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ORIGINAL ARTICLE

Thrombocytopenia in Patients with Gastric Varices and the Effect of Balloon-occluded Retrograde Transvenous Obliteration on the Platelet Count

W. E. Saad, W. Bleibel[1], N. Adenaw, C. E. Wagner[2], C. Anderson, J. F. Angle, A. M. Al-Osaimi[3], M. G. Davies[4], S. Caldwell[3]

Departments of Radiology, [2]Surgery and [3]Medicine, University of Virginia, Virginia, [4]Department of Surgery, Methodist Hospital, Cornell-Weiel School of Medicine, Houston, Texas, [1]Department of Internal Medicine, Owensboro Health Gastroenterology and Hepatology, Kentucky, United States

Address for correspondence:
Prof. Wael EA Saad,
Director of Vascular and Interventional Radiology, Cardiovascular Center, RM 5588, 1500 East Medical Center Drive, Ann Arbor, Michigan-48109, US.
E-mail: wsaad@umich.edu

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ABSTRACT

Objectives: Gastric varices primarily occur in cirrhotic patients with portal hypertension and splenomegaly and thus are probably associated with thrombocytopenia. However, the prevalence and severity of thrombocytopenia are unknown in this clinical setting. Moreover, one-third of patients after balloon-occluded retrograde transvenous obliteration (BRTO) have aggravated splenomegaly, which potentially may cause worsening thrombocytopenia. The aim of the study is to determine the prevalence and degree of thrombocytopenia in patients with gastric varices associated with gastrorenal shunts undergoing BRTO, to determine the prognostic factors of survival after BRTO (platelet count included), and to assess the effect of BRTO on platelet count over a 1-year period. **Materials and Methods:** This is a retrospective review of 35 patients who underwent BRTO (March 2008–August 2011). Pre- and post-BRTO platelet counts were noted. Potential predictors of bleeding and survival (age, gender, liver disease etiology, platelet count, model for end stage liver disease [MELD]-score, presence of ascites or hepatocellular carcinoma) were analyzed (multivariate analysis). A total of 91% (n = 32/35) of patients had thrombocytopenia (<150,000 platelet/cm^3) pre-BRTO. Platelet counts at within 48-h, within 2 weeks and at 30-60 days intervals (up to 6 months) after BRTO were compared with the baseline pre-BRTO values. **Results:** 35 Patients with adequate platelet follow-up were found. A total of 92% and 17% of patients had a platelet count of <150,000/cm^3 and <50,000/cm^3, respectively. There was a trend for transient worsening of thrombocytopenia immediately (<48 h) after BRTO, however, this was not statistically significant. Platelet count was not a predictor of post-BRTO rebleeding or patient survival. However, MELD-score, albumin, international normalized ratio (INR), and etiology were predictors of rebleeding. **Conclusion:** Thrombocytopenia is very common (>90% of patients) in patients undergoing

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BRTO. However, BRTO (with occlusion of the gastrorenal shunt) has little effect on the platelet count. Long-term outcomes of BRTO for bleeding gastric varices using sodium tetradecyl sulfate in the USA are impressive with a 4-year variceal rebleed rate and transplant-free survival rate of 9% and 76%, respectively. Platelet count is not a predictor of higher rebleeding or patient survival after BRTO.

Key words: Balloon-occluded retrograde transvenous obliteration, bleeding, balloon-occlusion, gastric varices, platelet count

INTRODUCTION

Gastric varices have a high association (>80%) with spontaneous gastro-renal shunts in cirrhotic patients with portal hypertension.[1-5] Portal hypertension is associated with splenomegaly and thrombocytopenia.[6-9] The degree of thrombocytopenia is a reflection of the degree of portal hypertension and is associated with a higher risk of variceal bleeding.[6,7] Moreover, balloon-occluded retrograde transvenous obliteration (BRTO) of gastric varices is associated with worsening splenomegaly in greater than one-third of patients.[10,11] This increase in spleen size is probably because of the loss of the gastro-renal shunt, which, prior to the BRTO, acts as the outflow for the splenic venous outflow. Loss of the gastro-renal shunt due to BRTO potentially reduces the splenic outflow and causes engorgement of the spleen. This, hypothetically, may increase platelet sequestration and reduce the platelet count.

The aim of this study is to determine the prevalence of thrombocytopenia in patients with gastric varices associated with gastro-renal shunts and to evaluate the effect of BRTO on the platelet count. In addition, our aim was to determine if pre-BRTO platelet count is a predictor of post-BRTO hemorrhagic episodes (rebleeding rates) and patient survival.

MATERIALS AND METHODS

Study design and population studied

This is a retrospective study of consecutive adult patients undergoing BRTO for gastric varices from March 2008 to August 2011 (3.5 years) at a single academic center. Institutional review board approval was obtained. We used the electronic medical records to obtain patients' demographics and laboratory data. Patients with a prior transjugular intrahepatic portosystemic shunt (TIPS) and those undergoing a combined BRTO and TIPS procedure were excluded from the study. Technically failed BRTO procedures were excluded from the study. Patients without any laboratory follow-up data (platelet count) were excluded from the analysis evaluating the effect of BRTO on platelet count but were included in the evaluation of predictors of post-BRTO rebleeding and patient survival. Of the patients that were included, there was no patient who had undergone pre- or post-BRTO endoscopic guided prophylactic treatment directed at the gastric varices. A total of 44 consecutive patients undergoing BRTO were reviewed. Nine were excluded (7 had TIPS and 2 were BRTO technical failures) leaving 35 patients for the study purpose. Sixteen were female (43%) with a mean age of 57 years (range 23-83 years). Nine patients had nonalcoholic steatohepatosis, seven had alcohol and hepatitis C-related liver cirrhosis, seven had alcohol-related cirrhosis, four had hepatitis C cirrhosis, two had cryptogenic cirrhosis, two had cirrhosis due to autoimmune hepatitis, two had primary biliary cirrhosis, one patient had hemochromatosis-related liver cirrhosis, and one patient had cirrhosis-related to cystic fibrosis.

BRTO procedure

The BRTO procedure was performed in the standard trans-renal approach from a jugular or femoral access utilizing standard catheter techniques.[11-18] Occlusion of the gastrorenal shunt by balloon-occlusion catheters was followed by placement of a coaxial microcatheter in the gastric varices. The sclerosant utilized was 3% sotradecol (STS: Sodium Tetra-decyl Sulfate, Angiodynamics, Inc., Queensbury, NY) as mixed 1-part lipiodol, 2-parts 3% sotradecol, and 3-parts air.[19,20] Occlusion catheters were left inflated and in position for 4-36 h and then deflated.[19,20] Technical success of the BRTO procedure was considered when the gastro-renal shunt is successfully cannulated, balloon-occluded, and the sclerosant completely fills the gastric variceal system (gastric varices and gastrorenal shunt) in its entirety. Filling of the entire gastric variceal system was monitored by intraprocedural fluoroscopy and cone-beam rotational computer tomography (CT).

Thrombocytopenia and platelet count

Thrombocytopenia was defined as a platelet count less than 150,000/cm^3. The time-lapse before and after the BRTO procedure when the platelet counts were sampled was noted. Some variability was evident due to a lack of

standardized follow-up intervals (retrospective study). The post-BRTO platelet count was categorized into several time brackets as follows: 1-15, 15-30, 31-60, 61-90, 91-120, 121-150, 151-180, and >180 days after the BRTO procedure. Each missing patient's platelet count was curve fitted with the assumption that the missing value was a straight line between the two adjacent known platelet count values. Patients with no available platelet values at 180 days post-BRTO were excluded from the analysis of BRTO effect on platelet counts. Only missing platelet counts before the lapse of 180 days were curve fitted.

Statistical analysis

All demographic values, model for end stage liver disease (MELD) score values (and components), platelet count are presented as mean, median, and range with standard deviation. Similarly, the sampling dates for the platelet count pre- and immediately (within 2 weeks) post-BRTO was expressed as mean, median, and range with standard deviation. Comparison between all pre- and post-BRTO platelet values (in the different time brackets above) was by Mann–Whitney test. A multivariate Cox-proportional hazard analysis for post-BRTO upper gastro-intestinal bleeding and patient survival was used for age, gender, MELD score, serum bilirubin, creatinine, INR, platelet count (100,000 platelet/cm^3), presence of ascites and/or hepatocellular carcinoma at the time of the BRTO-procedure. A *P* value of less than 0.05 was considered statistically significant.

Kaplan–Meier method was used to measure the transplant-free patient survival, upper gastrointestinal rebleeding rate (from all upper gastrointestinal bleeding sources), and variceal rebleed rate (all variceal bleeding sources) after technically successful BRTO-procedures. All documented upper gastrointestinal bleeding sources including variceal bleeding (esophageal varices, gastric varices, duodenal varices, as well as other ectopic varices), portal hypertensive gastropathy, and peptic ulcer disease.

RESULTS

Forty-four consecutive patients underwent BRTO procedures in the 3.5-year study period. Seven patients had BRTO in the presence of a patent TIPS and thus were excluded from the study. Of the remaining 37 patients who underwent BRTO only (without a TIPS) 2 were technical failures (technical success of 95%, *n* = 35/37). The intent to treat (technical failures included) hemodynamic (obliterative) success rate was 89% (*n* = 33/37). All the 37 patients included had an index bleed within 30 days prior to the BRTO-procedure except 2 who had never bled but underwent BRTO for high-risk gastric varices (impending bleeding). All the 37 patients were hemodynamically stable without active bleeding at the time of the procedure, thus all the BRTO-procedures were performed on elective basis.

Of the 37 patients, 92% (*n* = 34/37) were thrombocytopenic (platelet count < 150,000/cm^3). Table 1 demonstrates the distribution of the 37 patients according to platelet count [Figure 1] of which 17% (*n* = 6/37) had severe thrombocytopenia (platelet count < 50,000/cm^3) [Table 1 and Figure 1]. Twenty-five patients had adequate post-BRTO follow-up platelet counts and were included in the detailed analysis of the effect of BRTO on platelet count. The results are shown in Table 2 and Figure 2. There was no statistically significant change in the platelet count over the 180-day-period after BRTO. However, there was a trend for a slight reduction in platelet count (*P* = 0.057, from 98,000+/-36,000/cm^3 to 79,000+/-27,000/cm^3) in the immediate post-BRTO period (within 2 weeks after the BRTO-procedure) [Table 2 and Figure 2]. The baseline platelet sample time was at a mean of 0.7 days +/-1.6 (median: 0 days, range: 0-7 days) prior to BRTO. The immediate (<14 days) post-BRTO platelet sample time was at a mean of 4.0 days +/-3.1 (median: 3 days, range: 1-14 days) post-BRTO. The last (labeled >180 days post-BRTO in Table 2) post-BRTO platelet sample time was at a mean of 450 days +/-176 (median: 430 days, range: 183-793 days) after BRTO.

Table 1: Platelet count pre-balloon-occluded retrograde transvenous obliteration in the 37 patients included in the study

Platelet count (per cm^3)	Number of patients	Percentage of patients
>150,000	3	9
125-149,000	4	11
100-124,000	5	14
75-99,000	14	40
50-74,000	3	9
25–49,000	6	17
<25,000	0	0

Table 2: Platelet count pre- and post-balloon-occluded retrograde transvenous obliteration based on time brackets after BRTO (values are in thousands/cm^3)

	Median	Mean	Standard deviation	Range	*P* value*
Pre-BRTO**	94	98	36	37-174	Baseline
Post-BRTO					
1-14 days***	79	79	27	32-153	0.057
15-30 days	90	91	32	33-160	0.505
31-60 days	92	96	38	34-208	0.716
61-90 days	93	98	38	35-190	0.883
91-120 days	96	102	39	36-182	0.931
121-150 days	100	102	39	36-182	0.789
151-180 days	101	105	42	30-183	0.670
>180 days****	101	110	45	38-238	0.432

P*-value is calculated utilizing the Mann-Whitney U test and compares with the pre-BRTO platelet count. **The platelet sample was obtained at a mean time of 0.7 days ±1.6 prior to the BRTO procedure (median: 0 days, range: 0-7 days prior to BRTO). * The platelet sample was obtained at a mean time of 4.0 days ±3.1 after the BRTO procedure (median: 3 days, range: 1-14 days after BRTO). ****The platelet sample was obtained at a mean time of 450 days ±176 (15 months) after the BRTO procedure (median: 430 days, range: 183-793 days after BRTO), BRTO: Balloon-occluded retrograde transvenous obliteration

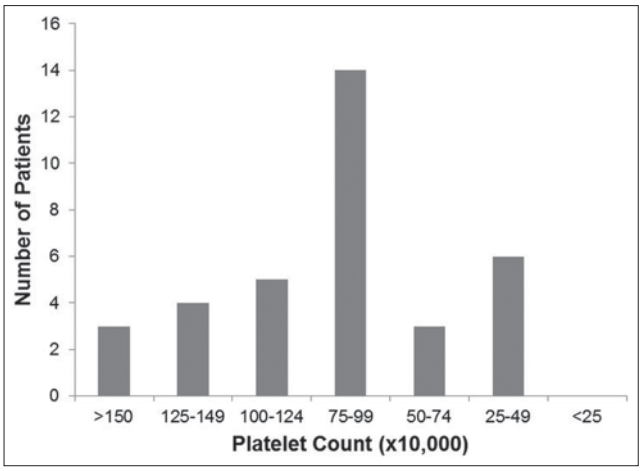

Figure 1: Histogram of the prevalence of thrombocytopenia and varying platelet counts in patients with gastric varices prior to undergoing BRTO.

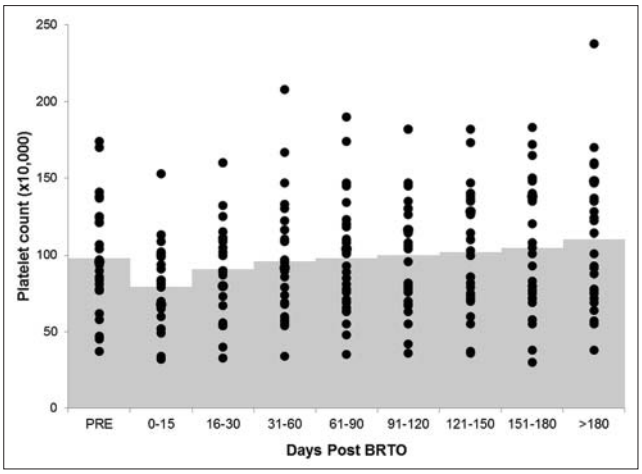

Figure 2: Histogram and scatter pattern (plot) of platelet counts in patients with gastric varices before and after the BRTO-procedure. The platelet count values after BRTO are along time brackets (time along the x-axis). The histogram column correlates and corresponds to mean platelet count values. The data points correspond to each given patient platelet value in that time bracket.

Table 3 demonstrates the results of the multivariate analysis for determining risk factors for developing post-BRTO bleeding (upper gastro-intestinal rebleeding) and post-BRTO patient survival. From the multivariate analysis we did not identify any predictors of patient survival [Table 3]. Predictors of post-BRTO rebleeding were only MELD-score, serum albumin, INR, and the combined etiology of alcohol and hepatitis C related liver cirrhosis [Table 3]. The baseline platelet count was not a predictor for either post-BRTO bleeding or patient survival. Table 4 shows the rebleed rate and transplant-free patient survival rate up to 4-years after the BRTO-procedure.

Seven patients experienced post-BRTO bleeding at a mean interval of 21.3 months (Range: 0.4-34 months) after BRTO. Among these patients, four experienced bleeding from portal hypertensive gastropathy and were treated conservatively. One patient bled from a duodenal peptic ulcer at 29 months post-BRTO and was treated with endoscopic clips. Another patient bled 23 months after the BRTO procedure with no clear source. This patient was considered as a gastric variceal rebleed. The seventh patient exhibited esophageal variceal bleeding 7 months after the BRTO procedure. This patient eventually succumbed to hepatic failure and coagulopathy.

DISCUSSION

Majority of patients with gastric varices are patients with portal hypertension with or without cirrhosis;[4-5] and thus have presumed splenomegaly. The high prevalence of portal hypertension and splenomegaly in the cirrhotic population would lead to a high prevalence of thrombocytopenia. Thrombocytopenia and platelet dysfunction are common in patients with cirrhosis. The decreased platelet count in this population is mainly attributable to pronounced platelet sequestration in the enlarged spleen. Reduced

Table 3: Predictors of rebleeding and patient survival after balloon-occluded retrograde transvenous obliteration of gastric varices (multivariate analysis)

	Risk for rebleeding			Risk for survival		
	P value	Hazard ratio	Standard deviation	*P* value	Hazard ratio	Standard deviation
Age above 65 years	0.202	1.72	0.06	0.963	0.05	0.18
Gender	0.965	0.002	0.0006	0.716	0.37	0.14
Etiology (Hep C + ETOH)	0.048	4.37	0.15	0.545	–0.61	0.08
Platelet count $<100,000/cm^3$	0.551	0.37	0.01	0.380	–0.9	0.18
MELD-score	0.044	4.54	0.16	0.758	0.31	0.23
Serum bilirubin	0.078	3.44	0.12	0.241	–1.2	0.08
INR	0.046	4.47	0.15	0.276	–1.12	0.46
Creatinine	0.273	1.26	0.04	0.123	–1.6	0.11
Serum Albumin	0.003	10.96	0.37	0.945	–0.07	0.20
Ascites at time of BRTO	0.483	0.51	0.02	0.383	0.85	0.15
HCC at time of BRTO	0.474	0.53	0.02	0.962	–0.89	0.25

Etiology (Hep C+ETOH): Viral Hepatitis C and ethanol abuse, MELD: Model for end-stage liver disease, INR: International normalized ratio, HCC: Hepatocellular carcinoma, BRTO: Balloon-occluded retrograde transvenous obliteration

Table 4: Kaplan-meier transplant-free patient survival and rebleed rate after technically successful balloon-occluded retrograde transvenous obliteration of gastric varices

	Transplant-free survival		All-cause rebleed rate		Variceal rebleed rate*	
	Rate (%)	95% CI	Rate (%)	95% CI	Rate (%)	95% CI
1 month	91	87-95	3	0-6	0	0-0
3 months	91	86-96	3	0-6	0	0-0
6 months	91	86-96	3	0-6	0	0-0
9 months	87	81-93	7	3-11	4	1-7
12 months (1 year)	84	78-90	7	2-12	4	1-7
18 months	76	68-84	7	2-12	4	1-7
24 months (2 years)	76	68-84	18	10-26	9	3-15
36 months (3 years)	76	65-87	47	35-59	9	1-17
48 months (4 years)	76	58-94	47	29-65	9	0-20

* Variceal rebleed rate includes esophageal varices, gastric varices, and/or duodenal varices. 95% CI: 95% Confidence interval

levels of liver derived thrombopoietin may further aggravate the thrombocytopenia in cirrhotic patients.[21,22]

The majority of patients with gastric varices have splenomegaly due to underlying cirrhotic or non-cirrhotic portal hypertension.[4,5] The exact incidence of thrombocytopenia in this particular population is unknown and would depend on spleen size and the severity of liver dysfunction among other factors. Our study confirms that thrombocytopenia is very prevalent (>90%) in this population with 17% of the patients in our cohort having severe thrombocytopenia (<50,000 platelets/cm^3).

BRTO obliterates the entire gastric variceal system (defined as the gastric varices and the draining portosystemic shunt: the gastro-renal shunt), thus the gastrorenal shunt is obliterated during the procedure.[23-25] This is the natural outflow of, at least part, of the spleen. In theory, obliteration of this gastro-renal shunt would presumably cause engorgement of the spleen (aggravating splenomegaly) and thus may lead to further platelet sequestration and worsening of the thrombocytopenia. Indeed, worsening splenomegaly after BRTO has been reported in excess of one-third of patients.[10,11] However, the effect of BRTO on the platelet count has not been studied. The current study shows that BRTO has no significant effect on the platelet count, although there was a trend for platelet count reduction ($P = 0.057$) within 14 days of the procedure [Table 2 and Figure 2]. This slight reduction, may be due to transient splenic engorgement, but also may be due to the hemolytic effect of the sclerosant used (3% sodium tetradecyl sulfate). In the long-term, the increased flow to the liver as a result of BRTO may increase thrombopoietin production from the liver, which compensates for the spleen engorgement. In other words, from a thrombocytopenia standpoint, the negative effect of BRTO on spleen size is nullified by the positive of liver function.

Platelet count has commonly been considered as a gauge of portal hypertension and surgical candidacy for cirrhotic patients.[6-9] Moreover, platelet count has an integral part in hemostasis in general and variceal bleeding to be specific. Hemostasis in liver disease is a complex process with many variables that are not well elucidated. This is due to the alternations in both pro- and anticoagulant factors in this patient population.[21,26] As a result, an evaluation of the pre-BRTO baseline platelet count as a predictor of both patient survival and rebleed rates after the BRTO-procedure was considered as an aim for this study. However, we could not find an association between lowered platelet counts (<100,000/cm^3) and patient survival or rebleeding post-BRTO. In fact, we could not detect any predictors of survival after BRTO. The study did, however, find that INR, MELD-score, serum albumin, and etiology of ethanol abuse and viral hepatitis C are predictors of post-BRTO upper gastrointestinal rebleeding.

The threshold for thrombocytopenia (platelet count <150,000/cm^3) is the standard definition for thrombocytopenia. However, over 90% of the population had a platelet count of less than 150,000/cm^3. Due to the small sample size, we chose a cutoff of 100,000/cm^3 to reach a comparative analysis. Further limitations to this study are its retrospective nature and its small sample size. Although 35 patients is not a small sample given the clinical nature of gastric varices it is statistically small. Moreover, the retrospective nature confined the platelet count sampling times to ranges because there was no set protocol (this is not a prospective and deliberate study but a retrospective audit of data).

The current study shows the impressive results of the BRTO procedure (utilizing 3% sodium tetradecyl sulfate) in controlling gastric variceal bleeding. The gastric variceal rebleed rate following successful BRTO is 4% at 12-18 months with an overall rebleed rate (regardless of source/etiology) of 7% at 12-18 months. Patient survival during the same time period (12-18 months post-BRTO) is approximately 80% (76-84%). The current authors believe that any mortality, worsening hepatic reserve, and bleeding from portal hypertensive gastropathy after 12-18 months is not related to the BRTO procedure or exacerbation of portal hypertension associated with BRTO, but is more likely due to the progression of liver disease and portal hypertension.

If the sample size had been larger, the findings (that are not significant in this study) may show a slight and transient reduction of platelet count within 10-14 days after the BRTO-procedure and then a gradual increase of the platelet count (above the pre-BRTO baseline count) over the next 6 months [Table 3]. We can only speculate that such a gradual increase in platelet count may be a reflection of increased hepatic volume, hepatic reserve, and the resultant increase in liver synthesized thrombopoietin. In the long-term, the increased flow to the liver as a result of BRTO may increase thrombopoietin production from the liver, which compensates for the spleen engorgement. In other words, from a thrombocytopenia standpoint, the negative effect of BRTO on spleen size is nullified by the positive of liver function.

CONCLUSION

In conclusion, thrombocytopenia is prevalent in patients with gastric varices undergoing BRTO-procedure (>90% of patients). However, the BRTO procedure has no effect on

the platelet count up to 6 months following the procedure. In particular, BRTO of gastric varices does not exacerbate thrombocytopenia. However, there is a trend of reduced platelet count, which is slight (not statistically significant) and transient not lasting more than 14 days following the BRTO-procedure. The baseline pre-BRTO platelet count (of less than 100,000 platelets/cm^3) is not a predictor of post-BRTO rebleeding or patient survival.

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