



CHECK AND CORRECT? ASSESSING THE SAFETY OF THORACENTESIS OR TUBE THORACOSTOMY FOR PATIENTS WITH UNCORRECTED BLEEDING TENDENCIES



THE CLINICAL QUESTION

Is it safe to perform a thoracentesis or tube thoracostomy in patients with uncorrected coagulopathy, thrombocytopenia, or platelet dysfunction?

STUDY CONCLUSION

Among patients with uncorrected coagulopathy/thrombocytopenia and those receiving antiplatelets or anticoagulants who underwent thoracentesis or tube thoracostomy, major bleeding and mortality complications were uncommon (pooled risk of major bleeding and mortality was 0% [95% CI 0-1%]).

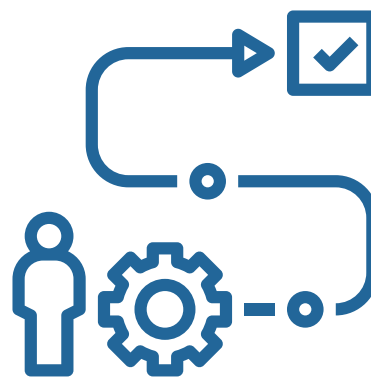


STUDY BACKGROUND

Patients needing pleural procedures often have one or more risk factors for bleeding (Puchalski et al., 2013). Anatomical variation in vascular structures (such as the intercostal arteries) pose an increased theoretical bleeding risk for pleural procedures (Helm, 2013). Previously reported risks of bleeding with pleural procedures comprise hemothorax, hemoptysis, need for blood transfusions, or need for further surgical/endovascular interventions.

CURRENT PRACTICE

Most guidelines approach pleural interventions more conservatively. However, it remains uncertain if there is an actual increased risk of bleeding in patients with coagulopathy. The British Thoracic Society 2010 guidelines provide guidance for delaying nonurgent pleural procedures until the correction of platelet defects or coagulopathy (with a goal INR < 1.5), including holding medications. (Havelock et al., 2010) However, these guidelines also acknowledge a prior retrospective study that showed no difference in the risk of bleeding for patients with mild to moderate thrombocytopenia or coagulopathy compared to patients with normal coagulation or platelet counts (McVay et al., 1991). These guidelines and other studies do not address the role of preprocedural lab work in reducing bleeding risk.



CURRENT PRACTICE CONT.

The 2019 Society of Interventional Radiology Consensus Guidelines for the Periprocedural Management of Thrombotic and Bleeding Risk in Patients Undergoing Percutaneous Imaged-Guided Interventions classify chest tube placement as low risk and do not recommend routinely checking preprocedural lab work unless patients have a perceived higher bleeding risk. (Thresholds provided are to correct INR to the range of 2-3 and to transfuse if the platelet count is <20,000). Additionally, there is no recommendation to hold antiplatelet or anticoagulant medications (Patel et al., 2019). Several observational studies support low rates of complications from pleural procedures, including in patients with coagulopathy. If pleural procedures are considered safe even in patients with bleeding tendencies from disease states or medications, this can in turn lower the threshold to perform thoracenteses and tube and avoid unnecessary testing or blood product transfusions.

STUDY DESIGN



Type of trial:

Systematic review and meta-analysis
Randomization, blinding, controls: There were no randomization, blinding, or controls in this meta-analysis.

N: Eighteen studies were selected for a total of 5,134 procedures.

Study groups:

There were no consistent study groups among the various studies.

Settings:

All 18 included studies were conducted in various clinical settings from four different countries (U.S., U.K., France, and Italy) from 1947 to 2019. Primary proceduralists had varying levels of training.

Enrollment:

There were no consistent enrollment criteria for procedures across studies.

Treatment period: Included studies were published or submitted in abstract form from 1991 to 2019. Procedures were conducted from 1947 to December 31, 2019.

Follow up:

There was no consistent follow up reported with this meta-analysis.

Primary outcome:

Pooled rate of major bleeding and mortality
-“Major bleeding” was defined as new development of hemothorax, hemoptysis, hemoglobin decrease >2g/dL, bleeding requiring transfusion, and bleeding requiring procedural intervention

Secondary Outcomes:

Risk of bias
-Risk of bias was assessed using the Risk of Bias in Non-Randomised Studies of Interventions (ROBINS-I) tool, which assesses 7 different domains such as confounding and missing data.

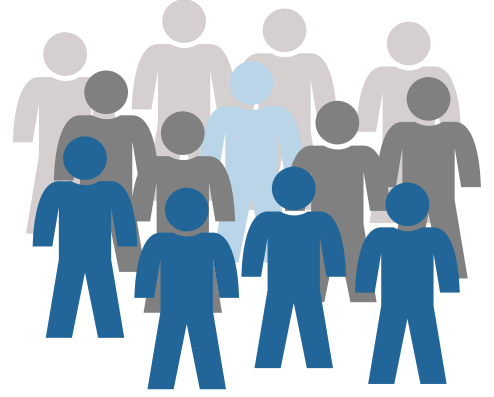
Statistical analysis:

A random-effects model was used to estimate pooled complication rates from the studies. Statistical heterogeneity across the included studies was assessed with the I² statistic. Publication bias was evaluated with the Egger’s test and funnel plot for small-study effects

POPULATION

Inclusion criteria:

Studies were considered for inclusion if they reported rates of major bleeding (defined as above) and death for patients undergoing thoracentesis or tube thoracostomy while having uncorrected coagulopathy. The term “coagulopathy” for the purpose of enrollment was inclusive of thrombocytopenia, platelet dysfunction, or impaired coagulation. Patients could be considered coagulopathic due to either disease states or active medications.



Exclusion criteria:

Studies were excluded if they focused on an irrelevant topic/question, did not include coagulopathic patients, did not include patients undergoing thoracentesis or tube thoracostomy, were missing the primary outcome, or performed the wrong analysis.

Baseline characteristics:

- 18 studies included (12 full manuscripts, 6 conference abstracts)
- 5 prospective studies, 13 retrospective studies
- Number of procedures included in each study ranged from 7 to 1133
- Number of studies reporting patients with thrombocytopenia $<50\text{k}/\mu\text{L}$: 7
- Number of studies reporting patients on clopidogrel: 11
- Number of studies reporting patients on anticoagulant medication: 5
- Number of studies reporting patients with liver disease: 1
- Number of studies reporting patients with renal disease: 8
- Number of studies including patients with $\text{INR} > 1.5$: 11
- 5,134 procedures were conducted in 4 countries (US, UK, France, Italy) from 1947 to 2019.
 - 4,255 thoracenteses, 749 tube thoracostomies, and 130 blind pleural biopsies



INTERVENTIONS

No interventions were made as part of this meta-analysis.

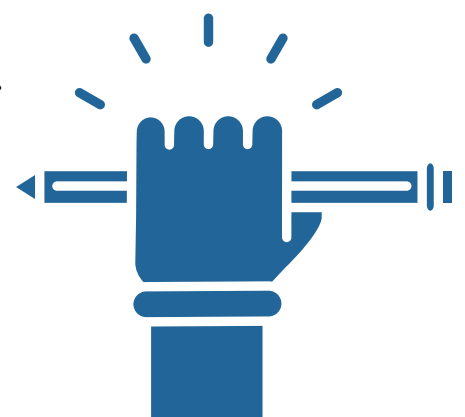
STUDY STRENGTHS

This meta-analysis included studies with a variety of medical conditions and medications.

The number of included procedures amongst the studies is large.

Subgroup analysis yielded results consistent with the overall analysis on all 18 studies.

There was overall low risk of bias amongst 15 of the 18 included studies with no identified publication bias.



FUNDING

The authors received no funding for this study.



OUTCOMES

Primary outcomes

- Pooled major bleeding and mortality rates: 0% (95% CI 0-1%)

Subgroup analysis for the primary outcome:

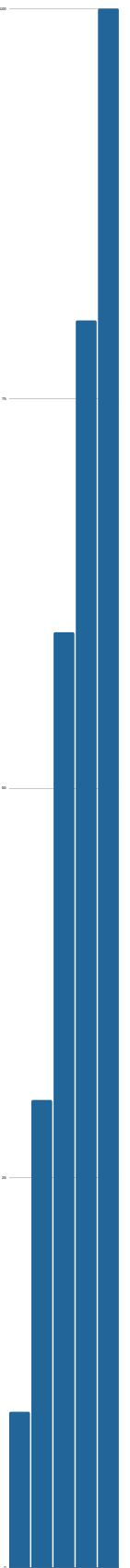
- Published studies (excluding abstract form submissions): 12 studies; 0% (95% CI 0-2%)
- Isolated drug-related bleeding risk: 6 studies; 0% (95% CI 0-0%)
- Isolated thrombocytopenia risk: 1 study; 0% (95% CI 0-9%)
- Isolated elevated INR risk: 1 study; 0% (95% CI 0-5%)
- Tube thoracostomy only: 3 studies; 0% (95% CI 0-2%)
- Thoracentesis only: 13 studies; 0% (95% CI 0-1%)
- Retrospective studies only: 13 studies; 0% (95% CI 0-1%)
- Prospective studies only: 5 studies; 0% (95% CI 0-1%)

Secondary outcomes

- The overall risk of bias was serious in two studies and moderate in one study; the remaining 15 studies showed a low risk of bias in the assessable domains.
- Variation in effect estimate attributable to study heterogeneity: 80.27% (high)
- There was no evidence of publication bias based on Egger's test for small-study effects ($P= 0.484$) and funnel plot assessment.

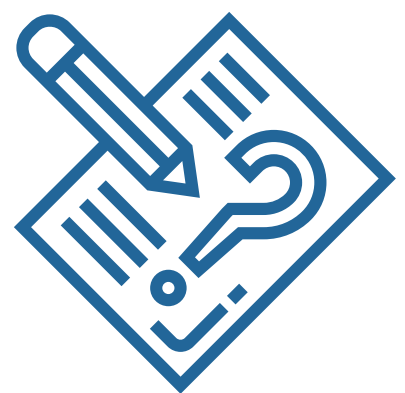
Adverse events

- Not applicable



RESEARCH QUESTION

This study highlights the need for prospective studies to further explore of the risk of major bleeding and mortality for patients undergoing thoracentesis or tube thoracostomy with combined bleeding risk factors.



Dangers et al. from 2021 (which was excluded from this analysis) recently published a study that concluded that antiplatelet therapy was associated with an increased risk of bleeding and serious bleeding after a pleural procedure. Inclusion of this study into the pooled analysis for bleeding complications found that the major bleeding complication rate remained 0%. Additionally, in the Dangers et al. 2021 study were significant differences in baseline characteristics for the small subset of patients receiving antiplatelet therapy compared to controls (such as an increased rate of renal dysfunction). Lower use of image guidance (<80%) and higher percentage of junior operators (>50%) may have also contributed to the study's observed outcomes.

SUGGESTED READING

1. Dangers L, Giovannelli J, Mangiapan G, et al. Antiplatelet drugs and risk of bleeding after bedside pleural procedures: a national multicenter cohort study. *Chest*. 2021;159(4):1621-1629
2. 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
3. Patel PP, Singh S, Atwell TD, et al. The safety of ultrasound-guided thoracentesis in patients on novel oral anticoagulants and clopidogrel: a single-center experience. *Mayo Clin Proc*. 2019;94(8):1535-1541
4. Patel IJ, Rahim S, Davidson JC, et al. Society of Interventional Radiology Consensus Guidelines for the Periprocedural Management of Thrombotic and Bleeding Risk in Patients Undergoing Percutaneous Image-Guided Interventions—part II: recommendations. *J Vasc Interv Radiol*. 2019;30(8):1168-1184



STUDY LIMITATIONS

Clinical Question:

While the authors specify that a complication rate from pleural procedures of <3% is considered low, there is not a clear definition of what would be considered acceptably low risk.

Study Selection, Inclusion, and Exclusion:

While the studies used in the meta-analysis included patients with coagulopathy, platelet dysfunction or thrombocytopenia, not all studies contained a majority of patients with increased bleeding propensity.

Only 5 out of the 18 studies were prospective studies, and most studies were observational studies.

Patient Population:

There was significant heterogeneity in the type and degree of bleeding tendencies in the various studies. Patients at low versus high risk of bleeding were not defined.

There was low inclusion of patients with reported liver disease or patients taking anticoagulant medications.

More severe levels of thrombocytopenia (<20,000k/ μ L) or coagulopathy (INR >3) were not explicitly reported or assessed.

Results Analysis:

There was considerable missing information across the studies in terms of medication use, comorbidities, average INR, and platelet counts.

There was no clear comparison of patients at low and high for bleeding in the meta-analysis.

There was no specific assessment of outcomes for combined platelet dysfunction/thrombocytopenia and coagulopathy or combined disease- and medication-related bleeding risks.

The meta-analysis includes studies assessing the effect of preprocedural interventions for patients with coagulopathy or platelet dysfunction, but this meta-analysis does not directly assess this as a primary or secondary outcome (Hibbert et al 2013).

Generalizability:

The results may not be as representative of the risk for patients with combined bleeding tendencies.

TAKE HOME MESSAGE

This meta-analysis of 18 retrospective and prospective studies demonstrated a very low pooled rate of major bleeding and mortality from thoracentesis and tube thoracostomy in patient populations with increased rates of coagulopathy, platelet dysfunction, or thrombocytopenia.



Increased heterogeneity of effect among studies suggests that factors such as the use of ultrasound guidance and/or operator experience may play an important role in the rate of complications.

More data and evidence are needed to better understand rates of complications in patients with multiple risk factors for bleeding.

There is a need to review existing procedural guidelines given recent studies highlighting the low risk of complications from thoracentesis and tube thoracostomy. A personalized approach should be considered.

ARTICLE CITATION



Puchalski JT, Argento AC, Murphy TE, et al. The safety of thoracentesis in patients with uncorrected bleeding risk. *Ann Am Thorac Soc.* 2013;10(4):336-341

Helm EJ, Rahman NM, Talakoub O, Fox DL, Gleeson FV. Course and variation of the intercostal artery by CT scan. *Chest.* 2013 Mar;143(3):634-639

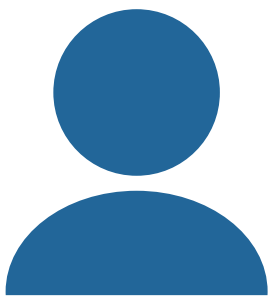
Havelock T, Teoh R, Laws D, et al. Pleural procedures and thoracic ultrasound: British Thoracic Society pleural disease guideline 2010. *Thorax.* 2010;65(suppl 2): ii:61-76

McVay PA, Toy PT. Lack of increased bleeding after paracentesis and thoracentesis in patients with mild coagulation abnormalities. *Transfusion* 1991;31:164-71

Patel IJ, Rahim S, Davidson JC, et al. Society of Interventional Radiology Consensus Guidelines for the Periprocedural Management of Thrombotic and Bleeding Risk in Patients Undergoing Percutaneous Image-Guided Interventions—part II: recommendations. *J Vasc Interv Radiol.* 2019;30(8):1168-1184

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