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Management of bleeding risk before pleural procedures: A consensus statement of Turkish respiratory society – Pleura study group

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Abstract:

Pleural effusion is a common clinical entity. Pleural procedures performed for the diagnosis and management of pleural effusions may increase the risk of bleeding, especially in patients with coagulopathies and comorbidities and those in need for antithrombotic drugs. Current literature provides sparse, low level of evidence, which is insufficient for safe implementation of pleural procedures among these patients. Thoracentesis, pleural biopsy (closed or percutaneous), catheter or chest tube drainage, and thoracoscopy are the main pleural procedures performed in these patients. Considering the bleeding risk associated with a specific pleural procedure, the risk is low for thoracentesis, moderate for insertion or removal of the chest tube or tunneled catheter, and moderate high for pleural biopsies and thoracoscopy. The current statement is prepared mainly for the pulmonologists and intended to provide recommendations to reduce the risk of bleeding following pleural procedures. The management of bleeding complication is out of the scope of this statement.

Keywords:

Biopsy, bleeding risk, chest tube, pleura, procedure, thoracentesis, thoracoscopy, tunneled catheter

Introduction

Pleural effusion is a common clinical entity. Pleural procedures performed for the diagnosis and management of pleural effusions may increase the risk of bleeding, especially in patients with coagulopathies and comorbidities and those in need for anti-thrombotic drugs. Current literature provides sparse, low level of evidence, which is insufficient for

safe implementation of pleural procedures among these patients.^[1,2] Furthermore, there is a lack of uniformity among the published reports, especially in relation to the type of the procedures, comorbidities, and the types of antithrombotic and antiplatelet agents under the consideration. Current guidelines, which are directly related to the pleural procedures, are mainly expert opinions than evidence-based recommendations.^[2-4] We searched PubMed, Web of Science,

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and the Cochrane Library using the combinations of words that included pleural effusion, thoracentesis, pleural biopsy, medical thoracoscopy/pleuroscopy, tube thoracostomy, chest tube, tunneled catheter, antiplatelet, anticoagulation, and antithrombotic therapy. Nonhuman and Non-English literature was excluded. Each subtitle was written by a separate author. These subtitles were discussed at online meetings and face-to-face meetings in detail. Two authors (NYD and DK) compiled the final version. This consensus statement mainly intended for pulmonologists to reduce the risk of bleeding following pleural procedures and is not related to any other complications such as pneumothorax, infection, or reperfusion edema. The management of bleeding complication is out of the scope of this statement.

The group of patients considered to have increased risk of bleeding following the pleural procedure is presented in Table 1. It is to be realized that patients with more than one risk factor have much higher risk of developing the complication.^[5-10]

Thoracentesis, pleural biopsy, catheter or chest tube drainage, and thoracoscopy are the main pleural procedures in the area of pleural diseases. Considering the bleeding risk associated with specific pleural procedures, the risk is low for thoracentesis, moderate for insertion or removal of chest tube or tunneled catheter, and moderate-high for pleural biopsies and thoracoscopy [Table 2].^[3,5-10] We make certain recommendations to reduce the risk of bleeding complication. These include the use of a patient checklist [Supplement 1] before pleural procedures, cognizance related to pharmacokinetics of antithrombotic and antiplatelet agents, image-guidance, and experience.

Pleural Procedure with Low-Bleeding Risk

Thoracentesis is a pleural procedure with a low risk of bleeding.^[3] Possible complications are bleeding in the puncture site, chest wall hematoma, and hemothorax. Although no randomized controlled study has been conducted, some recent retrospective, observational, case-control, and prospective cohort studies have reported that thoracentesis can be performed safely

in patients with bleeding risk. In a cohort study evaluating 9320 patients undergoing thoracentesis over a 12-year period, the incidence of significant bleeding was <1%. There was no relationship between bleeding complications and international normalized ratio (INR), partial thromboplastin time, or the platelet count.^[11] In another retrospective study evaluating 1076 patients who underwent ultrasonography (USG)-guided thoracentesis, there was no bleeding complication in 139 patients with INR >2, and in 58 patients with a platelet count <50,000/ μmL .^[12] A prospective study comparing 130 patients with increased bleeding risk (INR >1.5, platelet count <50,000/ μL , creatinine >1.5 mg/dl, clopidogrel, or low-molecular-weight heparin [LMWH] use) to 182 patients without bleeding risk revealed no difference in terms of bleeding.^[13] In the presence of mild-to-moderate INR elevation (INR = 1.5–3) or low platelet counts (25,000–50,000/ μL), observational studies emphasized that thoracentesis can be performed without any replacement therapy since blood products also have their own risks.^[14]

Performing thoracentesis with the guidance of USG significantly reduces the risk of complications.^[4,14] Even in patients with abnormal coagulation parameters, USG-guided thoracentesis was found to be safe.^[15] It is recommended to visualize the intercostal artery by using a vascular probe, especially in elderly patients with tortuous vessels and also while puncturing close to the vertebral column [Figure 1].^[16]

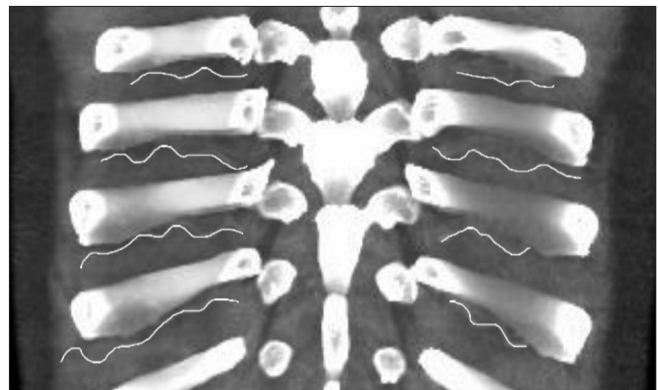


Figure 1: Variations of the posterior intercostal arteries

Table 1: Patients with a high risk of bleeding following pleural procedures

Impaired coagulation parameters (INR >1.5 and platelet count <50,000/ μL)
 Receiving antithrombotic therapy (Anticoagulant* and/or antiplatelet** therapy)
 Chronic liver disease*** (elevation in PT/ INR and aPTT)
 Renal failure**** (Creatinine>1.5 mg/dl and renal replacement therapy requirement)

*Anticoagulant drugs: Heparin, low-molecular-weight heparin (enoxaparin, dalteparin, and nadroparin), fondaparinux, warfarin, and direct-oral anticoagulants (dabigatran, rivaroxaban, edoxaban, and apixaban), **Antiplatelet drugs: Aspirin, clopidogrel, ticagrelor, prasugrel, and ticlopidine, ***In patients with cirrhosis, there is a prolongation of PT/INR, aPTT, and bleeding time depending on the degree of hepatic decompensation. While these parameters are useful for predicting prognosis of chronic liver disease, the prediction of bleeding or thrombosis is low. The risk of bleeding increases when platelet count is lower than 50,000/ μL , ****Renal insufficiency is defined as the creatinine level above 1.5 mg/dl or requirement for renal replacement therapy. Progressive impairment of renal function causes uremia and associated risk of bleeding. The risk of bleeding increases as a result of thrombin-mediated platelet activation inhibition, impaired coagulation due to uremia, impaired platelet function, and the interaction of platelet and vascular wall. INR: International Normalized Ratio; PT: Prothrombin time; aPTT: Activated partial thromboplastin time

Complete blood count analysis should be performed in all patients before elective thoracentesis. INR measurement is recommended for patients taking Vitamin K antagonist and patients with chronic liver disease. Activated partial-thromboplastin time (aPTT) measurement is recommended for patients using heparin.^[3] Bleeding time measurement is not necessary.^[17] The guideline prepared in partnership with the American Association for the Study of Liver Diseases recommends against routinely measuring clotting parameters in patients with chronic liver diseases. It is also not recommended to correct thrombocyte levels and coagulopathy before thoracentesis since the risk of transfusion outweighs its potential benefit.^[9]

There is no need to discontinue aspirin or a second-antiplatelet agent (clopidogrel, ticagrelor, prasugrel, etc.) before thoracentesis.^[18] If the patient takes a therapeutic dose of LMWH, the dose before the procedure should be skipped. The discontinuation of direct-oral anticoagulants (DOAC) is mostly based on expert opinion.^[19,20] Information about the timeframe of discontinuation of antithrombotic drugs before thoracentesis is summarized in Table 3.^[21-24]

In conclusion, in cases without a need for urgent thoracentesis (complicated parapneumonic effusion and hemothorax), the procedure should be performed under ideal conditions (INR <1.5, platelet count >50,000/ μ l, and creatinine <6 mg/dl). Particular caution should be taken when creatinine >3 mg/dl. In patients with renal failure, performing thoracentesis after dialysis reduces the risk of bleeding. The use of USG is highly recommended to locate the fluid and to avoid intercostal vessels.

Summary of Recommendations

1. Thoracentesis is a procedure with low bleeding risk. USG-guided thoracentesis can further reduce the risk
2. If there is no need for an urgent thoracentesis (such as complicated parapneumonic effusion and hemothorax), ideal conditions should be provided: INR <1.5, platelet count >50,000/ μ l, and creatinine <6 mg/dl
3. Thoracentesis can be performed while the patient is on either single or dual antithrombotic drugs
4. Anticoagulant agents should be discontinued for a sufficient period of time before thoracentesis.

Pleural Procedures with Moderate and Moderate-to-high Bleeding Risk

While the insertion or removal of a chest tube or tunneled catheter are considered as pleural procedures with moderate risk for bleeding, pleural biopsy and thoracoscopy are considered as pleural procedures with moderate-to-high risk of bleeding. When these

Table 2: Bleeding risk of pleural interventional procedures

Bleeding risk	Pleural procedure
Low	Thoracentesis
Moderate	Insertion or removal of a chest tube or tunneled catheter
Moderate-to-high	Pleural biopsy Thoracoscopy

Table 3: Discontinuation times for antithrombotic drugs before pleural procedures

Drug group	Name of drug	Discontinuation time*	
Antiplatelet drugs	Aspirin	-	
	Clopidogrel	5-10 days	
	Prasugrel	5-10 days	
	Ticagrelor	5-10 days	
	Ticlopidine	10-14 days	
Vitamin K antagonists	Warfarin	5 days (with INR monitoring)	
Heparin	Unfractionated heparin	4-6 h	
	Low molecular weight heparin	Enoxaparin Dalteparin Nadroparin	24 h 24 h 24 h
	Synthetic heparin	Fondaparinux	24 h
Direct oral anticoagulants	Dabigatran	48 h	
	Argatroban	48 h	
Direct factor Xa inhibitors	Rivaroxaban	At least 24 h	
	Apixaban	At least 24 h	
	Edoxaban	At least 24 h	

*Duration may be longer in renal and liver failure. INR: International Normalized Ratio

procedures are performed electively, a patient's bleeding risk should be evaluated and necessary precautions should be taken. In patients receiving antithrombotic drugs, the risk of thrombosis and bleeding should be seriously weighted. Considering the patients' comorbidities, anticoagulants should be discontinued for a specified timeframe before the procedure and should be restarted within 24–48 h after an uneventful procedure.^[21-24] The management of anti-platelet and anticoagulant therapy before pleural procedures is summarized in Figures 2 and 3, respectively.

The current literature about the use of pleural catheters in patients with bleeding risk is mostly case series.^[25,26] There is no study investigating the bleeding risk of tunneled catheter insertion/removal or medical thoracoscopy. In a nonrandomized, controlled, prospective cohort study investigating the safety of inserting a thin-pleural catheter (14F), 25 patients who continued to take clopidogrel were compared to 50 patients who discontinued the treatment. The study excluded the patients with INR >2 or a platelet count <50,000/ μ l. The pleural procedures were performed with the guidance of USG by or under the supervision of an experienced physician. There was no bleeding complication in the patient group which continued to receive clopidogrel,

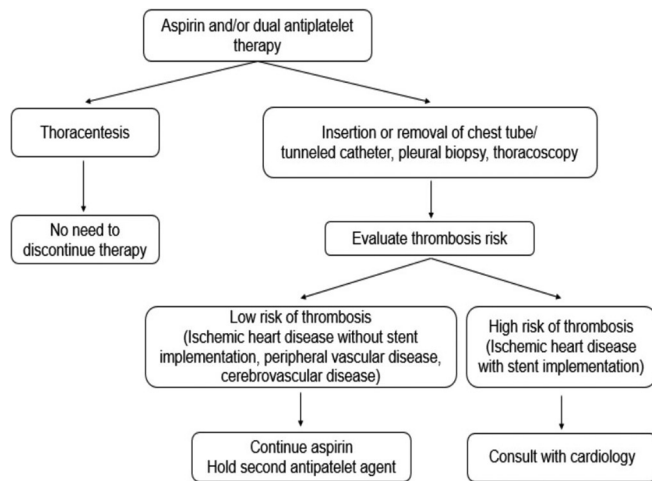
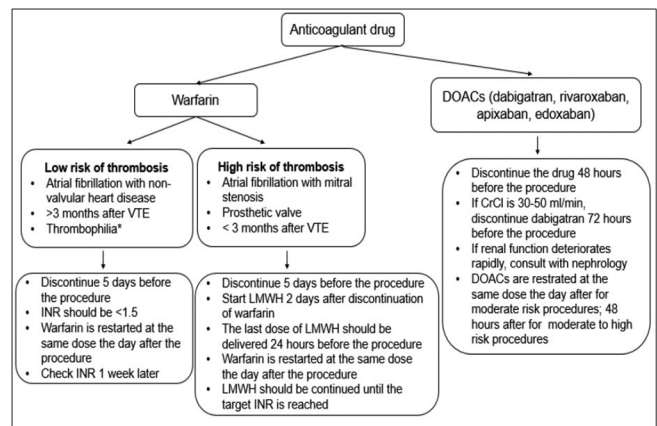


Figure 2: Antiplatelet therapy in patients scheduled for a pleural procedure

even though 88% of the patients were also receiving aspirin.^[25] In a retrospective case series including a limited number of patients who receives both clopidogrel and aspirin, there was no bleeding complication after thin-pleural catheter insertion.^[26,27] These reports state that thin-drainage catheters are safe in patients using clopidogrel. However, these studies have a low level of evidence due to including the small number of patients, performing the procedure with USG guidance, and mostly inserting thin 6–7 F catheters using the Seldinger technique. Therefore, further prospective randomized controlled studies are necessary.

Among patients receiving warfarin, if the risk of thrombosis is low (>3 months after venous thromboembolism, atrial fibrillation without valve disease, and thrombophilia), current evidence does not recommend bridging, warfarin should be discontinued 5 days before the procedure and INR should be <1.5.^[24] Warfarin can be restarted at the same dose the day after the procedure. In patients with a high risk of thrombosis (atrial fibrillation with valve disease, mitral stenosis, mitral valve prosthesis, <3 months after venous thromboembolism, or severe thrombophilia), warfarin should be discontinued 5 days before the procedure, for bridging LMWH should be started 2 days after warfarin is discontinued. The last dose of LMWH should be delivered 24 h before the procedure. The day after the procedure, warfarin is restarted at the dose previously being used, and LMWH is continued until INR reaches a therapeutic level.^[5,6,24,28]

In patients receiving DOAC treatment, discontinuation of these drugs (direct thrombin inhibitor dabigatran or factor Xa inhibitors rivaroxaban, apixaban, and edoxaban) is based on the expert opinion only. All DOACs are excreted by the kidneys to some extent, but the pharmacokinetics of dabigatran is the one most affected by renal function. In pleural procedures with a



* Patients with thrombophilia should be consulted to the hematology department
VTE: Venous thromboembolism; DOACs: Direct oral anticoagulants; LMWH: Low Molecular Weight Heparin; CrCl: Creatinine clearance

Figure 3: Anticoagulant therapy in patients scheduled for a pleural procedure

high risk of bleeding, DOACs should be discontinued 48 h before the procedure and restarted 48 h (24–72 h) after the procedure. In renal failure, DOACs should be discontinued earlier. Dabigatran is discontinued 72 h before the procedure when the creatinine clearance is 30–50 ml/min. In a patient whose renal function is rapidly deteriorating, a consultation with a hematologist is required.^[5,6,24,28]

It is recommended to perform complete blood count analysis and INR measurement in patients who underwent pleural procedures with moderate and moderate-high bleeding risk under elective conditions. It is important to perform such procedures when INR <1.5, aPTT <normal × 1.5 times and platelet count >60,000/μl, in order to prevent bleeding complications.^[29] Since platelet dysfunction due to chronic renal and liver failure increases the risk of bleeding, the patients should be consulted to relevant specialists. If the creatinine level is >3 mg/dl, the risk of bleeding increases. In the presence of chronic renal failure, intervention after the dialysis reduces the risk of bleeding. Patients using anti-platelet drugs for cardiac comorbidities should be consulted with the cardiology department. If the patients have a low risk of thrombosis, they should continue using aspirin, but other anti-platelet agents should be discontinued 5 days before the pleural procedure. In patients with a high risk of thrombosis, the decision is made considering the benefits and losses. Anti-platelet drugs can be resumed 24 h after the procedure.^[5,6,23,28]

Summary of Recommendations

1. The risk of bleeding is moderate for insertion or removal of a chest tube or tunneled catheter, it is moderate-to-high for pleural biopsy and thoracoscopy
2. If the insertion or removal of a chest tube or tunneled catheter, pleural biopsy or thoracoscopy is to be performed under elective conditions, the patient's

bleeding risk should be evaluated in detail and necessary precautions should be taken

3. Ideal conditions include INR <1.5, aPTT <normal × 1.5 times, platelet count >60,000/μl, and creatinine <3 mg/dl
4. In patients receiving antithrombotic therapy, the risk of thrombosis and the risk of bleeding should be weighed, and antithrombotic medications should be held for a certain period of time according to the half-life of the medication and considering the comorbidities of the patient. These drugs should be restarted within 24–48 h after an uneventful procedure
5. Aspirin does not need to be discontinued; procedure can be performed while the patient is receiving
6. Anti-platelet agents other than aspirin should be discontinued 5 days before the procedure
7. Anticoagulant treatments (heparin, LMWH, warfarin, and DOAC) should be discontinued for a sufficient period of time before the procedure [Table 3].

Conclusion

This expert opinion report on pleural procedures is prepared for pulmonologists and recommends suggestions for elective procedures, mostly for diagnostic purposes. In routine clinical practice, scheduled pleural procedures, and patient factors (age, comorbidity, and treatments) should be evaluated, and the procedures should be performed under the ideal conditions by considering the benefits and risks.

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Conflicts of interest

There are no conflicts of interest.

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