

## CONTROL OF ACUTE VARICEAL HAEMORRHAGE— A COMPARISON OF OCTEROTIDE AND BALLOON TEMPONADE

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*A multicenter prospective randomised control trial of patients with acute bleeding from oesophageal varices. Patients not fit for immediate sclerotherapy or band ligation because of severe torrential haemorrhage. This study was conducted at three centers of District Sialkot, i.e., Govt. Sardar Begum Hospital, Allama Iqbal Memorial Hospital, Memorial Christian Hospital from March 1999 to April 2002. The objective was to compare the efficacy and practicality of two commonly used techniques Octeriotide vs Balloon Temponade (BT) for the control of acute variceal haemorrhage. A total of 86 patients were studied in two groups, 46 in Balloon Temponade and 40 in Octeriotide infusion group. These patients presented with acute variceal bleeding. The diagnosis was confirmed by upper GI endoscopy. Stoppage of bleeding was achieved in 44 of 46 patients. Efficacy was 95.65% in Balloon group whereas this was achieved only in 37 of 40 patients. Efficacy was only 85% in Octeriotide group and in BT group complete stoppage of bleeding was seen in 40 (86.96%) whereas minor ooze present in 6 (13.04%) at the end of 12 hours. In octeriotide group 25 (62.50%) patients achieved complete stoppage of bleeding in (30%) and minor ooze was present, in 3 (7.5%). No effect on bleeding after 12 hours infusion at 50 µg/hour. Balloon Temponade is the only certain way to control acute profuse variceal haemorrhage. This technique is especially valuable during the transport of patients. The efficacy of octeriotide is limited only to minor/moderately severe cases of variceal bleeding or in combination with balloon temponade when patients are bleeding from gastric fundal varices or from portal hypertensive gastropathy.*

### INTRODUCTION

Bleeding oesophageal varices are the commonest cause of upper GI haemorrhage and accounts for 50 – 60 % of cases in Pakistan<sup>28</sup>, with a mortality rate of approximately 15-20% if not treated appropriately<sup>27</sup>. There are two well proven methods of treatment for actively bleeding oesophageal varices—one is sclerotherapy and the other is band ligation<sup>7,10,11,13-15</sup>, but these techniques may not be applicable in patient who are bleeding profusely as endoscopy vision is very poor, moreover the patients are haemodynamically unstable<sup>21</sup>. In these patients one needs the ways to stop or at least reduce the degree of bleeding so that definitive procedures of variceal treatment could be offered<sup>10,11</sup>.

The expert advice may not be available at the time of need; the patient may have to be transported to another center for a specialised treatment. In these situations one needs to gain time and look for means to stop bleeding even temporarily. There are two methods of controlling the variceal bleeding temporarily, one is time tested Balloon Temponade with Sengstaken-Blackemore tube the other is bolus of octeriotide followed by infusion.

The mechanism of Balloon Temponade is mechanical compression at the site of variceal bleeding but the tolerance of this procedure is generally thought to be poor. Although respiratory complications may develop<sup>20,21,28</sup>, the efficacy of this procedure is 100%<sup>20,22</sup>. During our study we found it well tolerated by our patients, as we have

only used nasal route for introducing SBT as compared to oral route which appears to be rather uncomfortable for the patients. There were no serious respiratory complications as we used continuous suction of oesophageal and gastric ports. This also gave us an idea about continued bleeding.

On the other hand the octeriotide works by reducing the blood flow into the varices by lowering the portal vein pressure<sup>24</sup>. A more potent and longer acting analogue of somatostatin having half life of 90 – 120 minutes in the plasma and more stable in the solution than naturally occurring somatostatin<sup>27</sup>. The efficacy is 85% in controlling acute variceal bleeding. The side effects especially cardiac are less frequent.

In our study the patients who were bleeding profusely and were not fit to undergo ligation / sclerotherapy, were studied in two matched groups. The aim of the study was to evaluate and compare the effectiveness of octeriotide infusion with balloon temponade in controlling acute severe variceal bleeding.

## PROCEDURE

Sengstaken-Blackmore four lumen tube (SBT) requires two/three assistants to place the tube. The tube is tested before introduction. It is stiffened with a metallic guide wire which if not available the tube can be placed in the icebox of refrigerator for 30 minutes to allow it stiffened. The lubricated tube is passed through nose/mouth (we prefer nose, as it is more comfortable for the patient and cause less retching once in the stomach). The stomach balloon is inflated with 250 ml of air by using 50 ml syringe. Then the tube is pulled back until resistance is encountered and oesophageal balloon is inflated to a pressure of 40 mm Hg greater than expected in the portal vein. The tube is secured to the side of face to provide skin traction. The traction has to be optimal. If necessary 500 ml of saline bag can be taped to the tube and hanged over the side of bed. As too little traction means that gastric balloon falls back into stomach too much and causes discomfort with retching and also potentiates gastroesophageal ulceration. The position of tube can be checked by X-rays. The head of bed is raised. The rebleeding rate following removal of the tube is high (50%),<sup>15,20,21</sup> therefore a definitive procedure like

sclero-therapy / ligation has to be planned immediately. We remove the tube in endoscopy room with preparation to proceed to a more definitive procedure. Regular suction of oesophageal and stomach ports decreased the aspiration complication of the procedure and also gives an idea of continued bleeding.

## PATIENTS AND METHODS

Patients presented with acute upper GI bleeding defined as haematemesis and malena from March 1999 to April 2002 were included in the study. The Inclusion criteria were (1) age between 20-70 years, (2) acute bleeding from oesophageal varices, (3) the cause of portal hypertension was cirrhosis. Acute oesophageal variceal bleeding was defined when blood was seen by endoscopy to issue from oesophageal varices (active bleeding).

The patients were excluded from the study, (1) if they did not show any blood coming from oesophageal varices, (2) history of asthma, or cardiac disease, (3) gastric varices being an active source of bleeding, (4) refused to participate in the trial or (5) patients with mild bleeding.

All patients were considered suitable for the trial, received resuscitation and nasogastric irrigation and underwent emergency endoscopy within 12 hours of admission. The standard therapy, included blood and frozen plasma transfusion, fluid and electrolytes replacement. All patients and or relatives signed consent forms.

At the time of enrollment, the severity of liver disease was classified according to Childs-Pugh classification<sup>30</sup>. The sizes of oesophageal varices were classified according to Beppu's criteria<sup>2</sup>.

All *P* values were 2-tailed. A *P* value of <0.05 was considered significant.

## RESULTS

During the study period, a total of 165 cirrhotic patients with acute variceal bleeding were encountered. A total of 79 patients were excluded because of not actively bleeding from oesophageal varices as they had an immediate band ligation / sclerotherapy (41). History of cardiac or respiratory disease (18). Bleeding from gastric varices (19) and refusal to participate (1) thus 86 patients were eligible for inclusion in our study.

The balloon temponade (BT) group comprised 46 patients and octeriotide group comprised of 40 patients. The characteristics of both groups are

shown in Table 1. Both groups were comparable in age, sex, cause of cirrhosis and severity of liver disease.

**Table 1:** Characteristics of Both Groups

	Balloon Temponade N = 46	Octeriotide group N=40	P value
Men/Women	28/28	26/16	NS
Age (years)	52 ± 12	51 ± 13	NS
Causes of Cirrhosis			
Alcoholism	01	0	NS
Hepatitis B	10	09	NS
Hepatitis C	31	28	NS
Hepatitis B+C	04	03	NS
Albumin (gm%)	3.5 ± 1.5	3.1 ± 1.2	NS
Bilirubin (mg%)	2.5 ± 2.1	2.7 ± 1.2	NS
Creatinine (mg%)	1.0 ± 0.5	1.0 ± 0.6	NS
Ascites present	23(50%)	19 (32%)	NS
Prothrombin time(S)	13.6 ± 4.3	13.2 ± 3.8	NS
Encephalopathy	2 (4.35%)	2 (5.0%)	NS
Child –Pugh Class			
A	15 (32.6%)	13 (32.5%)	NS
B	20 (43.48%)	15 (32.5%)	NS
C	11 (23.9%)	12 (30%)	NS
Previous Bleeding	08 (23.9%)	13 (32.5%)	NS
Haemoglobin(gm%)	9.1 ± 2.2	9.0 ± 2.5	0.05
Size of Varices			
F1/F2 ab	0/28	1/25	
F3 c	18	14	
F1 small varices(a)			
F2 medium varices(b)			
F3 large varices (c)			

**Table 2:** Result after 12 hours

Control of Bleeding	Balloon Temponade N=46	Octeriotide N=40	P value
Bleeding completely stopped	40 (86.96%)	25 (62.50%)	<0.05
Moderate Control	6 (13.05%)	12 (30%)	<0.05
No control	0	3 (7.50%)	<0.01

**Table 3:** Blood transfusion /plasma expander's requirements

	345-875 ml	895-1530 ml	<0.01
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**Table 4:** Complication resulting in termination of procedure

	3 (7.5%)	None	<0.01
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The two groups were evaluated on three points during and after 12 hours treatment study period. In BT group the Sengs-taken tube was placed and kept for 12 hours. It was removed and upper GI endoscopy performed for band ligation / sclerotherapy procedure. In Octeriotied group I/V bolous of 0.1 mg followed by continuous infusion at the rate of 50 ug/hour. Results noted during and after 12 hours at endoscopy.

1. Efficacy to control acute variceal bleeding.
2. Blood transfusion / plasma expander requirement.
3. Complication and patient tolerability of the procedure.

The efficacy to control bleeding was assessed and graded.

In our study BT group showed significant difference in comparison with octeriotide group in controlling acute oesophageal varices bleeding and generally our patients tolerated the procedure very well. Our results are comparable with studies carried out by others<sup>20,21,24,26</sup>. One study showed result of balloon temponade efficacy 90% (Panes<sup>26</sup>), but they included cases of gastric varices. In our study we excluded the patients of gastric varices and included only with active oesophageal varices bleeding. There were only 3 (7.5%) patients in whom the procedure had to be terminated due to pain, whereas two patients developed respiratory embarrassment. There was no serious complication of the procedure followed during our study. On endoscopy minor ulcerations were due to pressure effect of oesophageal/gastric balloon in nearly all patients. The octeriotide group patients only had minor side effects and were not severe enough to terminate the procedure.

## DISCUSSION

The use of Sengstaken tube has been decreased markedly since the introduction of vasoactive drugs, oesophageal sclerotherapy, band ligation and TIPS,<sup>7,10,11,13,14,18,24</sup> however in our study we found it very useful in *torrential bleeding* from oesophageal varices especially if the patient has to be transferred to another center. It has proved valuable even for gastric varices if these are located in near proximity of stomach balloon.

When the patient is bleeding profusely the endoscopic vision is very poor, moreover the

experienced endoscopic services may not be available in most of the centers. In this situation one needs an emergency measure to stop bleeding at least temporarily and gain time for a definitive procedure.

Most of the studies have shown result with balloon temponade similar to our observation. The efficacy of the procedure for bleeding oesophageal varices is nearly 100% with complication rate of about 5-10%<sup>20,21</sup>. The complication rate is linked with the experience of endoscopic team.

The complications are rather highlighted and general impression of the procedure being very unpleasant and uncomfortable. This is not our observation. Our patients tolerated the procedure well. Some studies have shown efficacy around 90%, but in these the continued bleeding was gastric fundal varices or from portal hypertensive gastropathy (Panes<sup>21</sup>).

*It may be stressed that the use of Sengstaken tube should not be given up.* In Pakistan the commonest cause of upper GI haemorrhage is variceal bleeding. The amount and speed of blood can be devastating therefore something has to be done immediately before an expert action is made available. Only a few units in our country are capable of providing 24 hours expert services, even in the units which are fully equipped, the need for balloon temponade arises very often.

The use of Temponade is *easy* and much *cheaper* as the tube can be reused many a time after sterilization in glutaraldehyde solution. On the other hand the octeriotide use may not be practical in our setup because people live mostly in rural population and expense involved is much more and to maintain the stocks and therefore refrigeration of the drug may not be possible.

The use of balloon temponade can be combined with vaso-active drugs if it alone is not effective in gastric varices or when bleeding / ooze is coming from portal hypertensive gastropathy.

## CONCLUSION

We conclude that Sengstaken tube has an important place. Its use is life saving in many situations as it is cheap, easy and more practical in our setup. It is nearly 100% effective in active oesophageal variceal bleeding and is also useful in gastric fundal variceal bleeding if located in near proximity of stomach balloon.

Its use can be combined with vasoactive drugs when alone it is not effective or when bleeding site is portal hypertensive gastropathy. The procedure should be made available at all emergency medical centers. The doctors dealing with emergency situations should be made familiar with the use of this procedure.

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