheter and portal vein pressure and right atrium pressure were measured. Afterwards, the shunt tract was dilated with an angioplasty balloon ranging from 6 to 12 mm, and a covered stent with a diameter of 6 or 12 mm was utilized.

The varicose coronary gastric vein was embolized to prevent future gastrointestinal bleeding and the portal vein angiography and pressure measurements were performed again. The PSG was determined before and after the shunt creation.

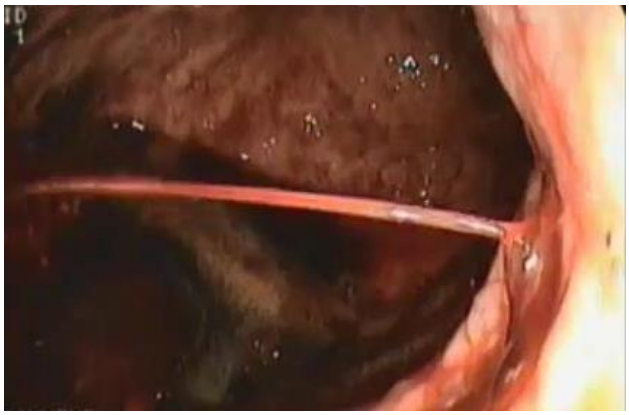

Figure 1: Early formation of acute ulcers at the site of ligation of varicose veins with signs of bleeding.

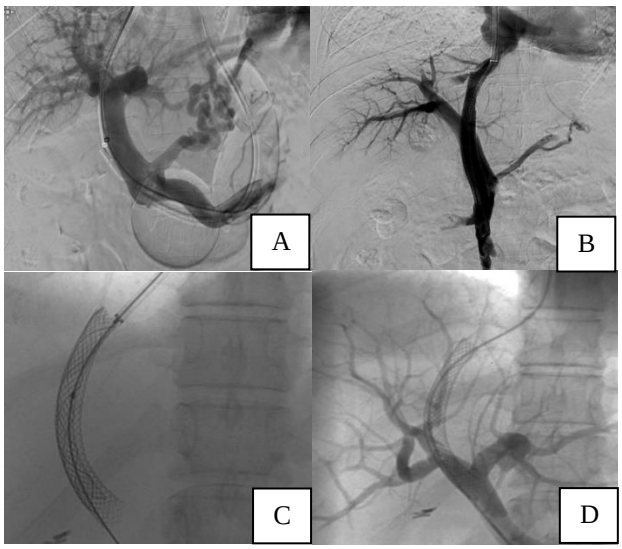

Figure 2: TIPS placement and embolization gastro-esophageal varicose veins.

Statistical analysis

Microsoft Office Excel 2013 in Windows 7 MS was used for data processing and statistical analysis, with paired sample t test for data measurement. Data are summarized and as frequencies and continuous variables as mean ± standard deviation (SD). P <0.05 was considered statistically significant.

RESULTS

Clinical and laboratory data

Seventy-two patients were assigned to variceal ligation and Sclerotherapy, other 24 patients to TIPS. The

severities of the index bleed, as reflected by transfusion requirements and need for balloon tamponade, were similar in both groups. Clinical and biochemical parameters were not importantly different in the two groups with the exception of serum bilirubin level, which was significantly higher in the combined therapy group. The time interval between an index bleed and randomisation was 46 and 48 hours for the Ligation + Sclerotherapy and TIPS groups, respectively.

The time interval between randomisation and TIPS procedure was 16 (14) hours. In the ligation combined Sclerotherapy group, a second treatment was performed 8–10 days after the initial endoscopy. The number of patients with a history of previous variceal bleeding or non-bleeding fundal varices was similar in both groups.

Analysis of results of ES and EL in patients with liver cirrhosis showed important effectiveness of TIPS in comparison with ligation and Sclerotherapy methods. If ES was used to eradicate varicose veins of the esophagus, patient was subjected to repeated endoscopy, EL was performed in a single session using a multiply ligation device.

Most often during ES we faced such a problem as bleeding from the injection points (26.87%), which required prolonged compression of the distal end of the endoscope location of bleeding after the introduction of varicose vein sclerosing agent. Deterioration of portal gastropathy was observed in 9 (9.4%) cases after EL and 24 (25.0%) after ES ($p < 0.05$).

Table 2: Patients' characteristics at randomisation.

	EL combined ES (n=72)	TIPS (24)
Age (y)	46.8 (9.87)	51.7 (12.4)
Sex (M/F)	57/15	15/7
Etiology of liver disease (n)		
Alcoholism	29	16
Hepatitis B virus	20	3
Hepatitis C virus	9	1
PBC	4	1
Autoimmune hepatitis	1	0
Haemochromatosis	2	2
HBV+HCV+Histiocirrhosis	4	1
Alcoholism+HBV	3	0
Previous variceal bleed (n)	7	10
Previous sclerotherapy (n)	5	6
Associated fundal varices (n)	12	4
Blood units (index bleed)	3.2 (2.6)	3.1 (2.3)
Time from index bleed to randomisation (hours)	48 (32)	44 (31)
Time from randomisation to TIPS (hours)		16 (14)
Balloon tamponade	5	9
Pugh score	9.6 (1.5)	9.3 (1.4)
Serum bilirubin (μmol/l)	91 (95)	51 (36)*
Serum albumin (g/l)	23.8 (5.1)	22.9 (3.9)
Haemoglobin (g/l)	87 (19)	79 (17)
Prothrombin (INR)	1.42 (0.28)	1.36 (0.25)

PBC – primary biliary cirrhosis; INR – international normalized ratio; *p<0.05

Clinical effects of TIPS

The short-term hemostasis rate was 100% when TIPS was used in the treatment of emergency hemorrhage and recurrent hemorrhage unresponsive to medication, endoscopy or surgery. Ascites disappeared completely in 58% of patients, decreased obviously in 26% and remained in 16%. The total effective rate was 84%. Hydrothorax completely disappeared in 100% of patients. Ascites completely disappeared in 6 patients and was obviously reduced in 8 after 7-14 day of observation.

Hemodynamic changes

TIPS altered the portal pressure in all patients after the second operation. The mean portal system pressure prior to TIPS placement was 53.67±4.21 mm Hg, which decreased to 25.10±4.06 mmHg after the first shunt tract

was established (P <0.001). The mean portal system pressure prior to the second TIPS was 43.68 ± 3.98 mm Hg and decreased to 25.14±4.67 mm Hg after the procedures (P <0.001). The mean PSG prior to the TIPS placement was 43.80±6.18 mmHg, which decreased to 15.27±3.32 mm Hg after shunt tract was established (P <0.001). The mean PSG prior to the next TIPS was 37.40±2.76 mm Hg and decreased to 16.20±3.17 mm Hg after the procedures (P <0.001).

Follow-up

All the 67 patients who underwent TIPS were followed up. Stent function, hemorrhage, hepatic encephalopathy, hepatorenal syndrome and survival were observed during the follow-up. The incidence of recurring hemorrhage was 8% in 12 month, 18% in 24 month and 37% in 36 month. The incidence of stent stenosis was 24% in 12 month and 34% in 24 month postoperatively (Table 1). The incidence of hepatic encephalopathy was 14% in 3 month, 17% in 6 month and 19% in 12 month. The cumulative survival rate was 86% in 12 month, 81% in 24 month, 75% in 36 month, 57% in 48 month and 45% in 60 month. In our center, 3 patients died 1 month after TIPS, of whom 2 died of hepatic failure and 1 of septicemia.

Table 3: Complications in study groups.

Complications	Endoscopic intervention (group A, n=72)		TIPS (group B, n=18)	
Liver insufficiency	37	51.4%	6	33.3%
Thrombosis of Portal vein	11	15.3%	2	11.1%
Rebleeding of VV	43	59.8%	3	16.7%
Plevritis	7	9.72%	1	5.56%
Thromboembolism pulmonary artery	14	19.4%	0	0%
Hepatic encephalopathy	31	43.06%	7	38.9%
Lethality, %	26	36.11%	4	22.2%

Survival

Four patients died in the TIPS group and 26 patients in EL combined ES group. Causes of death are listed in table 3. Two patients in the TIPS group underwent liver transplantation in India (Fortis Hospital, New Delhi) compared with four in the ligation group.

The cumulative two year survival rate made a difference between the TIPS and ligation groups (36.7% v 56.8% respectively). Survival rates remained similar when patients with previous variceal bleeding or with associated fundal varices were excluded from the analysis (data not shown). Multivariate analysis showed that among the variable examined (treatment group, age, alcoholism, sex, Pugh score, and treatment group), Pugh score was the only independent predictor of survival (odds ratio 1.5; 93% CI 1.2–2.2; p<0.005).

Rebleeding

The causes of rebleeding are indicated in table 4. Rebleeding of non-variceal sources was observed in seven patients in the TIPS group and in twelve in the endoscopic intervention group. Seven episodes of variceal rebleeding were observed in six patients in the TIPS group (25.0%), because of stent stenosis in five patients and late shunt thrombosis in three patients. Stent stenosis was treated by shunt dilatation and shunt thrombosis by reopening of the shunt and insertion of an additional stent.

Table 4: Causes of gastrointestinal bleeding within two years of randomisation in the endoscopic ligation combined with Sclerotherapy and transjugular intrahepatic portosystemic shunt (TIPS) groups.

Source of bleeding	Ligation + Sclerotherapy	TIPS
Varices	14	7
Oesophageal ulcer due to EL and ES	6	2
Mallory-Weiss	3	1
Oesophagitis	2	-
Haemobilia	1	-
Gastropathy	-	1
Peptic ulcer	2	2
Total number of episodes	28	13

Shunt dysfunction

During the follow-up, 16 episodes of shunt dysfunction were observed in 13 patients. The cumulative probability of developing shunt dysfunction was 66.7% at two years.

Duration of hospital stay

Duration of hospitalisation for the index bleed was 14.6 (2.5) days in the endoscopic intervention group compared with 16.4 (1.7) days (mean (SD)) in the TIPS group (NS). During a two year follow up, the number of hospitalisation days per patient was similar in the endoscopic intervention and TIPS groups (45 (6) days v 42 (7) days; mean (SD)).

DISCUSSION

Variceal bleeding is associated with a high rate of rebleeding and death within months after the index bleed. In recent years, the use of endoscopic sclerotherapy and ligation, and beta-blockers has markedly lowered the rebleeding rate but the effect on survival has been more modest. The TIPS procedure was first used in 1989 and

initial results were encouraging. Treatment of variceal bleeding is an emergency due to the frequency and severity of early rebleeding during the first two weeks. Early intervention is the only way to significantly influence survival. Therefore, patients were randomised 24 hours after haemodynamic stabilisation, achieved in both groups by standard treatment for acute variceal bleeding (that is, vasoactive drugs and endoscopic therapy). The TIPS procedure was performed soon after randomisation whereas the second endoscopic treatment was delayed 7–10 days to avoid occurrence of bleeding from ligation related ulcers.[15]

The ultimate goal of endoscopic treatment for varicose veins is the most complete obliteration of varicose veins. As in the case of the combination (EL+ES) method, the impact was potentially dangerous in terms of bleeding varices throughout the process. This "aggressive" approach has ensured a high percentage of eradication of the veins regardless of the method (84.8%-EL and 83.4% EL+ES). Similar results were obtained Umehara.[11] In his study, the frequency of varicose eradication was achieved in 80.8% of the after EL and in 84% after the combination of EL and ES.

The diagnosis of the esophageal bleeding caused by PH, cirrhotic source was the reason to implement a complex of systematic measures. Options often include curative primary link assistance in such patients is not so high, but if the timely application is highly effective. They preserve the life and deed to stop to die the patient from acute bleeding, the inspiring for beginning the complex diagnostic and treatment activities must be mere assumption esophageal hemorrhage. The primary therapeutic action is to install the probe Blakemore and intravenous terlipressin (up to 1000 µg bolus, repeating if necessary after 4-6 hours, but not more than 4 mg per day), creating a significant portal decompression. Note that keeping the balloon in an inflated state for more than 12 hours contributes to ischemia of the esophageal wall and leads to the formation of bedsores. Simultaneously with the establishment of the deficit of circulating blood volume, drop in hemoglobin and hematocrit should be compensation for plasma - and blood loss and a set of standard hemostatic procedures.

It is also appropriate to use of proton pump inhibitors (intravenous omeprazole 80 mg/day) for the prevention of lysis of a blood clot on the free due to gastro-esophageal reflux, which contributes to the abandonment of in the esophagus at half-mast cylinder Blakemore. There is cirrhosis of the liver the patient holding him FEGDS with only one goal – visualization bleeding varicose (without intent, and technical viability of ligation) is not only inappropriate but also dangerous. Endoscopic ligation at the height of bleeding is an extremely effective procedure, but only under the condition that its specialists, confidently skilled at this manipulation. Periodic inspections of the area ligation are important, as well as the appointment of the enveloping means and proton pump inhibitors. If necessary, the procedure of ligation should be repeated in the identification varicose, a threatened break-up. The introduction of selective vasoconstrictors for a purpose of medical portal decompression (at least 5-7 days) is currently considered the procedure with proven efficacy.[11,14] The best results, in our opinion, provide terlipressin (600-1000 mcg/day every 6 hour intravenous bolus) and a synthetic analogue of somatostatin-octreotide (400-800 mg/day intravenously by infusion pump).

The above activities in a significant number of cases provide a stop esophageal bleeding, but do not guarantee from the risk of recurrence of hemorrhage, which on the background of aggravated liver failure can be fatal for the patient. The main reason for repeated bleeding is portal hypertension, which remains fixed factor. At this stage of treatment actualised surgical treatments aimed to prevent the development of recurrence of hemorrhage. Operations azygoportal separation and well-known varieties of portosystemic shunting (including distal splenorenal anastomosis) is very effective. However, the majority of patients presenting with threatened or established event esophageal bleeding, developed on the background of cirrhosis of the liver, in the vast majority of cases are sub - and decompensated stage of liver failure.

The use of transabdominal interventions, accompanied by many hours of surgical and anesthetic aggression can be unbearable such patients. Operation TIPS that are minimally invasive and at the same time providing an effective portal decompression, justly claims to be considered optimal in this severe category of patients. Selective embolization of the left gastric vein, complementing the TIPS and thus does not significantly complicate the primary procedure bypass surgery, can reduce the risk of recurrence of esophageal hemorrhage even in the case of dysfunction (thrombosis) of the shunt.

CONCLUSION

We concluded that TIPS is the most effective method to prevent bleeding and decline of portal hypertension. This is one of the most effective methods to control patients with liver cirrhosis. In addition, TIPS can change patients' condition according to Child-Pugh classification. Technically, this is the best scarce method. It can decrease all pathological hemodynamic changes. We can reach clinical success to control bleeding and other complications of cirrhosis. TIPS may improve quality of patients' lives.

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