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Prophylactic Versus Emergency Sclerotherapy of Large Esophageal Varices Prior to Liver Transplantation

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From January 1985 through July 1987, adult patients accepted for liver transplantation with large esophageal varices were enrolled in a study evaluating the use of prophylactic vs emergency sclerotherapy. Six hundred forty-eight subjects received prophylactic sclerotherapy, and 172 received emergent sclerotherapy. Esophageal stricture formation was increased 12.9-fold ($P < 0.001$), esophageal perforation 6.4-fold ($P < 0.005$), and postsclerotherapy bleeding esophageal ulcers 3.7-fold ($P < 0.001$) in those receiving emergency sclerotherapy as opposed to prophylactic sclerotherapy. These differences were even greater if the number of sclerotherapy sessions rather than the number of patients was used as the denominator for the comparisons. In total, 19.6% of emergency sclerotherapy cases were associated with an untoward outcome of sclerotherapy; only 1.9% of cases receiving prophylactic sclerotherapy experienced an untoward outcome ($P < 0.001$). These data demonstrate that emergency sclerotherapy is associated with a greater prevalence of complications and support earlier studies that show that sclerotherapy prevents variceal bleeding over the short term. The data also suggest that when applied to patients with large varices awaiting orthotopic liver transplantation, it enhances the chance of a patient surviving to be transplanted by preventing a variceal bleed and the spiral of liver failure and death that frequently follows an episode of acute variceal bleeding.

KEY WORDS: liver transplantation; sclerotherapy; varices.

Advanced chronic liver disease is a health problem of considerable magnitude that is thought to affect as many as two million people in the United States (1–3). The major cause of death among such persons is hepatic failure that is frequently precipitated as a consequence of variceal bleeding (4–6). In several studies, sclerotherapy initiated to treat acute variceal bleeding has been reported to stop the bleeding and to reduce the rate of subsequent hemorrhage, thereby improving at least the short-term survival of those patients, who survive their sentinel hemorrhage (7–29). Unfortunately, the long-term survival of these patients has not been affected substantially, probably because it is more dependent upon the severity of the underlying liver disease rather than the occurrence or absence of an earlier bleeding episode (4–29).

This experience with sclerotherapy in patients surviving an esophageal variceal bleed has led others to attempt to prevent variceal bleeding alto-

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gether with prophylactic sclerotherapy (30–36). The early results with such an approach were impressive, but subsequent controlled studies have been less positive and even rather discouraging (30–36). The major problem with each of these studies, whether for or against prophylactic sclerotherapy, has been the fact that in each, the underlying problem, that is the liver disease responsible for the portal hypertension in the patients studied, has not been corrected; therefore, the effect of such therapy, even when effective, has been limited by the severity of the underlying liver disease (4–6, 25, 28, 29, 36). Clearly other factors, such as patient selection, the characteristics of the varices, and the technique of sclerotherapy utilized, also may have contributed to either the success or failure of some of these studies. Nonetheless the problem of the underlying liver disease appears to be the most important factor determining patient outcome across most studies.

Liver transplantation currently offers individuals with advanced liver disease an opportunity for continued life without liver disease and free of the many vicissitudes of advanced liver disease such as recurrent variceal bleeding and hepatic encephalopathy (37, 38). A major factor limiting the wider application of liver transplantation is donor organ paucity (38). As a consequence of the current shortage of donor organs, many patients evaluated and accepted for liver transplantation die waiting for an appropriate donor organ (38). Most of the deaths among accepted candidates awaiting liver transplantation occur either as an immediate result of a variceal bleeding episode or the accelerated hepatic failure or hepatorenal syndrome that follows an episode of variceal bleeding while they are waiting to be transplanted (38).

Because of these data and because of the apparent effectiveness of esophageal sclerotherapy in stopping acute variceal bleeding and possibly in preventing subsequent variceal bleeding, at least over the short-term, the following study was performed in adult patients accepted for and awaiting orthotopic liver transplantation at the University of Pittsburgh.

MATERIALS AND METHODS

Patients. All adult patients admitted to the Presbyterian-University Hospital, Pittsburgh, Pennsylvania, and evaluated for orthotopic liver transplantation since 1981 have undergone a formal liver transplantation evaluation, which includes pan-upper gastrointestinal endoscopy with an evaluation of the presence and size of any esophageal varices. The varices in each case are graded based upon their ability to fill the lumen of the air-distended esophagus. Grade 1 varices fill 25% or less of the esophageal lumen, grade 2 varices fill 50% or less of the esophageal lumen, grade 3 varices fill 75% or less of the esophageal lumen, and grade 4 varices fill greater than 75% of the air-distended esophageal lumen. All of those with grade three or four varices evaluated between January 1985 and July 1987 were enrolled into the following study. Patients admitted for liver transplantation evaluation on the medical service received elective sclerotherapy when indicated by the size of their varices as the attending surgeon was an advocate of sclerotherapy, while those admitted to the surgical service received sclerotherapy only under emergency conditions associated with active variceal hemorrhage as the attending surgeon was skeptical of the role of sclerotherapy in the management of potential transplant recipients. Patients were admitted to either service based solely upon the basis of the referral. No difference other than the use of prophylactic sclerotherapy on the medical service but not on the surgical service existed between the two services. A majority of the patients with hepatocellular carcinoma and cholangiolar carcinoma were admitted to the surgical service, while more patients with advanced nonmalignant chronic liver disease were admitted to the medical service.

Sclerotherapy Procedure. Sclerotherapy was performed using an Olympus 2T flexible fiberoptic endoscope and 5% sodium morrhuate. Each injection was made free hand and consisted of 4 ml of sclerosant solution. All attempts at variceal injection were meant to be intravariceal. A total of 11 injections was made at each sclerotherapy session beginning at the gastroesophageal junction and proceeding cephalad at 1-cm intervals in a spiral manner such that after four injections a full spiral was completed and a distance of 4 cm had been traversed. Elective sclerotherapy was performed on a fixed schedule as follows: days 1, 4, 7, 14, 21, 28, and then weekly thereafter until all of the esophageal varices either were obliterated or liver transplantation had been accomplished. For those patients on the surgical service, sclerotherapy was performed using the identical schedule and procedures but was initiated only as a result of an episode of clinical variceal bleeding.

All endoscopy and sclerotherapy procedures were performed under intravenous midazolam (2–10 mg) and meperidine (50–200 mg) conscious sedation by fellows in gastroenterology rotating on the liver transplant service and under the direct supervision of one of the four physician authors of this manuscript. Sucralfate (Marion Laboratories, Kansas City, Missouri) was administered as a suspension (1-g capsule dissolved in water) four times daily during the course of the sclerotherapy treatments.

Data Analysis. The endpoints for the analysis were established prospectively and included death prior to transplantation or transplantation, an episode of variceal bleeding or an emergency sclerotherapy session, esophageal stricture formation, esophageal perforation and/or the occurrence of bleeding esophageal ulcers formed as a consequence of sclerotherapy. Bleeding was defined as

an episode of hematemasis, melena, or an unexplained hematocrit drop of 6% or more. A nonvariceal site for bleeding was considered to be present only if an active bleeding site other than a varix was identified at endoscopy.

Differences in proportions were tested using chi square. Associations were assessed using the odds ratio as an approximation to the relative risk (39, 40). A P value less than 0.05 was considered to be statistically significant.

RESULTS

During the 2 1/2 years of patient accrual, a total of 2988 adult patients were evaluated and accepted for possible liver transplantation at the University of Pittsburgh. Sixty-five percent of these were on the surgical service and 35% were on the medical service. Of the total number, 1314 had grade 3 or 4+ varices that met the study entry criteria; 628 were on the surgical service, and 686 were on the medical service.

Prophylactic sclerotherapy was performed in 648 patients of the 686 on the medical service. Those not receiving prophylactic sclerotherapy either received emergency sclerotherapy for bleeding varices prior to being scheduled for "prophylactic sclerotherapy" (N=38). Eighty-five percent of those on the medical service survived to be transplanted; the other 15% died awaiting liver transplantation. Of this latter group, 18 died of esophageal bleeding. All of these were in the group receiving emergency sclerotherapy. Progressive hepatic failure and combined multiorgan failure (liver, kidneys, and lungs) accounted for the majority of the deaths.

Eighty-one percent of those on the surgical service survived to be transplanted; the remaining 19% died awaiting transplantation. Of this latter group, 89 died of esophageal variceal bleeding or hepatic failure precipitated as a direct consequence of a variceal bleed; compared to the medical service, the odds of dying of a varix bleed or its consequences were increased 6.1-fold (95% CI: 3.6, 10.3; P < 0.025). The remaining 30 patients died of multiorgan failure (10), hepatic failure (18), and sepsis unrelated to an episode of variceal bleeding (2). Emergency sclerotherapy was required in 21.3% (134/628) of the patients admitted to the surgical service; thus, compared to the medical service, the estimated risk of requiring emergency sclerotherapy was increased 4.6-fold (95% CI: 3.2, 6.8, P < 0.001).

TABLE 1. CLINICAL CHARACTERISTICS OF PATIENT GROUPS STUDIED

	Medical service	*Surgical service*
Number	648	628
Emergency sclerotherapy	38	134*
Elective sclerotherapy	648	0
Survival to OLTx	85%	81%
Albumin (<3.0 g/dl)	82%	75%
PT (>5.0 sec)	39%	32%
Ascites present	87%	81%
Encephalopathy present	72%	65%
Pugh's classification		
A	10%	12%
B	72%	63%
C	18%	25%

*All data below this entry in this row refer only to this group of 134 patients who bled.

In order to evaluate the side effects of sclerotherapy performed under conditions of prophylaxis as compared to an emergency situation, two analysis groups were formed: The first group was designated as the prophylactic sclerotherapy (PS) group. It comprised 648 patients admitted to the medical service who received prophylactic treatment. The second group was designated as the emergency sclerotherapy (ES) group. It was composed of 172 patients (38 from the medical service and 134 from the surgical service) who initially received emergency sclerotherapy. These two groups were found to be comparable clinically at time of admission to hospital for the evaluation, and similar levels of albumin and prothrombin and similar prevalences of ascites and encephalopathy (Table 1).

Esophageal stricture formation was rather common and occurred in 55.8% of the emergency sclerotherapy group and in 9.0% of the prophylactic sclerotherapy group. As compared to the PS group, this represents a 12.9-fold increased estimated risk of stricture formation among patients undergoing ES, (95% CI: 8.6, 19.2; P < 0.001); it should be noted that ES was performed under difficult circumstances of active bleeding, hypotension, inadequate visualization because of the bleeding, and esophageal motion associated with tachycardia. Eight cases of esophageal perforation occurred; five while undergoing ES and three while undergoing PS; this represents a 6.4-fold increased risk of esophageal perforation with ES as opposed to PS (95% CI: 1.52, 27.2; P < 0.005). Five of these perforations were recognized only at the time of autopsy. Of the remaining three, two were treated medically with

antibiotics and parenteral nutrition and one was treated surgically. All three survived.

The same pattern of results was evident when one examines the rate of bleeding esophageal ulcers in the two groups. A sclerotherapy-induced ulcer was the source of subsequent bleeding in 3.1% of the PS group and 10.5% of the ES group. Thus the odds of experiencing a postsclerotherapy bleeding ulcer were increased 3.7-fold in the ES group as opposed to the PS group (95% CI: 1.9, 7.1; $P < 0.001$). In contrast, the frequency of nonvariceal bleeding in the two groups prior to transplantation was similar. Most such episodes occurred as a result of gastritis (portal hypertensive gastropathy) with only a few arising as a consequence of duodenal ulcer disease.

This difference between the two groups was even greater when the number of procedures (PS, $N=3468$; ES, $N=490$) rather than the number of patients treated per group was considered. Ninety-six of the 490 procedures performed in the ES group (19.6%) were followed by an untoward outcome defined as either a serious esophageal ulcer or stricture, while only 58 of the 3468 procedures in the PS (1.7%) group were followed by such an event. This represents a 11.7-fold increased risk for an untoward event in the ES group as compared to the PS group (95% CI: 10.1, 20.2, $P < 0.001$).

DISCUSSION

This study demonstrates quite clearly that when elective sclerotherapy is utilized as an integral part of a liver transplant program, as was the case for those patients on the medical service, that the number of esophageal bleeding episodes and the number of deaths due to variceal bleeding experienced prior to liver transplantation is reduced (Table 1). More importantly, it demonstrates that elective as compared to emergency sclerotherapy, when applied to patients with advanced liver disease (Table 1), is associated with fewer untoward consequences of esophageal variceal sclerotherapy including esophageal stricture ($P < 0.001$), esophageal perforation ($P < 0.005$), and bleeding due to an esophageal ulcer occurring as a consequence of prior variceal sclerotherapy ($P < 0.001$). These differences between the two groups for untoward consequences of sclerotherapy were even greater if the number of sclerotherapy sessions rather than the number of patients was used as the denominator in the calculations.

These data support, therefore, the early uncontrolled observations that prophylactic esophageal variceal sclerotherapy is of value and advantageous, at least for the short-term, for patients with advanced liver disease and large esophageal varices (30–35). In contrast, these data are clearly contradictory to the controlled studies performed that report that prophylactic sclerotherapy is not beneficial (30, 33).

The major difference between the present study and the controlled studies that have failed to demonstrate an advantage for prophylactic sclerotherapy in patients with advanced liver disease is that the outcome variable or endpoint chosen was different. In the present study, the endpoints were death prior to transplantation or transplantation, episodes of variceal bleeding, performance of an emergency sclerotherapy session, esophageal stricture formation, esophageal perforation, and bleeding esophageal ulcers occurring as a consequence of sclerotherapy. In previous studies, the endpoints have been death, duration of survival, and number of episodes of esophageal variceal bleeding. In the present study, liver transplantation was used to treat the underlying liver disease; sclerotherapy was used only to prevent a varix bleed and bleeding associated hepatic failure leading to death in those awaiting liver transplantation. In all other studies reported to date, the varices have been treated with sclerotherapy, but no specific treatment for the underlying liver disease has been utilized.

Despite the apparent differences between this report and previous studies, the present data are consistent with the other studies in which prophylactic sclerotherapy has been used, in that in both, the number of episodes of bleeding from varices has been reduced, at least over the short-term (three to four months to as long as one year). As a result, the number of emergency sclerotherapy sessions performed in the first year after sclerotherapy is reduced markedly. As a direct consequence, the frequency and number of complications experienced as a result of emergency sclerotherapy are reduced also. It should be noted that the average waiting time for a liver transplant is 3.3 ± 1.2 months. Thus the period of time during which variceal bleeding can be reduced encompasses the time interval required to identify an appropriate donor and transplant a potential (accepted) transplant recipient.

Because all of the sclerotherapy procedures in this study were performed by the same group of physicians, this study documents further that phy-

sicians expert in the technique of esophageal sclerotherapy experience fewer complications when they perform sclerotherapy under elective circumstances compared to when they perform sclerotherapy under emergency conditions. In this regard it is important to note that the complications experienced in this study as a result of esophageal sclerotherapy were similar to those reported by others (41–58). Moreover they occurred at a lower rate in the prophylactic group than has been reported previously but at a rate similar to that reported by others for emergent sclerotherapy (41–58).

Finally, it should be noted that there is also a downside to prophylactic sclerotherapy. Specifically an occasional esophageal proximal gastric perforation occurring as a consequence of prophylactic sclerotherapy can prolong and/or complicate the posttransplant course of an otherwise uncomplicated transplant recipient. However, when balanced against the net gain for all of the patients so treated in terms of the reduction in bleeding episodes and death prior to OLTx, this price does not appear to be excessive.

These data suggest, therefore, that prophylactic sclerotherapy utilized to prevent variceal bleeding and death or medical deterioration of a patient with advanced liver disease awaiting liver transplantation is of substantial benefit and reduces the number of bleeding episodes, the frequency of emergency sclerotherapy sessions, and therefore the complications of sclerotherapy experienced by patients awaiting transplantation with advanced liver disease and large esophageal varices.

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