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Outcomes in variceal hemorrhage following the use of a balloon tamponade device

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Abstract

Background—Variceal hemorrhage is associated with high morbidity and mortality. A balloon tamponade device (BTD), such as the Sengstaken-Blakemore or Minnesota tube, may be used in cases of variceal hemorrhage. While these devices may be effective at controlling acute bleeding, the effect on patient outcomes remains less clear. We sought to describe the number of patients with variceal hemorrhage and a BTD who survive to discharge, survive to one-year, and develop complications related to a BTD.

Methods—In this retrospective study, we identified patients at a single, tertiary care center who underwent placement of a BTD for upper gastrointestinal hemorrhage between 2003 and 2014. Patient characteristics and outcomes were summarized using descriptive statistics.

Results—34 patients with a BTD were identified. Median age was 57.5 (IQR 47–63) and 76% (26/34) were male. Approximately 59% (20/34) of patients survived to discharge, and 41% (13/32) were alive after one year. Two patients were lost to follow-up. Of those surviving to discharge, 95% (19/20) had undergone transjugular intrahepatic portosystemic shunt (TIPS), while 36% (5/14) of patients who did not survive to discharge had TIPS ($p < 0.01$). One complication, an esophageal perforation, was identified and managed conservatively.

Conclusion—In this cohort of patients undergoing BTD placement for variceal hemorrhage, approximately 59% of patients were alive at discharge and 41% were alive after one year.

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Placement of a BTD as a temporizing measure in the management of acute variceal hemorrhage may be helpful, particularly when utilized as a bridge to more definitive therapy.

Keywords

Balloon tamponade device; Variceal hemorrhage; Transjugular intrahepatic portosystemic shunt; Tips; Sengstaken-Blakemore; Minnesota tube

1. Introduction

Acute hemorrhage from upper gastrointestinal varices is a common and fatal complication of cirrhosis [1-4]. Up to one third of patients with varices may develop variceal hemorrhage [5], which has a high morbidity and an estimated mortality of up to 20% [6-8]. Despite improvements in endoscopic and pharmacologic therapies being used for management of acute variceal bleeding [4,6,9,10], such treatments may not be able to control variceal hemorrhage in as many as 20% of patients [4, 11].

Balloon tamponade devices (BTD) have been available for management of acute variceal hemorrhage since 1950 [10,12,13]. In cases of uncontrollable bleeding a BTD may be placed as a temporizing measure for up to 24 h until definitive treatment, such as placement of a transjugular intrahepatic portosystemic shunt (TIPS) [4,11,14]. Effectiveness of BTDs to maintain hemostasis for at least 24 h has been reported to be between 80 and 91.5% [12,15]. However, with the development of new treatments, BTDs are now typically regarded only as salvage and their usage has decreased substantially in the last decades [10]. This decline may be attributed to the increasing availability of advanced endovascular therapy – namely, TIPS – as a way to modulate portal hypertension and reduce the risk of variceal bleeding [6]. The perception of low utility, coupled with the known risks such as gastric or esophageal erosion and perforation if misplaced or over-inflated, may further discourage clinicians from using BTDs [11,16,17]. However, there are few data available in the literature on the outcomes of patients with acute variceal hemorrhage who have a BTD placed during an episode of bleeding.

In this study, we sought to describe the number of patients with variceal hemorrhage who undergo placement of a BTD who (1) survive to hospital discharge, (2) survive to one-year following hospital discharge, and (3) develop complications related to BTD.

2. Methods

2.1. Design, setting and population

This retrospective chart review study was conducted at Beth Israel Deaconess Medical Center, an urban tertiary care center in Boston, Massachusetts. Based on 1CD-9 codes (96.06 and 96.07), we identified all adult patients (≥ 18 years old) with an upper gastrointestinal placement of a Sengstaken-Blakemore or Minnesota tube placement during hospitalization between 2003 and 2014. Once patients were identified, demographic information and clinical data were abstracted from the electronic medical record. Survival at one year was assessed using available electronic medical records as well as a query of the Social Security Death Index (SSD1). Two patients without verification of death using SSD1

or direct contact were lost to follow-up. MELD scores were calculated using the latest Organ Procurement and Transplantation Network's (OPTN) policy 9.1.D. The study was approved by the Institutional Review Board at Beth Israel Deaconess Medical Center.

2.2. Statistical analysis

Clinical characteristics and survival data were tabulated. Descriptive statistics were used to characterize the study population and to calculate rates of TIPS procedures, survival, and complications. Continuous data were compared with the Wilcoxon Rank-Sum Test and categorical data with the Fisher's Exact Test. Categorical variables are presented as counts with frequencies, and continuous variables as medians with quartiles. All calculations were completed using STATA, version 14.2 (College Station, TX, StataCorp LP, USA).

3. Results

We identified 34 instances of BTD placements. Two patients were lost to follow up after hospital discharge. In this cohort, 26 (76%) patients were male and the median age was 57.5 (IQR47–63) years. Additionally, 23 (68%) of the patients had an established diagnosis of cirrhosis at presentation with a median MELD score of 30 (IQR 24– 40), and 14 (41%) patients had a history of prior gastrointestinal bleeding. Esophagogastroduodenoscopy (EGD) for bleeding during the hospitalization was performed in 28 of the 34 patients (82%), with 15 documented endoscopic procedures, mostly banding or epinephrine injections of varices. BTDs were most often placed immediately after EGD due to failure to control bleeding. TIPS procedures were performed in 24 of the 34 patients (71%) during this hospitalization. Only one adverse event directly attributed to the BTD was identified; in this case, an esophageal perforation was treated conservatively and the patient was alive after one year. (See Table 1).

Of the 34 patients evaluated, 20 (59%) survived to hospital discharge, of which 19 patients (95%) had TIPS performed during that hospitalization. Of the patients who expired prior to hospital discharge, 5 out of 14 patients (36%) had TIPS performed ($p < 0.01$). Patients who expired prior to hospital discharge had significantly lower age ($p < 0.05$), a higher 1NR at BTD placement ($p < 0.01$) and had more total units of packed red blood cells (PRBCs) administered in hospital ($p < 0.01$) compared to survivors at hospital discharge. We found no significant difference in hematocrit (HCT) nadir at admission ($p = 0.24$) between the two groups. Additionally, one patient who did not survive to hospital discharge had BTD placement before angioembolization for a gastric variceal hemorrhage. (See Table 2).

Among those who survived to hospital discharge, one patient underwent liver transplantation several months after the episode of variceal hemorrhage. Thirteen of the 18 patients (72%) who survived until hospital discharge were still alive after one year. Patients who expired within one year from hospital discharge had a significantly higher INR at BTD placement ($p < 0.01$) compared to those who survived. We found no significant differences in age ($p = 0.92$), total PRBCs administered in hospital ($p = 0.20$) and HCT nadir at admission ($p = 0.77$). (See Table 3).

4. Discussion

In this retrospective cohort study of 34 patients who had a BTD placed for variceal hemorrhage, approximately 59% survived to hospital discharge and 41% were still alive after one year. Of those who survived to hospital discharge, 72% were still alive after one year. The higher than expected survival rate suggests that although a BTD has been considered a salvage measure to control bleeding in acute variceal hemorrhage [18], the utility of this procedure may be greater than what has previously been suggested.

Currently, BTDs are recommended only as a “bridge” to TIPS within 24 h in patients with uncontrollable acute variceal bleeding [4,11,14]. In our study 95% of those who survived to hospital discharge had TIPS performed compared to 36% in those who did not survive to hospital discharge. In fact, all of the 13 patients who were alive at one-year after hospital discharge had undergone a TIPS procedure during the hospitalization. A recent meta-analysis of nine randomized controlled trials involving 608 cirrhotic patients found that early TIPS placement significantly reduced one-year mortality (RR, 0.68; 95% CI, 0.49–0.96; $P = 0.03$) and one-year incidence of variceal re-bleeding (RR, 0.28; 95% CI, 0.20–0.40; $P < 0.001$) compared to endoscopic therapies [8]. While there has been a decrease in BTD usage over the past decades, evidence for early TIPS being superior to endoscopic treatment may lead to increased use of BTDs as a bridge to TIPS.

Major complications, such as esophageal/gastric erosion and rupture, are known risks related to the duration of BTD use and may influence a clinician's decision to utilize this intervention [19]. Additionally, BTD placement performed by inexperienced staff may account for higher frequency of major complications [20], suggesting that only experienced staff should perform the procedure [19]. While we do not have data on the experience level of our staff, only one patient out of 34 who had a BTD placed suffered a documented adverse event directly attributed to the device; in that case, a small esophageal perforation was identified and treated conservatively, and this patient was alive at one year after hospital discharge.

Our study was limited by the fact that it was retrospective in nature and the overall number of patients was small. Two patients without verification of death using the SSD1 or in the available medical records were considered lost to follow-up, however both were discharged with comfort-focused care orders and likely expired before one year, although this cannot be definitively determined. We were only able to evaluate patients who had received a BTD based on the appearance of the relevant 1CD-9 code in the medical record, so it is possible that some patients who received this therapy were not included. Additionally, almost all the patients had the BTD placed *after* EGD, and the optimal timing of the use of this device remains unknown. Lastly, patients who expired before hospital discharge had a significantly higher INR at the time of device placement and received a significantly higher number of blood transfusions, likely indicating a more severe state of hemorrhage.

In this retrospective cohort of patients undergoing BTD for variceal hemorrhage, 59% of patients survived to hospital discharge and 41% of patients survived to one year. As TIPS has been shown to be superior to endoscopic treatments in reducing one-year mortality

among patients with upper variceal bleeding, BTD placement may be a more useful temporizing measure than traditionally regarded, particularly when utilized to bridge patients to TIPS.

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Abbreviations

BTD	Balloon Tamponade Device
TIPS	Transjugular Intrahepatic Portosystemic Shunt
EGD	Esophagogastroduodenoscopy
PRBC	Packed Red Blood Cells
HCT	Hematocrit
INR	International Normalized Ratio

Table 1

Patient characteristics[a]

	Total cohort (*n* = 34)
Demographics	
Age (years)	57.5 (47–63)
Sex (male)	26 (76)
Race (white)	21 (62)
Past Medical History	
Known cirrhosis	23 (68)
MELD Score	30 (24–40)
Diabetes mellitus	13 (38)
Esophageal varices	20 (59)
Gastrointestinal bleeding	14 (41)
Interventions performed during hospitalization	
EGD	28 (82)
TIPS	24 (71)

[a]Categorical variables are presented as count (frequency) and continuous variables as median (interquartile range). Abbreviations are listed as EGD: Esophagogastroduodenoscopy, TIPS: Transjugular intrahepatic portosystemic shunt.

Table 2

Patient characteristics by survival status at hospital discharge[a]

	Survival at discharge (*n* = 20)	Expired while in hospital (*n* = 14)	*P*-value
Age (years)	62 (53.5-65.5)	50.5 (44-56)	< 0.05
INR on date of BTD placement	1.5 (1.4-1.75)	2.4 (2.2-2.9)	< 0.01
Total units of PBRCs administered in hospital	10 (8-16.5)	30 (14-46)	< 0.01
HCT nadir during admission	24 (22-26.1)	21.65 (20.4–24.9)	0.24
TIPS performed	19 (95)	5 (36)	< 0.01

[a]Categorical variables are presented as count (frequency) and continuous variables as median (interquartile range). Abbreviations are listed as PRBC: Packed red blood cells, HCT: Hematocrit, TIPS: Transjugular Intrahepatic Portosystemic Shunt, BTD: Balloon Tamponade Device, INR: International Normalized Ratio.

Table 3

Patient characteristics by survival status at one year from hospitalization[a]

	Survival at one year (*n* = 13)	Expired at one year (*n* = 19)	*P*-Value
Age (years)	60 (50-62)	54 (44-66)	0.92
INR on date of BTD placement	1.5 (1.5-1.6)	2.2 (1.7-2.8)	< 0.01
Total units of PBRCs administered in hospital	12 (9-16)	21 (8-43)	0.20
HCT nadir during admission	24 (22-26)	22.8 (21.0-26.4)	0.77
TIPS performed	13 (100)	9 (47)	< 0.01

[a]Categorical variables are presented as count (frequency) and continuous variables as median (interquartile range). Abbreviations are listed as PRBC: Packed red blood cells, HCT: Hematocrit, TIPS: Transjugular Intrahepatic Portosystemic Shunt, BTD: Balloon Tamponade Device, INR: International Normalized Ratio.