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Correction of abnormal coagulation parameters as prophylaxis for post-procedural bleeding is unnecessary prior to ultrasound-guided thoracentesis

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ABSTRACT A critical appraisal and clinical application of Hibbert RM, Atwell TD, Lekah A, et al. Safety of ultrasound-guided thoracentesis in patients with abnormal preprocedural coagulation parameters. *Chest*. 2013;144(2):456-463. doi: [10.1378/chest.12-2374](https://doi.org/10.1378/chest.12-2374).

Keywords: *ultrasound-guided thoracentesis, coagulation, transfusion*

Clinical Context

KM is a 36-year-old Caucasian female on a general inpatient unit with liver cirrhosis who presented to the emergency department with shortness of breath, orthopnea, and anasarca. On admission one month ago, chest x-ray and lab work demonstrated right-sided transudative pleural effusion consistent with hepatic hydrothorax. During this admission, chest x-ray demonstrates enlargement of hepatic hydrothorax with collapse of the lung lobes. Lab values (serum creatinine 1.02 mg/dL, serum total bilirubin 17.1 mg/dL, international normalized ratio (INR) 2.54, serum sodium 123 mmol/L) contribute to a Model for End-stage Liver Disease (MELD) score of 28 and MELDNa score of 32. Complete blood count indicates a platelet count of 109,000/uL and hemoglobin of 8.0 g/dL. Therapeutic thoracentesis is deemed necessary to relieve increasing dyspnea, however, interventional radiology refuses to perform the procedure without correction of the patient's elevated INR.

Clinical Question

Does elevated INR in end-stage liver disease require correction with fresh frozen plasma (FFP) as prophylaxis for post-procedural bleeding prior to therapeutic thoracentesis?

Research Article

Hibbert RM, Atwell TD, Lekah A, et al. Safety of ultrasound-guided thoracentesis in patients with abnormal preprocedural coagulation parameters. *Chest*. 2013;144(2):456-463. doi: [10.1378/chest.12-2374](https://doi.org/10.1378/chest.12-2374)

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Related Literature

Literature review performed in the PubMed database utilizing the search terms “coagulopathy thoracentesis safety,” produced four results, including the article selected for this critical appraisal. Literature review was expanded using the Google Scholar database. Search there produced 3,250 results. Several review articles published in the early 2000s identified the clinical question addressed in this paper as a topic requiring further research, which prompted the author to focus on articles published since 2010. These criteria identified 16 articles applicable to the clinical question within the first 200 results, sorted by relevance; these included one prospective observational cohort study, two retrospective cohort studies, one randomized clinical trial (RCT), one current opinion piece, one consensus guideline, and seven review articles. Amongst the current opinion piece, consensus guideline, and review articles, authors concluded correction of coagulation abnormalities prior to thoracentesis is either unnecessary or a clinical question requiring further research.²⁻¹⁰

The Puchalski et al. prospective observational cohort study evaluated 312 patients who underwent thoracentesis categorized by bleeding risk. Those with increased bleeding risk (42%) had no difference in post-procedural hematocrit or bleeding events compared with patients who had normal bleeding risk.¹¹ The Patel retrospective cohort study evaluated 1,076 thoracentesis procedures categorized by pre-procedural INR and platelet count. Post-procedural complications did not differ between those with normal and abnormal coagulation profiles.¹² These two articles are inferior because they do not investigate the effect of correcting abnormal coagulation in patients with increased bleeding risk.

The Warner retrospective cohort study evaluated 1,803 interventional radiology procedures with pre-procedural elevated INR. Patients receiving prophylactic FFP (10.9 percent) experienced higher blood transfusion and post-procedural intensive care unit (ICU) admission rates compared with patients not receiving transfusion.¹³ The Müller RCT investigated the effect of FFP transfusion on post-invasive procedure bleeding rates among 81 coagulopathic non-bleeding ICU patients. Patients not receiving FFP had no difference in post-procedural bleeding events compared with patients receiving FFP.¹⁴ Both of these studies are inferior because they included all interventional radiology procedures with few subjects receiving thoracentesis: one patient in the Warner study and zero in the Müller trial (19 patients underwent chest tube placement). Furthermore, the Müller RCT did not have sufficient enrollment to demonstrate similar post-operative bleeding rates regardless of pre-procedure FFP administration. The study design required 200 patients per treatment, but slow enrollment led to termination with only 81 total subjects.

This critical appraisal focuses on the Hibbert et al. retrospective cohort study. It was selected because it provides the highest quality evidence available regarding correction of abnormal coagulation parameters prior to thoracentesis. As previously discussed, the best available RCT – typically the preferred evidence source due to decreased bias – is the Müller study that has design flaws and does not match the clinical scenario presented. Furthermore, the Hibbert et al. article is superior to other cohort studies because it focuses solely on thoracentesis and includes the largest number of participants who underwent thoracentesis.

Critical Appraisal

The Hibbert et al. study fulfills Strength of Recommendation Taxonomy (SORT) criteria for level 2 evidence. It contributes to the larger body of evidence that provides B strength clinical recommendation for peri-procedural management of abnormal coagulation parameters. This means that with relation to correction of abnormal coagulation parameters prior to thoracentesis there is still room for future good quality studies and RCTs that can further validate the findings of this study.

In this study, patients were identified in the electronic medical record. After excluding patients not authorized for research studies, 1,009 procedures amongst 773 patients remained. Inclusion criteria were: age 18 years or older; elevated INR greater than 1.6, thrombocytopenia less than 50,000/uL or both; and ultrasound-guided thoracentesis performed by an experienced radiologist, supervised radiology resident, or ultrasound imaging fellow. Subjects were categorized into two cohorts, those who did not undergo correction of abnormal coagulation parameters prior to thoracentesis (group 1) and those who received FFP or platelet transfusion (group 2). The primary outcome of interest was post-procedural hemorrhagic complication, defined using the National Institutes of Health Common Technology Criteria for Adverse Events, reported at the research institution in a patient’s discharge summary or within the first 10 days following thoracentesis. Grade 1 hematomas and isolated declines in serum hemoglobin were not included as complications. This is reasonable because both are acceptable adverse effects from thoracentesis and do not warrant clinical intervention. Importantly, this protocol may have failed to identify all complications. If a patient presented with a hemorrhagic



complication outside the research institution it was not reported. Similarly, hemorrhagic complication occurring more than 10 days following thoracentesis may have been missed. That being said, it's unlikely a statistically significant number of complications were excluded.

Patients receiving FFP transfusion were statistically younger with a lower platelet count (154,000/uL vs 216,000/uL), higher INR (1.9 vs 1.8), and lower hemoglobin (9.7 g/dL vs 10.8 g/dL) before thoracentesis. This does not change the standard of care the groups should receive. No difference in hemoglobin change, procedure location, or volume removed was noted. Four hemorrhagic complications occurred, all in patients receiving pre-procedural transfusion. The hemorrhagic complication rates were 0% and 1.32% for groups 1 and 2, respectively, corresponding to a number needed to harm (NNH) of 76 patients. 543 of the 773 patients experienced an average drop in hemoglobin of 0.8 mg/dL. The rate of hemoglobin drop was 78% and 77% in groups 1 and 2, respectively, corresponding to a NNH of 100 patients. Of note, the differences in complication rate and hemoglobin drop rate were not statistically significant between the groups.

The retrospective cohort study design introduced several sources of bias. First, participants were not randomized to treatment groups leaving correction of abnormal coagulation values to the discretion of clinicians. This likely explains the baseline differences between the two groups: patients receiving preprocedural correction were likely perceived as clinically sicker. This could also explain why group 2 subjects were the only patients that experienced hemorrhagic complications. Furthermore, this design eliminates the possibility of blinding. This introduces the risk of detection bias; it's possible that clinicians correcting abnormal coagulation parameters evaluated patients more vigilantly for complications. Also, the study design prohibits equal treatment of subjects because protocol was developed after treatment. On the other hand, this study design eliminates concern for attrition bias and per-protocol bias because all subjects were included in analysis. Finally, no third parties sponsored this study, eliminating the risk of funding bias.

It is important to the clinical application of this study that all thoracenteses were performed by an unspecified number of physicians from the radiology department with varying skill levels that may have affected complication rates. In contrast, the clinical scenario in this appraisal was on an inpatient general practice unit where internal medicine residents perform thoracentesis procedures. With that in consideration, the internal medicine residents who perform thoracentesis use ultrasound to guide the procedure and are certified to perform the procedure. Therefore, they are equally qualified to perform a routine thoracentesis.

Another important consideration is the similarity of this study population to the patient in the clinical scenario. The Hibbert et al. article did not include underlying medical conditions, making it difficult to determine if the study patients are healthier or sicker than a 36-year-old female with a MELDNa score of 32. Her INR of 2.54 is higher than the study average, her hemoglobin of 8.0 mg/dL is lower than the study average, and her platelet count of 109,000/uL is lower than the study average. This suggests she may be sicker, however, all three are within two standard deviations of the study mean and her younger age makes her more resilient to invasive procedures.

Clinical Application

This study concludes that correction of abnormal coagulation parameters prior to thoracentesis has no effect on hemorrhagic complications and is an unnecessary prerequisite. Statistically equivalent complication rates support this conclusion. Thus, patients with abnormal coagulation parameters can benefit from expedited thoracentesis without concern for increased bleeding risk. However, clinicians should still apply clinical judgement and verify that thoracenteses are ultrasound-guided or performed by certified individuals. Failure to do so may put patients at increased risk of hemorrhagic complication.

The patient in the clinical scenario met the inclusion criteria of the Hibbert et al. study. Her shortness of breath worsened, and she requested therapeutic thoracentesis despite aversion to needles from a previous thoracentesis. Results of the Hibbert et al. study, as well as the various review articles that address this topic were discussed with the patient and her clinical team recommended thoracentesis without waiting for correction of elevated INR. The patient accepted this as the safe and timely intervention to relieve worsening dyspnea, and ultrasound-guided thoracentesis was performed without complication.



Take-home points:

1. Literature review enabled the clinical team to relieve this patient of bothersome dyspnea secondary to hepatic hydrothorax in a timely manner by avoiding correction of an abnormal coagulation profile prior to thoracentesis.
2. Given the body of evidence discussed in this paper, I will elect to not correct my future patients' abnormal coagulation profiles before thoracentesis, as it is an unnecessary prerequisite to intervention.
3. Most importantly, I want my colleagues to know that preprocedural correction of coagulation abnormalities has no impact on hemorrhagic complications following thoracentesis and delays treatment.

References

1. Hibbert RM, Atwell TD, Lekah A, et al. Safety of ultrasound-guided thoracentesis in patients with abnormal preprocedural coagulation parameters. *Chest.* 2013;144(2):456-463. doi: [10.1378/chest.12-2374](https://doi.org/10.1378/chest.12-2374)
2. Atwell TD, Wennberg PW, McMenemy BP, et al. Peri-procedural use of anticoagulants in radiology: an evidence-based review. *Abdominal Radiology.* 2017;42(5):1556-1565. doi: [10.1007/s00261-016-1027-x](https://doi.org/10.1007/s00261-016-1027-x)
3. Desborough M, Stanworth S. Plasma transfusion for bedside, radiologically guided, and operating room invasive procedures. *Transfusion.* 2012;52:20S-29S. doi: [10.1111/j.1537-2995.2012.03691.x](https://doi.org/10.1111/j.1537-2995.2012.03691.x)
4. Hogshire LC, Patel MS, Rivera E, Carson JL. Evidence Review: Peri-procedural Use of Blood Products. *Journal of Hospital Medicine.* 2013;8(11):647-652. doi: [10.1002/jhm.2089](https://doi.org/10.1002/jhm.2089)
5. Muller MCA, Stanworth SJ, Coppens M, Juffermans NP. Recognition and management of hemostatic disorders in critically ill patients needing to undergo an invasive procedure. *Transfusion Medicine Reviews.* 2017;31(4):223-229. doi: [10.1016/j.tmr.2017.05.008](https://doi.org/10.1016/j.tmr.2017.05.008)
6. Patel IJ, Davidson JC, Nikolic B, et al. Consensus guidelines for peri-procedural management of coagulation status and hemostasis risk in percutaneous image-guided interventions. *Journal of Vascular and Interventional Radiology.* 2012;23(6):727-736. doi: [10.1016/j.jvir.2012.02.012](https://doi.org/10.1016/j.jvir.2012.02.012)
7. Pathak V, Allender JE, Grant MW. Management of anticoagulant and antiplatelet therapy in patients undergoing interventional pulmonary procedures. *European Respiratory Review.* 2017;26(145). doi: [10.1183/16000617.0020-2017](https://doi.org/10.1183/16000617.0020-2017)
8. Potze W, Porte RJ, Lisman T. Management of coagulation abnormalities in liver disease. *Expert Review of Gastroenterology & Hepatology.* 2015;9(1):103-114. doi: [10.1586/17474124.2014.934673](https://doi.org/10.1586/17474124.2014.934673)
9. Puchalski J. Thoracentesis and the risks for bleeding: a new era. *Current Opinion in Pulmonary Medicine.* 2014;20(4):377-384. doi: [10.1097/mcp.0000000000000062](https://doi.org/10.1097/mcp.0000000000000062)
10. Wiltrout C, Kondo KL. Correction of Coagulopathy for Percutaneous Interventions. *Seminars in Interventional Radiology.* 2010;27(4):338-347. doi: [10.1055/s-0030-1267857](https://doi.org/10.1055/s-0030-1267857)
11. Puchalski JT, Argento AC, Murphy TE, Araujo KLB, Pisani MA. The safety of thoracentesis in patients with uncorrected bleeding risk. *Annals of the American Thoracic Society.* 2013;10(4):336-341. doi: [10.1513/AnnalsATS.201210-088OC](https://doi.org/10.1513/AnnalsATS.201210-088OC)
12. Patel MD, Joshi SD. Abnormal preprocedural international normalized ratio and platelet counts are not associated with increased bleeding complications after ultrasound-guided thoracentesis. *American Journal of Roentgenology.* 2011;197(1):W164-W168. doi: [10.2214/ajr.10.5589](https://doi.org/10.2214/ajr.10.5589)
13. Warner MA. Prophylactic plasma transfusion before interventional radiology procedures is not associated with reduced bleeding complications. *Mayo Clinic Proceedings.* 2016;91(8):1045-1055. doi: [10.1016/j.mayocp.2016.05.010](https://doi.org/10.1016/j.mayocp.2016.05.010)
14. Muller MC, Arbous MS, Spoelstra-de Man AM, et al. Transfusion of fresh-frozen plasma in critically ill patients with a coagulopathy before invasive procedures: a randomized clinical trial. *Transfusion.* 2015;55(1):26-35. doi: [10.1111/trf.12750](https://doi.org/10.1111/trf.12750)

