Real-Time Ultrasound-Guided Paracentesis by Radiologists: Near Zero Risk of Hemorrhage without Correction of Coagulopathy

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ABSTRACT

Purpose: To evaluate the rate and risk factors for hemorrhage in patients undergoing real-time, ultrasound-guided paracentesis by radiologists without correction of coagulopathy.

Materials and Methods: This was a retrospective study of all patients who underwent real-time, ultrasound-guided paracentesis at a single institution over a 2-year period. In total, 3116 paracentesis procedures were performed: 757 (24%) inpatients and 2,359 (76%) outpatients. Ninety-five percent of patients had a diagnosis of cirrhosis. Mean patient age was 56.6 years. Mean international normalized ratio (INR) was 1.6; INR was > 2 in 437 (14%) of cases. Mean platelet count was 122 x $10^3/\mu L$; platelet count was < 50 x $10^3/\mu L$ in 368 (12%) of patients. Seven hundred seven (23%) patients were dialysis dependent. Patients were followed for 2 weeks after paracentesis to assess for hemorrhage requiring transfusion or rescue angiogram/embolization. Univariate analysis was performed to determine risk factors for hemorrhage. Blood product and cost saving analysis were performed.

Results: Significant post-paracentesis hemorrhage occurred in 6 (0.19%) patients, and only 1 patient required an angiogram with embolization. No predictors of post-procedure bleeding were found, including INR and platelet count. Transfusion of 1125 units of fresh frozen plasma and 366 units of platelets were avoided, for a transfusion-associated cost savings of $816,000.

Conclusions: Without correction of coagulation abnormalities with prophylactic blood product transfusion, post-procedural hemorrhage is very rare when paracentesis is performed with real-time ultrasound guidance by radiologists.

ABBREVIATIONS

EMR = electronic medical record, FFP = fresh frozen plasma, INR = international normalized ratio, PRBC = packed red blood cell

Paracentesis is the most commonly performed procedure in patients with cirrhosis and is done for both diagnostic and therapeutic purposes. In 2014, it was the thirtieth most commonly performed inpatient procedure overall in the United States, with 174,825 procedures (1). In patients with tense ascites, a randomized controlled trial showed lower rates of hepatic encephalopathy, renal injury, and electrolyte abnormalities in hospitalized patients with ascites managed by paracentesis compared to diuretics (2).

While considered a very low-risk procedure, the most common major complication of paracentesis is hemorrhage. Previous estimates of post-paracentesis bleeding risk have ranged from 0% to 3% (3–9). No study has shown an association between low platelet count or increased international normalized ratio (INR) and bleeding risk. Despite this, many cirrhotic patients are transfused with fresh frozen plasma (FFP) and platelets prophylactically prior to paracentesis and other procedures (10,11). Blood product transfusions are costly and pose an added risk to the patient, including transfusion-associated complications, sepsis, and death (12–17).

A key factor in the variation in clinical practice is the discrepant state of widely used guidelines. The American

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Association for the Study of Liver Diseases guidelines have recommended against routine prophylactic blood product transfusion prior to paracentesis (Class C, Level 3 recommendation) (18). Conversely, current Society of Interventional Radiology (SIR) guidelines recommend transfusion of FFP for an INR > 2.0 and platelets for a platelet count $< 50 \times 10^3/\mu L$ (19). Prior studies have also varied in terms of the time period of the study, severity of liver disease, renal dysfunction, specialty, experience of the performing provider, inpatient versus outpatient setting, and use of ultrasound guidance.

The aim of this study was to determine the rate of hemorrhage after real-time, ultrasound-guided paracentesis when performed by a radiologist without the use of prophylactic blood product transfusions. Secondary aims included determining any risk factors associated with bleeding complications and an analysis of total blood product and transfusion-associated cost savings with a no-prophylactic-transfusion policy.

MATERIALS AND METHODS

Patients

After institutional review board approval, the electronic medical record (EMR) of all patients undergoing real-time, ultrasound-guided paracentesis in the radiology department of a single academic institution over a 2-year period from January 2016 to December 2017 were queried. The study population included both inpatient and outpatient procedures. Demographic and laboratory studies were collected: age at time of procedure, date of procedure, admission/discharge dates, hemoglobin, platelet count, INR, creatinine, bilirubin, need for dialysis, and ascites fluid studies when performed. For inpatients, volume of fluid removed was tabulated to allow for differentiation between diagnostic and therapeutic paracentesis. For inpatients, laboratory results from the day of the procedure were available. For outpatients, laboratory results closest to the time of the paracentesis were collected, as they were not routinely performed on the day of the procedure.

In total, 3116 paracentesis procedures were performed over the 2-year study period: 757 inpatients and 2,359 outpatients. There were 382 unique inpatients and 296 unique outpatients, most of whom underwent multiple procedures during the study period. Ninety-five percent of patients had a diagnosis of cirrhosis. Baseline demographic and laboratory parameters are included in Table 1. Mean age was 56.6 ± 13.2 years. Mean INR was 1.6 ± 0.6; INR was > 2 in 437 (14%) of cases. Mean platelet count was 121 ± 82 x $10^3/\mu L$; platelet count was < 50 x $10^3/\mu L$ in 368 (12%) patients. Seven hundred seven (23%) patients were dialysis dependent.

Table 1. Patient Characteristics and Laboratory Parameters (n = 123 patients)

Characteristic	Value
Age	56.6 ± 13.2
Hemoglobin (g/dL)	9.9 ± 2.0
Platelet count ($10^3/\mu L$)	121 ± 82
Platelet count ($10^3/\mu L$)	
< 50	368 (12)
≥ 50	2,749 (88)
INR	1.6 (0.6)
INR	
≤ 2	437 (14)
> 2	2,679 (86)
Creatinine (mg/dL)	2.0 ± 2.4
Dialysis dependent?	
Yes	707 (23)
No	2,409 (77)
Bilirubin (mg/dL)	3.5 ± 5.8
MELD score	18 ± 8

Note–Values mean ± standard deviation or number (%).
INR = international normalized ratio; MELD = Model for End-Stage Liver Disease.

Data Collection

For inpatients, any patient who received blood products or underwent an angiogram after paracentesis during the current hospitalization was recorded. For all patients, the EMR was also queried to identify any patient who was admitted, re-admitted, or presented to the emergency department within 2 weeks of paracentesis. This group included patients returning to the original institution or to any associated hospital in the health system throughout the region (23 additional hospitals in total). Patient charts for anyone who received blood products and who was admitted, re-admitted, presented to the emergency department, or underwent an angiogram were reviewed.

Paracentesis Procedure

The academic institution is a liver transplant center and performs a high volume of paracentesis procedures, 95% of which are done in patients with cirrhosis. The department has had a prophylactic transfusion policy for paracentesis for over 10 years, consistent with American Association for the Study of Liver Diseases guidelines. Prophylactic transfusion of blood products (FFP, platelets, cryoprecipitate, or desmopressin) were not given for any degree of abnormality in INR or platelet count. The radiologists performing the procedures were all board certified with at least 4 years of post-training experience.

At the institution, all outpatient procedures are performed in the radiology department. In the inpatient setting, approximately 90% of therapeutic paracentesis procedures are done by radiology. Diagnostic paracentesis procedures are typically attempted at the bedside first. Any patients deemed high risk or technically challenging (unsuccessful bedside procedure, large body habitus, or significant coagulopathy) are referred to radiology.

All paracentesis procedures were performed with real-time, ultrasound guidance. Color Doppler was used to ensure that no underlying vessels were present at the intended puncture site. The area was prepped and draped, and the needle tract was anesthetized. A 5-Fr multi-side-hole centesis catheter or a 16-gauge angiocatheter with added additional side-holes was used to access the abdominal cavity. In a minority of cases done with only diagnostic intent, a syringe with an attached 16-gauge needle was used for fluid sampling. The quantity and character of the fluid was documented in all reports.

To confirm compliance with the no-prophylactic-transfusion policy, the EMR was also queried to identify any patient who was admitted to the hospital from December 2016 to July 2017 who had a recorded diagnosis of cirrhosis and was transfused FFP during their hospitalization. These records were individually reviewed to determine the indication for FFP transfusion.

Statistical Analysis

The study sample was summarized by standard descriptive statistics. The Student *t*-test for continuous variables and the Fisher exact test for categorical variables were used to determine risk factors for post-ultrasound-guided abdominal paracentesis bleeding ($P < .05$ was considered significant). Analyses were performed using IBM SPSS Statistics for Windows software, version 23 (IBM Corp, Armonk, New York).

Blood Product and Transfusion-Related Cost Savings Analysis

All patients with an INR $>$ 2.0 were identified as patients who would have received FFP by current SIR guidelines. A previously validated formula was used to determine the number of units of FFP that would have been required for correction to an INR $\leq$ 2 (20). The cost of FFP was estimated at $400/unit based on a prior study of activity-based cost of transfusion (12). All patients with a platelet count $<$ 50 x 10^3/μL were similarly identified as patients who would have received a platelet transfusion. Total activity-based cost of platelet transfusion was estimated at $1000/transfusion, as reported in the literature (13).

RESULTS

Post-paracentesis hemorrhage requiring packed red blood cell (PRBC) transfusion occurred in 6 of 3116 (0.19%) patients (1 inpatient and 5 outpatients). Three patients received 1 unit, 2 patients received 2 units, and 1 patient received 5 units of PRBCs. Only 1 patient required an urgent angiogram with embolization of a bleeding abdominal wall vessel. Although the patient ultimately died during a 3-week hospitalization, he had also suffered extensive injuries and other complications associated with a motor vehicle accident. No patient died from paracentesis-related complications. Two other patients developed hemoperitoneum. One patient had evidence of bleeding a day after a cardiac catheterization related to inadvertently high access into the external iliac artery. Ultrasound-guided paracentesis had been performed 5 days prior. The second patient had undergone a recent transplant renal biopsy. A transperitoneal approach was required due to overlying bowel. Computed tomography findings at the time of recognition of bleeding were consistent with the biopsy as the etiology of the bleed, as there was bowel and fluid overlying the transplant kidney, with a small amount of layering fluid in the dependent right paracolic gutter. Therefore, bleeding was attributed to these other procedures.

Table 2. Univariate Analysis of Predictors of Hemorrhage

	No Bleeding Event n = 3110	Bleeding Event n = 6	*P* value
Hemoglobin (g/dL)	9.9 ± 2.0	9.8 ± 1.5	.9068
Platelet count (10^3/μL)	121 ±82	138 ± 63	.6234
Platelet count (10^3/μL)			1
$<$ 50	368 (12)	0 (0)	
$\geq$ 50	2,743 (88)	6 (100)	
INR	1.6 ± 0.6	2.0 ± 0.8	.1132
INR			.1992
$\leq$ 2	435 (14)	2 (33)	
$>$ 2	2,675 (86)	4 (67)	
Creatinine (mg/dL)	2.0 ± 2.4	2.3 ± 1.7	.8155
Dialysis?			.6239
Yes	705 (23)	2 (33)	
No	2,405 (77)	4 (67)	
Bilirubin (mg/dL)	3.5 ± 5.8	7.8 ± 10.4	.0656
MELD score	18 ± 8	24 ± 11	.0745
Paracentesis volume (L) (inpatients only)	3.6 ± 2.7	4.6	
$<$ 100 ml	23	0	
100 ml–999 ml	89	0	
1L–5 L	469	1	
$>$ 5 L	175	0	

Note–Values mean ± standard deviation or number (%).
INR = international normalized ratio; MELD = Model for End-Stage Liver Disease.

On univariate analysis (Table 2), no risk factors were identified that predicted post- paracentesis hemorrhage versus no hemorrhage, including platelet count (138 vs 121 × 10^3/μL, $P = .623$); INR (2.0 vs 1.6, $P = .113$); or need for dialysis (33% vs 23%, $P = .624$). No difference was observed in hemorrhage rates between inpatients and outpatients (0.13% vs 0.21%, $P = .999$).

Table 3 outlines characteristics of the 6 patients who had a bleeding complication. Two patients had INRs $>$ 2.0. None of the patients had platelet counts $<$ 50 × 10^3/μL. Patient 3, who had the most significant bleed requiring embolization, had an INR of 1.4, a platelet count of 234 × 10^3/μL, and creatinine of 1.7 mg/dL without dialysis dependence.

Table 3. Characteristics of Patients with Bleeding Event

	Hgb (g/dL)	Platelets ($\times 10^3$/μL)	INR	Creatinine (mg/dL)	Dialysis	Bilirubin (mg/dL)	MELD score	PRBCs	Angiogram
1	7.7	187	3.6	3.04	Yes	27.9	40	1	No
2	9.4	82	2.2	1.7	No	10	29	1	No
3	11.8	234	1.4	1.7	No	4.4	21	5	Yes
4	10	104	1.7	5.28	Yes	1.8	28	1	No
5	8.9	76	1.9	0.84	No	1.6	15	2	No
6	11.1	143	1.3	1	No	1.1	10	2	No

Hgb = hemoglobin; INR = international normalized ratio;
MELD = Model for End-Stage Liver Disease;
PRBCs = packed red blood cells.

Compliance with Transfusion Policy

Compliance with institutional policy of no prophylactic transfusions prior to ultrasound-guided paracentesis was very high. Only 2 cirrhotic patients over an 8-month period received FFP prior to a paracentesis. Over that period, 291 inpatient procedures were performed, equaling a compliance rate of 99.3%. Four patients with platelet counts $\leq 10 \times 10^3$/μL did receive a unit of single-donor platelets on the day of paracentesis. However, these transfusions were clinically indicated as standard prophylaxis against spontaneous hemorrhage in very severe thrombocytopenia.

Product and Transfusion-Associated Cost Savings Analysis

Two hundred forty-seven inpatients (33%) and 188 outpatients (8%) had an INR >2 and would have required FFP transfusion based on current SIR guidelines to obtain an INR ≤ 2. Total estimated product need ranged from 1 unit to 5 units. Total FFP need was 713 units in inpatients and 412 units in outpatients. This represented a savings of $450,000 over a 2-year period. One hundred thirty-one (17%) inpatients and 235 (8%) outpatients with a platelet count under 50 x 10^3/μL would have required transfusion. Therefore, 366 single-donor platelet transfusions were avoided. This represented a total savings of $366,000 over the study period.

DISCUSSION

The results of this study underscore the safety of ultrasound-guided paracentesis without prophylactic blood product transfusions to correct abnormal coagulation parameters. The rate of post-procedure hemorrhagic complications requiring PRBC transfusion or procedural intervention with angiogram/embolization was only 0.19%. No variables were found to be predictive of hemorrhagic complications, including INR, platelet count, degree of renal dysfunction, or inpatient versus outpatient status. Volume removed was also not predictive, although this was evaluated only in the inpatient group. The reported hemorrhage rate of 0.19% is identical to that found in a large series by Pache et al (6) of 4,729 inpatient paracentesis procedures (both ultrasound and non-ultrasound guided) performed over a 10-year period.

Abnormal coagulation parameters, including INR and platelet count, are commonly seen in cirrhotic patients and are referred to as coagulopathy of liver disease (21). These abnormalities were traditionally considered a hypocoaguable or high-risk bleeding state. However, multiple studies have shown that many other factors in the bleeding and clotting cascade are affected by abnormal synthetic liver function. Adequate hemostasis is maintained as the affected factors offset each other, termed rebalanced hemostasis (22,23). Primary hemostasis leads to the formation of a platelet plug, targeting mucocutaneous bleeding. It is driven by the number and function of platelets and the von Willebrand factor. While thrombocytopenia is common in cirrhosis, this is negated by the increased serum levels of von Willebrand factor. Secondary hemostasis most affects deep tissue bleeding. Multiple coagulation factors ultimately lead to the formation of a more durable fibrin plug on top of a platelet plug. Although low levels of factors II, VII, VIII, and X lead to an increase in INR and a pro-bleeding state, they are balanced by decreased production of inhibitors of clot formation such as protein C and S (24–26). Finally, alterations in the fibrinolysis pathway also occur in a proportional manner. Thromboelastography and rotational elastometry are 2 laboratory tests that provide a global assessment of all 3 phases of hemostasis and are increasingly being used in the management of coagulatopathy in cirrhotic patients. In most patients with cirrhosis, these tests are normal, which is consistent with rebalanced hemostasis (27).

No study has shown that increased INR or decreased platelet count leads to higher bleeding rates. Likewise, FFP and platelet transfusions have never been shown to decrease bleeding rates for paracentesis. One study found that low fibrinogen was a risk factor for post-paracentesis bleeding in hospitalized patients with acute-on-chronic liver failure (9). However, there are some questions regarding the study, as the overall bleeding rate of 3% was significantly higher than in any other series. Also, ultrasound guidance was not routinely used. Two smaller studies showed an association between bleeding and renal dysfunction; however, one of

the studies included both paracentesis and thoracentesis (28,29).

The blood product and transfusion-associated cost savings analysis demonstrated a compelling savings by following a no-transfusion policy. This was more pronounced in the inpatient setting considering the worse liver function in these patients. For the entire study population, transfusions of FFP and platelets were avoided in 435 (14%) patients and 366 patients (12%), respectively, for a total cost savings of $816,000 over a 2-year period at 1 institution. This analysis does not account for the significant patient risk that could result in other complications, costs, and resource-associated transfusions and management of transfusion-related complications (30). They can decrease the efficiency of a radiology department and likely increase outpatient procedure times and increase length of stay for inpatients, as has been seen in multiple studies of surgical patients (30,31).

A strength of this study is that it is specific to procedures performed by radiologists with real-time, ultrasound guidance. In the study by Pache et al (6), paracentesis was performed by either radiologists, hepatologists or residents with or without ultrasound guidance. In the next-largest study, 1100 outpatient procedures were performed by physician extenders (5). Since it is frequent practice for the highest-risk patients to be sent to radiology to use ultrasound guidance, these other studies could have underestimated bleeding risk. This study also included both inpatients and outpatients with a wide spectrum of disease severity, coagulopathy, and renal dysfunction. Furthermore, a large study population allows for more accurate analysis of rare events. Despite the large study population size, the event rate was extremely low. These strengths lead to excellent generalizability of the findings.

The present study had multiple limitations. Limiting bias was attempted by including all paracentesis procedures performed. Although this did increase the heterogeneity of the study population, it is difficult to predict, for example, whether a technically challenging diagnostic paracentesis in the setting of minimal ascites would be a lower-risk procedure. Most patients had cirrhosis and underwent a paracentesis with therapeutic intent. No correlation was found between bleeding risk and volume removed. The study was also retrospective in nature. Patient capture was based on query of the EMR for diagnosis and procedure codes. These records could have been incomplete or inaccurate. Likewise, patients could have presented to other hospitals with bleeding events, which would not have been identified. This is unlikely to be a major factor, however, as hospital records for re-admissions or emergency department visits from multiple hospitals in the region were reviewed. Also, minor bleeding events were possible since the search was limited to patients receiving PRBCs, requiring hospital/emergency room evaluation, or requiring extra procedures. The SIR classification system defines PRBC transfusion itself as a moderate-severity adverse event, so adverse events of moderate or severe severity were included (32). Finally, as there were so few bleeding events, the statistical power of the risk factor analysis was reduced. However, unidentified risk factors would be of questionable clinical significance with such a low event rate.

In conclusion, post-paracentesis hemorrhage is very rare when the procedure is performed by radiologists with real-time, ultrasound guidance and without the use of blood product transfusions to correct coagulation abnormalities. A no-prophylactic-transfusion policy leads to avoidance of unnecessary risks to the patient and to significant cost, time, and resource savings.

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Smile!
Scott Trerotola, MD

Taken at East End, St. John, United States Virgin Islands, in the wake of Hurricanes Irma and Maria. Hurricane Irma struck St. John as a Category 5 and remains one of the strongest hurricanes on record. A week later, Hurricane Maria struck the Virgin Islands, also as a Category 5. A few months later, as the island began to recover, this pod of dolphins seemed oblivious to the destruction above.