Efficacy of Balloon Tamponade in Treatment of Bleeding Gastric and Esophageal Varices Results in 151 Consecutive Episodes

J. PANÉS, MD, J. TERÉS, MD, J. BOSCH, MD, and J. RODÉS, MD

The efficacy and complications of esophageal tamponade as the first procedure in the routine management of acute variceal hemorrage were evaluated in 151 consecutive bleeding episodes treated at a specialized unit. The Sengstaken-Blakemore tube was employed in the 118 cases in which emergency endoscopy demonstrated bleeding esophageal varices, and the Linton-Nachlas balloon in the 33 cases with bleeding from gastric varices. Hemostasis lasting at least 24 hr was obtained in 91.5% of cases treated with the Sengstaken-Blakemore balloon and in 88% of those treated with the Linton-Nachlas balloon. Permanent hemostasis was obtained in 47.7% of all cases. The only severe complication noted in these 151 episodes of bleeding treated by tamponade was pulmonary aspiration, which was detected in 10% of cases. This complication was related to the presence and degree of encephalopathy (P < 0.001) and was prevented by orotracheal intubation prior to tamponade. These results indicate that balloon tamponade continues to be a reliable and valuable method to arrest bleeding from esophagogastric varices.

KEY WORDS: hemorrhage; esophagus; tamponade; varices; portal hypertension.

Since 1950, when Sengstaken and Blakemore introduced balloon tamponade as emergency treatment for bleeding esophageal varices (1), this procedure has become widely accepted. An alternative to the Sengstaken-Blakemore (SB) tube is the single-balloon triple-lumen tube introduced by Linton and Nachlas (LN) (2). The effectiveness of balloon tamponade varies according to different series from

50 to 92% and there is similar variation in the frequency and severity of the complications associated with the procedure (3–13). There is much controversy about the value of balloon tamponade in the therapy of bleeding varices, specially since the introduction of vasopressin (14) and endoscopic sclerotherapy (15).

A previous prospective comparative study on the efficacy and tolerance of the SB tube and the LN tube (3) showed that both were very effective in controlling variceal bleeding, although the SB tube was more effective than the LN tube in obtaining permanent hemostasis in bleeding esophageal varices, whereas the LN tube was more effective in

Manuscript received January 19, 1987; revised manuscript received May 20, 1987; accepted August 3, 1987.

From the Liver Unit, Hospital Clínic i Provincial, Medical School, Barcelona, Spain.

Address for reprint requests: Dr. J. Terés, Servicio de Hepatología, Hospital Clínic i Provincial, Villarroel, 170, 08036-Barcelona, Spain.

bleeding gastric varices. In addition, better tolerance and greater effectiveness were obtained when the SB tube was applied without external traction. The present study reports the results of balloon tamponade used according to the criteria established in the previous study and used as the first procedure in the management of active variceal bleeding in a consecutive series of 151 cases.

MATERIALS AND METHODS

The present study includes 140 patients admitted on 151 occasions in the Liver Unit of the Hospital Clínic i Provincial, Barcelona, between April 1982 and November 1984, because of actively bleeding esophageal or gastric varices. In all but 10 cases the source of bleeding was assessed by emergency endoscopy. Endoscopy was performed using a GIF D3 Olympus endoscope and was used to explore the esophagus, the whole gastric cavity, and the first two portions of duodenum in order to assess the presence of associated lesions. In 10 cases tamponade was applied without previous endoscopy: in three because a recent episode of bleeding was proved to be due to varices and in the remaining seven cases because of massive hemorrhage with shock that contraindicated endoscopy. During the same period 78 additional patients were admitted because of bleeding but endoscopy showed clean varices or varices with signs of hemostasis (adhered clot) but without active bleeding; those patients were not submitted to tamponade and, therefore, are not included in this study.

Hepatic cirrhosis was the cause of portal hypertension in 138 patients, 74 of whom were alcoholics. One patient was shown to have portal vein thrombosis, and another had idiopathic portal hypertension. One hundred patients were male. The average age was 56.8 ± 12.1 years (mean \pm sp).

All patients were managed in the Liver Intensive Care Unit, where they were attended by staff members or senior residents and by a nursing team with experience in the care of patients with liver disease and gastrointestinal bleeding. Balloon tamponade was the sole form of specific treatment to arrest variceal bleeding. In the 108 patients bleeding from esophageal varices, and in the 10 patients in whom endoscopy was not performed, an SB tube (Ch 21, manufactured by Willy-Rüsch, Waiblinger, West Germany, 204800) was passed. Before passage of the tube, the stomach was emptied to reduce the possibility of vomiting and aspiration, the channels of the tube were tested for patency, and the balloons checked for leaks. The tube was lubricated and passed through the nose into the stomach. The gastric balloon of the SB tube was inflated with 120 ml of air, and then the tube was slowly withdrawn until firm resistance was encountered at the esophagogastric junction. Then the esophageal balloon was inflated at a pressure of 60-70 mm Hg. The tube was kept in place by fixing it to the nose, and no external traction was applied. Every hour the gastric contents were aspirated and the pressure of the esophageal balloon was checked. Gastric and esophageal balloons remained inflated for 24 hr and both were then deflated at the same time. In patients with altered consciousness, the Boyce modification of the SB tube was used (4). In five patients with deep hepatic encephalopathy (grades III–IV), an endotracheal intubation was carried out before endoscopy (four cases) or after endoscopy but before balloon tamponade (one case).

The LN tube was applied in the 33 cases in which endoscopy showed a gastric varix actively bleeding. The LN tube used was the one modified by Bertrand and Michel (13) (manufactured by Marquat SA, France, Ref. C.14, adult size). After lubrication, the tube was passed through the nose into the stomach and the gastric balloon was inflated with 600 ml of air. The tube was kept under an external traction of 1000 g. Esophageal secretions were continuously aspirated through the esophageal lumen incorporated in the LN tube, which was kept in place for 36 hr.

After admission to the intensive care unit, heart rate, blood pressure, and the characteristics of gastric aspirate were controlled hourly. Blood was transfused to maintain a hemoglobin above 10 g/dl. When hemoglobin was above this level, other plasma volume expanders were used to correct hypovolemia, to keep the pulse rate below 100/min and blood pressure above 100/60 mm Hg. Patients were treated with intragastric neomycin, nystatin, and colistin, administered via the SB or LN tubes every 6 hr to prevent bacteremia from enteric organisms (16).

Efficacy of tamponade was evaluated according to the following predetermined criteria: hemostasis, when tamponade succeeded in arresting variceal bleeding as shown by the absence of blood in the hourly gastric aspirates, and stabilization of the hemodynamic status without need for further transfusion. Permanent hemostasis was defined as hemostasis after removal of the tube and lasting until the patient was discharged from hospital or submitted to an elective treatment for portal hypertension. Cases in which bleeding persisted despite correct positioning of the tube were considered as failures and given alternative therapy.

Tolerance to tamponade was evaluated according to the presence of epigastric pain, chest pain, and the need of analgesia. All patients were monitored clinically, by daily chest x-rays and by measurement of blood gases, for signs of airway aspiration. When present, this was considered a direct complication of tamponade. Liver function was assessed on admission by standard liver tests: albumin, prothrombin index, bilirubin, ASAT, ALAT, G-GTP, and alkaline phosphatase. Liver failure was graded according to the Child's classification as modified by Campbell et al (17).

Survival was defined as discharge of the patient alive from the hospital.

The $\chi 2$ and the Fischer's exact test were used in the statistical analysis of the differences between percentages.

RESULTS

Effectiveness of Tamponade. Hemostasis was achieved in 137 of the 151 cases (90.7%). Only 14

patients continued to bleed in spite of a well-inflated and correctly positioned balloon. Tamponade was effective in 108 of the 118 patients (91.5%) bleeding from esophageal varices and treated with the SB tube, and in 29 of the 33 patients (88%) bleeding from gastric varices and treated with the LN tube (P = NS). Permanent hemostasis was observed in 72 of the 151 cases (47.7%), 59 of the 118 (50%) bleeding from esophageal varices and 13 of the 33 (39.3%) bleeding from gastric varices (P = NS)(Table 1). Thus hemorrhage recurred in 65 of 137 in whom balloon tamponade had been effective in controlling bleeding. In 27 of these 65 patient (41.6%), rebleeding occurred within the immediate 24 hr after deflation of the balloon, and in the 38 remaining patients (58.4%) the hemorrhage recurred at 4.5 ± 5.6 days.

The effectiveness of the procedure varied according to the degree of hypovolemia. Hemostasis was obtained in 82 of the 86 patients (94.4%) who required less than 1500 ml of transfusion to stabilize their hemodynamic parameters, but only in 55 of the 65 patients (84%) with more severe hypovolemia (P < 0.05). The effectiveness of treatment was not related to the degree of hepatic failure (Table 2).

In 14 patients bleeding was not controlled by tamponade. In seven of these patients the hemorrhage ceased after vasopressin infusion, in one by emergency sclerotherapy, and six required emergency surgery after unsuccessful vasopressin therapy.

Tolerance and Complications. Most patients found esophageal tamponade uncomfortable. Nineteen patients treated with the SB tube complained of chest pain; in seven cases pain was severe enough to need analgesia and in one case pain led to removal of the tube. Six of the 33 patients treated with the LN tube experienced epigastric or thoracic pain. Other minor complications observed in patients treated with the SB tube were in three cases an extensive alae nasi necrosis resulting from ex-

TABLE 1. RESULTS OF SB AND LN BALLOON TAMPONADE

	SB	LN	Total	
Number of episodes	118	33	151	
Primary hemostasis	108 (91.5%)	29 (88%)	137 (90.7%)	
Permanent hemostasis	59 (50%)	13 (39%)	72 (47.7%)	
Deaths	38 (32.2%)	12 (36.4%)	50 (38.1%)	

cessive pressure of the fixing device on the nose, and one patient suffered a transient airway occlusion when the SB tube slid upwards (Table 3).

The sole major complication of balloon tamponade was aspiration pneumonia which appeared in 12 patients treated with the SB tube (10%) and in three treated with the LN tube (9%). This complication appeared more frequently in patients with hepatic encephalopathy, 13 of 60 (20%), as compared to two of 91 patients (2%) without encephalopathy (P < 0.001). The deeper the encephalopathy, the higher the prevalence of aspiration pneumonia: 8% (2/26) in grade I, 25% (4/16) in grade II, 36% (4/11) in grade III, and 43% (3/7) in grade IV (P < 0.001). Among patients with deep encephalopathy (grades III-IV), aspiration pneumonia appeared in none of the five patients who were intubated prior to tamponade, but in seven of the 13 patients who were not (P = 0.05).

Survival. The overall mortality was 33%. Eleven deaths were a result of continuing hemorrhage. In seven patients, aspiration pneumonia related to esophageal tamponade was a contributory factor to death.

Factors affecting the outcome were control of bleeding, liver function, and degree of hypovolemia at the time of tamponade. Mortality increased from 29% (39 of 137) in patients with primary hemostasis to 79% (11 of 14) in those in whom bleeding was not controlled by tamponade (P < 0.001). Furthermore, only 11 of 72 patients (15%) with permanent hemostasis died, whereas 28 of the 65 who rebled (43%) died (P < 0.001). Another factor influencing the outcome was liver function, assessed on admission according to the Child-Campbell criteria; the death rate was 9% (4/45) in group A, 33% (23/70) in group B, and 77% (23/30) in group C (P < 0.001) (Table 2). Finally, mortality was 24% (21/86) in patients with mild hypovolemia (transfusion of less than 1500 ml), but 45% (28/65) in those with more severe hypovolemia (P < 0.005) (Table 2).

DISCUSSION

The medical management of gastrointestinal hemorrhage in patients with portal hypertension is based primarily on the use of vasoactive drugs, different forms of balloon tamponade, and endoscopic sclerotherapy. As discussed below, to date, there is no evidence demonstrating the superiority of any of these forms of therapy.

TABLE 2. INFLUENCE OF HYPOVOLEMIA AND HEPATIC FAILURE ON EFFECTIVENESS AND MORTALITY OF BALLOON TAMPONADE

	Hypovolemia			Child's group			
	Moderate	Severe	P	A	В	C	P
Number of episodes Primary hemostasis Permanent hemostasis Deaths	86 82 (94.4%) 45 (52.3%) 21 (24%)	65 55 (84%) 27 (41.5%) 29 (45%)	<0.05 NS <0.005	45 43 (95.6%) 26 (57.8%) 4 (8.9%)	76 69 (90.8%) 33 (43.4%) 23 (30.3%)	30 25 (83.3%) 13 (43.3%) 23 (76.7%)	NS NS <0.001*

^{*} χ^2 test with FD = 2.

With regard to esophageal tamponade, and despite the large experience accumulated with this procedure, the controversy about its usefulness continues. While some authors (8, 10, 18) have cast doubt upon its safety and effectiveness, others (3–7) consider it a valuable procedure. Our previous data (3) also suggested that esophageal tamponade is an effective and relatively safe method to arrest variceal bleeding temporarily, thus allowing the patients to be managed electively.

In the present study, control of bleeding was obtained in 92% of patients bleeding from esophageal varices treated with the SB tube and in 88% of the patients bleeding from gastric varices using the LN tube. These results are similar to those of Hunt et al (5), Johansen and Baden (6), and Novis et al (7), who achieved hemostasis in about 90% of their patients using the SB tube. By contrast, in the study of Chojkier and Conn (8) bleeding was controlled in only 40% of patients treated with the SB tube and in 33% of patients treated with the LN tube. This difference may be a result of their use of the SB and LN tubes independently of the site of the hemorrhage and the lack of endoscopic diagnosis in some of their patients, since hemostasis was obtained in 70% of those with an actively bleeding varix demonstrated at endoscopy, but only in 23% of those who were supposed to be bleeding from varices on clinical grounds only.

Unfortunately, esophageal tamponade is not a definitive hemostatic procedure and, as expected,

TABLE 3. COMPLICATIONS OF BALLOON TAMPONADE

Major			
Aspiration pneumonia	15 (10%)		
Minor			
Chest pain	25 (16.5%) 3 (2%)		
Alae nasi necrosis			
Transient airway occlusion	1 (0.7%)		
Total	44 (29.2%)		

about half the patients rebled when the tube was removed after having achieved primary hemostasis, a proportion similar to that reported by others (5–7). Since most patients rebleed within the first few days after the initial bleeding episode (19), it is suggested that definitive endoscopic or surgical therapy should be carried out soon after cessation of the hemorrhage.

Although most patients found tamponade uncomfortable, only 25 patients complained of chest pain, seven of whom needed analgesia, and only in one case did the SB tube have to be removed because of chest pain. Thus, in general, tolerance to tamponade was reasonably good. The major complication of balloon tamponade observed in this series was aspiration pneumonia, which appeared in 10% of the patients, and in seven cases (4.6%) was probably a contributory factor to death. In other series the incidence of aspiration into the airways ranges from 0 to 21% (6–10, 20). Our results clearly show that this complication is more frequent in patients with hepatic encephalopathy. Confirming the suggestion by Hunt et al (5), the present study indicates that orotracheal intubation before passing the tube markedly reduces aspiration accidents in patients with altered consciousness. No case of esophageal rupture, the most severe complication of tamponade, was observed in our group of patients. This relatively low incidence of complications probably reflects the advantage of treating these patients in special units under close monitoring by well-trained medical and nursing staff.

The overall mortality in this series was 33%. Factors affecting the outcome were effectiveness in controlling hemorrhage, severity of liver failure, and degree of hypovolemia at the time of instituting therapy. In other series the death rate ranges from the low of 20% reported by Hunt et al (5) up to the 90% mortality of Chojkier and Conn (8). The excessive mortality of this last study may be related to the fact that balloon tamponade was rarely the

initial form of treatment and also to the high blood transfusion requirements before tamponade, which in many patients was applied after unsuccessful vasopressin infusions. According to our results, high pretreatment transfusion requirements negatively influence both the effectiveness of and survival to balloon tamponade.

The efficacy and safety of balloon tamponade must be compared to those of other nonsurgical procedures proposed for active variceal bleeding, mainly vasopressin infusion and endoscopic sclerotherapy. Recently, Pinto-Correia et al (20) reported a controlled comparison of vasopressin infusion versus balloon tamponade for bleeding esophageal varices. Bleeding was controlled in 65% of patients receiving vasopressin, a proportion similar to that of other published series (14, 21, 22), and in 70% of patients treated by tamponade (P = NS). However, in their study, Pinto-Correia et al inflated first only the gastric balloon, which was kept under traction, while the esophageal balloon was inflated only if the esophageal aspirates continued to be blood-stained. This may lower tamponade effectiveness since the SB tube hemostasis is obtained better by direct compression at the bleeding point than by interruption of the submucosal venous flow of the gastric fundus (3).

Therefore, although there is no objective evidence favoring the use of tamponade over that of vasoconstrictive therapy, the current study suggests that control of bleeding can be achieved by balloon tamponade in a higher proportion of cases (90%), at least when tamponade is applied in the setting of an experienced special unit. It is hoped that the recently proposed modalities of pharmacologic therapy, such as somatostatin (22), glypressin (23), and the association of vasopressin and nitroglycerin (24), will compare more favorably with balloon tamponade in the future.

In a recently published investigation, Paquet and Feussner (25) compared endoscoic sclerosis and esophageal balloon tamponade in 43 patients with proven actively bleeding esophageal varices. No statistically significant differences were found between the two therapeutic groups with regard to primary control of hemorrhage. Significant differences favoring sclerotherapy were only found when the two treatments were compared in terms of definitive control of hemorrhage and in terms of 30-day mortality and long-term survival. These late results could easily be expected since patients in the tamponade group did not receive other therapy

after bleeding had been controlled, whereas patients in the sclerotherapy group had repeated sclerotherapy that was reassumed four months later if varices reappeared. In this work, tamponade achieved hemostasis in 16 of 22 patients (73%), a lower percentage than in our series. Availability of the technique is an important variable to be introduced in the comparison between tamponade and sclerotherapy. Sclerotherapy requires a qualified endoscopist available on a 24-hr basis, and it may be difficult to perform when hemorrhage is massive. The efficacy and safety of these two techniques in obtaining control of active variceal bleeding should be compared in terms of therapeutic strategies, ie, treating a group of patients with sclerotherapy and the other with esophageal tamponade followed by sclerotherapy after removing the tube.

ACKNOWLEDGMENTS

This work was supported in part by grants from the CAICYT, Nos. 1851/82 and 1853/82. The authors thank the physicians and nurses who helped in the care of the patients, and Eulàlia Ventura for secretarial assistance.

REFERENCES

- Sengstaken RW, Blakemore AH: Balloon tamponade for the control of hemorrhage from esophageal varices. Ann Surg 131:781-789, 1950
- Nachlas MM: A new triple lumen tube for the diagnosis and treatment of upper gastrointestinal hemorrhage. N Engl J Med 252:720-721, 1955
- Terés J, Cecilia A, Bordas JM, Rimola A, Bru C, Rodés J: Esophageal tamponade for bleeding varices. Controlled trial between the Sengstaken-Blakemore tube and the Linton-Nachlas tube. Gastroenterology 75:566-569, 1978
- Boyce HW: Modification of the Sengstaken-Blakemore balloon tube. N Engl J Med 267:195–196, 1960
- Hunt PS, Korman MG, Hansky J, Parkin WG: An 8-year prospective experience with balloon tamponade in emergency control of bleeding esophageal varices. Dig Dis Sci 27:413-416, 1982
- Johansen TS, Baden H: Reappraisal of the Sengstaken-Blakemore balloon tamponade for bleeding esophageal varices; results in 91 patients. Scand J Gastroenterol 8:181-183, 1973
- Novis BH, Duys P, Barbezat GO, Clain J, Bank S, Terblanche J: Fiberoptic endoscopy and the use of the Sengstaken tube in acute gastrointestinal haemorrhage in patients with portal hypertension and varices. Gut 17:258-263, 1976
- Chojkier M, Conn HO: Esophageal tamponade in the treatment of bleeding varices. A decadal progress report. Dig Dis Sci 25:267–272, 1980
- Mardomingo P, Cosme A, Muro J, Cano JM, Ortiz-Vazquez
 Utilidad de la sonda-balon de Sengstaken-Blakemore.

EFFICACY OF BALLOON TAMPONADE

- Estudio prospectivo. Rev Esp Enferm Apar Dig 49:283–298, 1973
- Conn HO, Simpson JA: Excessive mortality associated with balloon tamponade of bleeding varices. JAMA 202:587–591, 1967
- Pitcher JL: Safety and effectiveness of the modified Sengstaken-Blakemore tube: A prospective study. Gastroenterology 61:291–298, 1971
- 12. Herman RE, Traul D: Experience with the Sengstaken-Blakemore tube for bleeding esophageal varices. Surg Gynecol Obstet 130:879-885, 1970
- Bertrand L, Michel H: La sonde de Linton-Nachlas. Sa superiorité sur celle de Sengstaken-Blakemore pour le tamponement des varices oesogastriques chez le cirrhotique. Arch Fr Mal Appar Dig 58:797-816, 1969
- Merigan TC, Plotkin GR, Davidson CS: Effect of intravenously administered posterior pituitary extract on hemorrhage from bleeding esophageal varices. A controlled evaluation. N Engl J Med 266:134-135, 1962
- Johnston GW, Rodgers HW: A review of 15 years experience in the use of sclerotherapy in the control of acute haemorrhage from oesophageal varices. Br J Surg 60:797-800, 1973
- Rimola A, Bory F, Terés J, Pérez-Ayuso RM, Arroyo V, Rodés J: Oral nonabsorbable antibiotics prevent infection in cirrhosis with gastrointestinal hemorrhage. Hepatology 5:463-467, 1985
- 17. Campbell DP, Parker DE, Anagnostopoulos CE: Survival

- prediction in portocaval shunts: A computerized statistical analysis. Am J Surg 126:748-751, 1973
- Orloff MJA: Emergency portocaval shunt. Ann Surg 166:456–478, 1967
- 19. Graham DY, Smith JL: The course of patients following variceal hemorrhage. Gastroenterology 80:800-809, 1981
- Pinto-Correia J, Martins-Alves M, Alexcandrino P, Silveira J: Controlled trial of vasopressin and balloon tamponade in bleeding esophageal varices. Hepatology 4:885–88, 1984
- Johnson WC, Widrich WC, Ansell JE, Robbins AH, Nabseth DC: Control of bleeding varices by vasopressin. A prospective randomized study. Ann Surg 186:369–376, 1977
- Kravetz D, Bosch J, Terés J, Bruix J, Rimola A, Rodés J: Comparison of intravenous somatostatin and vasopressin infusions in the treatment of acute variceal hemorrhage. Hepatology 4:442-446, 1984
- Freeman JG, Cobden I, Lishman AH, Record CO: Controlled trial of Terlipressin (glypresin) versus vasopressin in the early treatment of oesophageal varices. Lancet 2:66-68, 1982
- Gimson AES, Westaby D, Hegarty J, Watson A, Williams R: A randomized trial of vasopressin and vasopressin plus nitroglycerin in the control of acute variceal hemorrhage. Hepatology 6:410-413, 1986
- Paquet KJ, Feussner H: Endoscopic sclerosis and esophageal balloon tamponade in acute hemorrhage from esophagogastric varices: A prospective controlled randomized trial. Hepatology 5:580-583, 1985