Clinical Results of the Transjugular Intrahepatic Portosystemic Shunt

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Purpose: To evaluate the clinical results of transjugular intrahepatic portosystemic shunt (TIPS) for the control of variceal bleeding.

Materials and Methods: TIPS creation was attempted in 23 patients with endoscopically confirmed variceal bleeding. Most patients had multiple episodes of bleeding in the past and have been treated with multiple endoscopic sclerotherapies. Pre- and post-procedural hepatic and portal vein pressures were measured. After creation of TIPS patients were followed up at regular intervals.

Results: TIPS has been successfully accomplished in 22 of 23 patients using Wallstent (n=21) and Strecker stent (n=1). Immediate bleeding control was achieved in all patients with shunt creation. No procedure-related complication was noted. Portal vein pressure was reduced from 30.7±5.8 mmHg to 20.8±4.7 mmHg. The mean pressure gradient of portosystemic shunt dropped from 22.8±6.0 prior to TIPS to 12.2±4.1 immediately after. During the follow-up period (6–556 days, mean: 10 months), seven patients died: progressive hepatic failure (n=4), variceal rebleeding (n=2), and respiratory failure (n=1). Hepatic encephalopathy after TIPS was noted in 7 patients (31.8%). Variceal rebleeding occurred in 3 patients (13.6%). The remaining 15 patients have survived an average of 11 months.

Conclusion: These results suggest that TIPS is a safe and effective method for lowering portal pressure and controlling variceal bleeding. Furthermore if these initial results are encouraged by further long-term observation, TIPS could replace endoscopic and risky surgical intervention.

Index Words: Esophagus, varices
Liver, cirrhosis
Portal hypertension, varices
Shunts, portosystemic

INTRODUCTION

Variceal bleeding is a life-threatening complication of the portal hypertension. As a method of treatment, TIPS has been performed worldwide encouraged by the commercially available metallic stent since the first human application of the Palmaz balloon-expandable stent for the creation of TIPS in 1985(1). Many reports have been published in regard to technical refinements and clinical results(1-6). This report describes the clinical results of TIPS procedures in 22 Korean patients.

MATERIALS and METHODS

Twenty-three patients, 17 men and 6 women, admitted due to massive variceal bleeding were treated from October 1991 to July 1993. Ages ranged from 34 to 65 years (Mean: 52 years). In 14 patients, liver cirrhosis developed after hepatic infection (HBV: 10, HCV: 4); 9 patients had post-alcoholic liver cirrhosis. Staging of liver cirrhosis was classified based on the Child & Pugh classification (17): Child A 7; Child B 13; Child C 3. Most patients had multiple episodes of bleeding in the past and have been treated with multiple endoscopic sclerotherapies (Table 1). To enter the study, the patients had to fulfill certain preconditions: inoperability for clinical or technical reasons and prospectively inefficient sclerotherapy. The consent form...
Table 1. Clinical Data on Patients (Chronological Order)

| No. | Sex | Age | Child & Pugh Classification | Source of Liver disease | No. of Bleeding | No. of Sclerosis | No. of PTVO | Others |
|-----|-----|-----|-------------------------------|------------------------|----------------|-----------------|-------------|--------|
| 1   | F   | 65  | C                            | HCV                    | 3              | 2               | 1           |        |
| 2   | M   | 42  | B                            | HBV                    | 1              | 0               | 0           |        |
| 3   | M   | 53  | C                            | HBV                    | 3              | 2               | 1           |        |
| 4   | F   | 45  | B                            | HBV                    | 9              | 1               | 0           |        |
| 5   | M   | 58  | B                            | HCV                    | 6              | 1               | 0           |        |
| 6   | M   | 34  | A                            | HBV                    | 1              | 0               | 0           |        |
| 7   | M   | 52  | B                            | ALCOHOLIC              | 2              | 8               | 0           |        |
| 8   | F   | 52  | A                            | HBV                    | 2              | 0               | 0           |        |
| 9   | M   | 52  | B                            | HBV                    | 3              | 0               | 0           |        |
| 10  | M   | 54  | B                            | ALCOHOLIC              | 2              | 1               | 1           |        |
| 11  | M   | 53  | B                            | HBV                    | 4              | 4               | 0           |        |
| 12  | M   | 65  | B                            | HCV                    | 2              | 0               | 0           | failure of TIPS |
| 13  | M   | 43  | B                            | ALCOHOLIC              | 5              | 5               | 1           |        |
| 14  | M   | 50  | B                            | ALCOHOLIC              | 3              | 3               | 0           | esophageal ca. |
| 15  | M   | 57  | A                            | ALCOHOLIC              | 1              | 0               | 0           |        |
| 16  | M   | 60  | B                            | ALCOHOLIC              | 1              | 1               | 0           |        |
| 17  | F   | 59  | B                            | HBV                    | 1              | 0               | 0           |        |
| 18  | F   | 53  | A                            | HBV                    | 1              | 0               | 0           |        |
| 19  | M   | 50  | C                            | ALCOHOLIC              | 1              | 0               | 0           |        |
| 20  | F   | 52  | A                            | HBV                    | 3              | 0               | 0           |        |
| 21  | M   | 61  | A                            | HCV                    | 1              | 0               | 0           |        |
| 22  | M   | 53  | B                            | ALCOHOLIC              | 1              | 0               | 0           | hepatoma/portal vein thrombosis |
| 23  | M   | 52  | A                            | ALCOHOLIC              | 3              | 6               | 0           |        |

For the procedure was obtained from the patient and relatives. In preparation for the procedure, the following laboratory tests were performed: LDH, GPT, GOT, bilirubin, serum protein level, BUN/creatinine, RBC, WBC, thrombocytes, electrolytes, ammonium, PT/PTT. If permitted, highly abnormal laboratory values on admission were corrected. Abdominal ultrasonography was performed to quantify ascitic fluid and hemodynamic flow of portal and hepatic veins. The presence of focal hepatic mass lesion also had to be noted by ultrasonography. In one patient, TIPS was performed in spite of a hepatoma in the lateral segment of the left lobe. Endoscopy confirmed gastroesophageal varices. In some cases, enough time was not permitted for the preprocedural diagnostic steps and patients preparation because the patients were actively bleeding, and the procedures were performed on an emergency basis.

Some of the technical steps have already been published in great depth(1-6). We used the following procedure. After establishment of right internal jugular venous access, a free hepatic venogram or test injection of contrast medium was done for visualizing the anatomy of the main hepatic vein and for selection of the puncture site. Hepatic venous pressure was measured before the puncture. For the liver puncture, the Colapinto transjugular liver biopsy needle (Cook Inc., Bloomington, IN) was used. The artificial shunt tract was created by bridging the right hepatic vein with right main stem of portal vein (n=10), with main stem of portal vein (n=7) and with left main stem of portal vein (n=4) and by connection between the left hepatic vein and left main stem of portal vein (n=1). Then insertion of guidewire with soft tip was introduced deeply into the portal system followed by a catheter for portal pressure measurement and portal venogram to document the portal anatomy, location of catheter entrance site into portal vein and extent of varices. A stiff guidewire was then introduced and the liver puncture tract was dilated using a 8-mm or 10-mm wide and 4-cm long high-pressure balloon catheter. The portal vein wall offered significant resistance and a persistent waist was seen on the balloon until increased pressure was applied. The site of portal vein wall was indicated by a radioopaque material or remembered by bony landmarks for stent positioning. With the use of Wallstent (Schnieder (Europe) AG, Switzerland) (n=21), the stent covered with a protective sheath was advanced directly after balloon dilatation and applied. A catheter was then introduced into the portal vein for portal pressure measurement and a follow up portal venogram. If filling of varices persisted on the por-
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togram, the reduction in portal pressure was not significant and there was insufficient flow through the shunt, further dilatation using a larger diameter balloon catheter or direct variceal embolization with Gelfoam or stainless coils (3–8 mm) was performed. Portal pressure measurement and venogram were obtained again before the end of procedure (Fig. 1).

Following successful intervention, several parameters were carefully monitored, such as, gastrointestinal bleeding, change of ascitic fluid volume, pulmonary complications, hepatic encephalopathy, and changes of renal function, electrolytes, and liver function. Further hospital stay depended on the clinical status of the patient. Follow-up studies included the laboratory tests as performed before TIPS for hepatic and renal function, coagulation, and blood status. Imaging procedures included endoscopy and real-time and duplex ultrasound. Color doppler revealed luminal patency. Then shunt diameter was measured. In cases of suspicious stenosis or occlusion, flow velocity through the shunt was measured. Transvenous portography either transfermoral or transjugular was done if needed.

RESULTS

TIPS was successfully established in 22 of 23 patients. There was a technical failure of puncture and the variceal were treated with percutaneous transhepatic embolization. This represented a technical success rate of 95%. No complication related to the procedure was noted. In 11 patients, TIPS was performed on an emergency basis due to the uncontrollable active bleeding. A single shunt was constructed in 20 patients. Two stents were used in 2 patients due to

Fig. 1. a. Transjugular hepatic venogram was obtained before the TIPS procedure. b. During the dilatation of the artificial parenchymal tract with a balloon, the waist representing the resistance by the perforation site of the portal vein is noted. c. Redilatation of the tract after the deployment of the stent is shown.

Fig. 2. Pre- and postprocedural portograms are shown in a. and b. respectively. Note the disappearance of the marked esophageal varices and hepatopedal flow after TIPS.
to improper deployment of the initial stent. A second stent was placed in one patient (Patient 2). The stent diameter was 10mm(n=19) and 8mm(n=2) in Wallstent and 11mm(n=1) in Stretcher stent (Meditech, Denmark). Variceal embolization with gelfoam or coils was done in 7 patients. (Table 2).

Immediate bleeding control was achieved in all patients. Portal vein pressure was reduced from 30.7mm ± 5.8mmHg to 20.8 ± 4.7mmHg. The pressure gradient of portosystemic shunt dropped from an average of 22.8 ± 6.0mmHg (range 13.2 - 32.4mmHg) prior to creation of the shunt to 12.2 ± 4.1mmHg (range 5.1 - 19.1mmHg) immediately after. Mean postoperative hospital stay was 18 days.

New onset of hepatic encephalopathy after TIPS was noted in 7 patients. It occurred at the 1st, 3rd, 5th, 17th, 18th, 20th, and 30th days, respectively. Two patients with preexisting hepatic encephalopathy showed worsening of the hepatic encephalopathy after the TIPS procedure. Hepatic encephalopathy was controlled medically with lactulose, and all of the patients recovered. Three patients showed recurrence of hepatic encephalopathy after several months.

Variceal rebleeding occurred in three patients. Interestingly, there were no rebleeding in all patients treated with variceal embolization during the procedure. In one patient thrombosis of the splenic vein on portal angiogram prevented effective decompression and resulted in rebleeding. In two patients, occlusion of shunts was proven by angiography and with duplex ultrasonography respectively. A balloon dilatation through the occluded stent and variceal embolization with stainless steel coils were made in one patient resulting in effective decompression and control of rebleeding. Conservative medical therapy and sclerotherapy were done respectively in other two patients.

No difference in portosystemic pressure gradient was found between groups with and without rebleeding and hepatic encephalopathy. (10.5 ± 5.1mmHg in rebleeding group and 10.6 ± 4.9mmHg in non-rebleeding group (t-test, p>0.05); 10.2 ± 5.0mmHg in hepatic encephalopathy group and 10.8 ± 4.9mmHg in non-hepatic encephalopathy group (t-test, p>0.05). No statistically significant differences of portosystemic pressure gradient were also noted depending on Child's

Table 2. Immediate Morphological & Hemodynamic Results of TIPS

| Pt No | Location | Stent Kind | Diameter (mm) | Length (mm) | Embolization | Gradient(mmHg) | HE** | RB*** |
|-------|----------|------------|---------------|-------------|--------------|----------------|-------|-------|
|       | HV-PV    |            |               |             |              | Pre | Post |       |
| 1     | R-R      | WALL       | 1             | 8           | 56           | 17.6 | 5.1  | D5    |
| 2     | R-R      | WALL       | 2             | 8,10        | 56,51        | 21.3 | 15.4 | M4    |
| 3     | R-L      | WALL       | 2             | 10,10       | 34,34        | 28.7 | 11   | M5    |
| 4     | R-R      | WALL       | 1             | 10          | 85           | 25   | 16.9 |       |
| 5     | R-M      | WALL       | 1             | 10          | 56           | 29.4 | 14.7 | D3    |
| 6     | R-L      | WALL       | 1             | 10          | 58           | 19.9 | 6.6  |       |
| 7     | R-M      | WALL       | 1             | 10          | 68           | 19.9 | 16.2 |       |
| 8     | R-M      | WALL       | 1             | 10          | 51           | 29.4 | 10.3 | D18   |
| 9     | R-M      | WALL       | 1             | 10          | 51           | 5(2, 8(2) | 30.9 | 10.3  |
| 10    | R-R      | WALL       | 1             | 10          | 51           | 5, 8 | 13.2 | 11    |
| 11    | L-L      | WALL       | 1             | 10          | 51           | 27.9 | 10.3 |       |
| 12    | R-R      | WALL       | 1             | 10          | 51           | 27.2 | 11.8 |       |
| 13    | R-L      | WALL       | 1             | 10          | 55           | 22.1 | 10.3 |       |
| 14    | R-L      | WALL       | 1             | 10          | 55           | 5(2) | 17.6 | 10.3  |
| 15    | R-R      | WALL       | 1             | 10          | 55           | 3(2, 5(2) | 16.2 | 11    | D17   |
| 16    | R-R      | WALL       | 1             | 10          | 55           | 14   | 5.9  |       |
| 17    | R-R      | WALL       | 2             | 10,10       | 55,55        | 14   | 8.1  | D8    |
| 18    | R-R      | WALL       | 1             | 10          | 55           | 14   | 8.1  |       |
| 19    | R-L      | WALL       | 1             | 10          | 50           | 8(2) | 29.4 | 22.1  | D30   |
| 20    | R-R      | WALL       | 1             | 10          | 55           | 21.3 | 9.6  |       |
| 21    | R-M      | WALL       | 1             | 10          | 55           | 5, 8(2) | 17.6 | 12.15 | D1    |
| 22    | R-M      | WALL       | 2             | 10,10       | 62,92        | 27.2 | 15.4 |       |
| 23    | R-M      | STRECKER   | 1             | 11          | 40           | 32.4 | 19.1 |       |
| Mean ± SD |         |            |               |             |              | 9.9 ± 0.6 | 55.7 ± 12.2 | 22.8 ± 6.0 | 12.2 ± 4.1 |
| Minimum | 1        | 8           | 34            | 13.2        | 5.1         |       |
| Maximum | 2        | 11          | 92            | 32.4        | 19.1        |       |

*HV: Hepatic Vein, PV: Portal Vein **Hepatic Encephalopathy ***Rebleeding
D: Days, M: Months, + Coils; Size in mm(Number)
stage; Child A: 8.6 ± 3.7 mmHg, Child B: 12.1 ± 5.5 mmHg, Child C: 12.5 ± 4.5 mmHg (ANOVA test, Chi-Square = 0.65, P > 0.05).

As a follow-up study for full-diameter expansion and luminal patency of the stent, postprocedural duplex ultrasonography was made in 16 patients with irregular intervals (8-344 days). In all cases the stent had its full-diameter. Good patency (n=9), stenosis (n=6) and occlusion (n=1) were noted. The patient with complete occlusion who refused restenting died of uncontrollable rebleeding. Rebleeding did not occur in patients with luminal stenosis or patency, that is, functioning shunt. Partly due to the interobserver bias and inexpertise in the technique, the value of flow velocity had no statistical significance and was abandoned.

Transient sharp increase of the hepatic enzymes, GOT and GPT, was noted. All peak values were within 10 days except two patients; 13th and 19th days respectively.

During the follow-up period (6556 days, mean ± 10 months) 7 patients died after TIPS. The remaining 15 patients have survived an average of 11 months. The causes of death were progressive hepatic failure (n=4), variceal rebleeding (n=2), and respiratory failure (n=1). (Table 3)

**DISCUSSION**

Portal decompression through a percutaneously established communication was first achieved by Rösch et al in 1969(1). Subsequently, several experimental methods have been developed to expand the venous connection up to a diameter that would be adequate for portal decompression. In 1982, Colapinto et al first reported creating percutaneous infrahepatic shunts in humans(7). They used angioplasty balloon catheters and repeated dilation trying to establish a large transparenchymal tract. While these shunts were effective in lowering portal pressure, they tended to occlude rapidly because of elastic recoils in the adjacent hepatic parenchyma. Palmaz et al(8) in 1985 and Rösch et al(9) in 1987 used expandable metallic vascular stents to create TIPS in animals and showed the neointimal lining formed on the stent within just a few weeks. Palmaz et al in 1986 found that expandable metallic infrahepatic shunts placed in dogs with experimentally induced portal hypertension remained patent through 48 weeks. Richter et al(1) in 1990 successfully created infrahepatic shunts in three patients with use of the Palmaz balloon expandable stent (Johnson & Johnson Interventional systems, Warren NJ).

Using balloon-expandable Palmaz stent adaption of the shunt dimension to the individual hemodynamics is easy. That is, redilation and further increase of shunt diameter is simple with the insertion of bigger balloons and also may be performed in a second procedure by transjugular approach. TIPS with two other kinds of stents were reported. The Gianturco stent (Cook, Bloomington, Ind) has a tendency to occlusion and thrombus formation experimentally (9). The insertion technique of the Gianturco stent is similar to that of Palmaz stent in that it can be compressed and inserted through a 10-F sheath. The main difference is that it does not require a balloon catheter for insertion as the Palmaz stent.

Wallstent is directly mounted on 7-F delivery catheter and, unlike other available stents, does not require preliminary passage of a large, thin-walled introducer sheath into the portal vein. The delivery catheter is flexible so that it tends not to buckle or kink as it is advanced through hard cirrhotic liver parenchyma or around an acute portal vein entry angle. Once expanded, the Wallstent maintains a cylindrical lumen through relatively sharp bends and conforms to the course of the venous structures when it extends from a small peripheral portal branch into more central vein that has large enough diameter to form an adequate shunt. Because of these features, TIPS can be established with the Wallstent from virtually any point of entry into the portal venous system. But problems can occur which are related to the relatively poor radioopacity of the stent and its variable length. During deployment, these devices are shorten considerably and, because they are somewhat difficult to be visualized by fluoroscopy especially in patients with ascites, precise positioning may be difficult. Using the radioopaque marker or bony landmark, misdeployment can be avoided minimally. In two cases due to the mismatching of the stent in the parenchymal tract, an additional second stent was deployed to cover the segment of tract that had not undergone stent placement. Another important criticism of the Wallstent is that, as currently manufactured, it has a maximum diameter of only 10 mm, which, in some patients with severe portal hypertension, may not be large enough to reduce portal pressure sufficiently to prevent recurrent portal hypertension. In all patients with either Wallstent or Strecker stent, immediate bleeding control and pressure reduction were

| Pt. No | Causes of Death                  | Survival Days |
|--------|---------------------------------|---------------|
| 1      | Progressive Hepatic Failure     | 6             |
| 2      | Respiratory Failure             | 497           |
| 3      | Rebleeding                      | 280           |
| 4      | Progressive Hepatic Failure     | 274           |
| 10     | Progressive Hepatic Failure     | 78            |
| 14     | Progressive Hepatic Failure     | 278           |
| 17     | Rebleeding                      | 79            |

Table 3. Reasons for Death after TIPS
achieved.

Technically puncture of portal vein and exact deployment of the stent are main concerns. Conventionally, the passage of a needle from the hepatic vein into the portal vein was performed only with fluoroscopic monitoring, however, the puncture is blind. Several methods for targeting the portal vein has been previously reported including transhepatic venous catheterization, indirect portography (arterial catheterization), skin marking based on ultrasound mapping, and percutaneous placement of a metallic marker with real-time US guidance (13). Combination of these techniques may be helpful in difficult cases. In most of our cases, we could puncture easily only with fluoroscopic monitoring.

Exclusion of hepatic mass lesion was prerequisite for the TIPS previously. But with the presence of mass lesion TIPS can be performed for the control of emergent uncontrollable bleeding if hepatomas are exempt from the possible pathway of puncture or parenchymal tract in the risk of bleeding or seeding. For example, mass lesion in the locations of right lower inferior portion or left lateral peripheral portion seems to be relatively safe as authors experienced in one patient (Patient 22) with hepatoma in the lateral segment of the left lobe. Caution is needed especially in the case of subcapsular location and/or large size to prevent unexpected rupture or massive bleeding.

As a follow-up study, transfemoral, transjugular or transcatheter angiography clearly documents the status of the stent. But without any symptom including hepatic encephalopathy or rebleeding, the patients are reluctant to undergo such an invasive procedure. Recently two studies have been reported which emphasize the role of doppler ultrasonography in the follow-up study of the TIPS (14-15).

Sonography can provide a valuable information about the hemodynamics after TIPS. We also used duplex ultrasonography. Though they were not correlated with the angiography, the patency and flow status of the shunt can be easily checked out.

Percutaneous revision of an acutely thrombosed TIPS and a second TIPS parallel to the first in the patient with persistent portal hypertension were reported (16-17). We experienced a TIPS creation through the thrombosed portal vein in a patient (Patient 22). After dilatation of the occluded portal vein, two stents were used for effective hepatopedal flow; because entire segment of the portal vein and distal portion of the superior mesenteric vein were occluded, a shunt tract had to be established along the long course between hepatic vein and superior mesenteric vein throughout portal vein. (Fig. 3)

The concept of TIPS reflects the hemodynamic

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Fig. 3. a. Portal venogram obtained before TIPS placement shows transhepatic catheter which is deeply advanced in the superior mesenteric vein (arrow), occlusion of portal vein, and prominent collateral vessels.

b. Two Wallstents were deployed throughout the thrombosed segments of the portal vein and superior mesenteric vein.

c. Portal venogram obtained after TIPS creation shows good flow & disappearance of collateral vessels.
situation of a small-caliber H-interposition. Recently there has been a trend in surgical literature to recommend small-diameter portosystemic shunts to preserve hepatic perfusion and lower the incidence of postoperative encephalopathy. Rypins et al(18) and Johansen(19) reported favorable results with surgical establishment of this shunt type.

There are some controversies about hepatic functional impairment after TIPS. Our data showed a sharp increase of hepatic enzymes, GOT and GPT, which represents hepatocellular damage. Thereafter it was stabilized. So this phenomenon was transient and caused no significant effect on the prognosis.

Though the mortality rate of 32% in our series is insufficient to compare with that of the surgical and endoscopic therapies that are currently being used for variceal bleeding, it seems to be safer. Emergency shunt operation for patients in a stage Child's C is reported as high as 40–100%(20). Seven patients died. Two were in a stage Child's C and five in a stage Child's B. Of three patients in a stage Child's C, two died. However, because the total number of our patients is too small for definite conclusions on the basis of stage-related stratification, further study is recommended for the stage-dependent mortality of the TIPS patients.

In summary, TIPS is a safe and effective method for lowering portal decompression and controlling variceal bleeding, particularly in patients with acute variceal bleeding unresponsive to sclerotherapy or with highly risky surgical candidates. If this initial encouraging results are confirmed by further long term observation, TIPS could replace endoscopic sclerotherapy and risky surgical intervention.

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경내경정맥 간내문맥간정맥 단락술의 임상적 결과

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목 적: 문맥압 항진증에 의한 식도 및 위정맥류 출혈환자의 치료법으로 최근 유용하게 이용되고 있는 경내경정맥 간내문맥간정맥 단락술(Transjugular Intrahepatic Portosystemic Shunt : TIPS)의 효과와 유용성을 알아 보았다.

대상 및 방법: 1991년 10월부터 1993년 7월까지 위내시경으로 확인된 식도 및 위정맥류 출혈로 입원한 23명의 환자를 대상으로 시행하였다.

결 과: 22명에서 금속스텐트의(Wallstent : 21, Strecker stent: 1)설치에 성공하였고 스텐트설치에 따르는 합병증은 없었다. 문맥압은 시술전 평균 22.8mmHg에서 시술후 평균 12.2mmHg로 감소되었고 시술후 전례에서 효과적 감압으로 정맥류 출혈은 제어되었다. 추적기간(6-556일, 평균 10개월)중 7명이 사망하였고 사망원인은 4명은 진행된 간부전으로 2명은 재출혈로 1명은 호흡부전으로 사망하였다. 재출혈은 3명(13.6%)에서 간성뇌병증은 7명(31.8%)에서 관찰되었다. 나머지 15명의 평균생존기간은 11개월이었다. 문맥압과 간성뇌병증 유무 혹은 재출혈유무와는 통계학적으로 유의한 차이는 없었다.

결 론: 이상의 결과로 보아 시술수수는 적지만 경내경정맥 간내문맥간정맥 단락술은 문맥압 항진증에 의한 정맥류 출혈 시 안전하고도 효과적인 감압방법으로 여겨진다.