

Thrombolysis (Catheter Directed) for Acute Limb Ischemia and Pulmonary Embolism

Site Applicability

PHC Interventional Radiology (IR), Critical Care and High Acuity Units

Practice Level

Specialized:

- *Critical Care or High Acuity Care trained RNs*

Requirements

Patients receiving thrombolytic therapy for Acute Limb Ischemia and Pulmonary Embolism will have treatment initiated in Interventional Radiology and following this will be monitored in a critical care or high acuity unit

Quick Links

1. [Pre-Procedure](#)
2. [Intra-Procedure](#)/Immediately following procedure in Radiology
3. [Precautions](#)
4. [Post-Procedure Care in PACU/sHAU](#)
5. [Post Sheath Removal](#)

Need to Know

Acute vascular occlusion may be a result of an embolus or acute thrombosis and can be either arterial or venous. An embolus is often diagnosed based on a sudden onset of symptoms and a suspected source of thrombi (e.g. a patient with atrial fibrillation). Emboli tend to lodge in arterial bifurcations and can progress above and below the obstruction. A thrombosis is generally slower growing and often occurs when the arterial wall has been damaged possibly a result of atherosclerosis.

Acute Limb Ischemia:

Symptoms of acute limb ischemia are marked by the 6 “P’s”: **pain**, **pallor**, **pulselessness**, **paralysis**, **paresthesia**, and **polar** (cool). The part of the limb below the occlusion is markedly often colder and paler than the part above the occlusion. The medical status of the patient and the physical findings of the ischemic limb are the main guides to treatment. Depending on the severity there are four immediate treatment options: anticoagulation alone, catheter directed thrombolysis, surgical

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intervention, or amputation. Using the presenting symptoms the severity of limb ischemia is categorized (See [Appendix A](#): Classification of Acute Limb Ischemia) and treatment options are determined.

For limbs that are considered viable or marginally threatened, catheter directed thrombolysis is often considered to be first line treatment option when:

- symptoms of limb ischemia is present for less than 14 days,
- no absolute contraindications to thrombolysis exist (See [Appendix B](#): Contraindications to fibrinolytic therapy for deep venous thrombosis or acute pulmonary embolism) and
- the predicted time to re-establish antegrade flow is short enough to preserve limb viability.
- the clot is within reach of thrombolytic catheter and the clot burden must also be suitable for thrombolysis in a reasonable length of time.

Pulmonary Embolism:

Pulmonary embolus (PE) refers to obstruction of the pulmonary artery or one of its branches by material (e.g., thrombus, tumor, air, or fat) that originated elsewhere in the body. Acute pulmonary embolism (PE) is a form of venous thromboembolism (VTE) that is common and sometimes fatal. The clinical presentation of PE is variable and often nonspecific making the diagnosis challenging. Hemodynamically unstable PE is also called "**massive**" or "**high-risk**" PE. Hemodynamically stable PE is called "**submassive**".

Hemodynamically unstable PE is that which results in hypotension that is defined as: systolic blood pressure less than 90 mmHg; or a drop in systolic blood pressure of equal to or greater than 40 mmHg from baseline for a period more than 15 minutes; or hypotension that requires vasopressors or inotropic support and is not explained by other causes (Thompson and Kabrhel, 2023).

When a patient presents with suspected acute pulmonary embolism (PE), initial resuscitative therapy should focus upon oxygenating and stabilizing the patient. Resuscitative therapy may range from supplemental oxygen to ventilatory and hemodynamic support. Once the diagnosis is made, the mainstay of therapy for patients with confirmed PE is anticoagulation, depending upon the risk of bleeding. Patients with life-threatening PE may require additional treatment beyond anticoagulation, including thrombolysis (Thompson and Kabrhel, 2023).

Thrombolytic therapy is used in patients with acute pulmonary embolism (PE) to rapidly dissolve the embolic burden and improve cardiorespiratory hemodynamics. Preference in administration of tissue-type plasminogen activator (tPA) is based upon the widespread availability and clinical experience with this agent, as well as the rapidity with which it can be administered in life-threatening situations. Thrombolytic agents can be infused directly into the pulmonary artery via a pulmonary arterial catheter (i.e., Catheter-Directed Thrombolysis or CDT). CDT has the potential advantage that lower doses of lytic agent can be administered, thereby reducing the risk of bleeding compared with systemic therapy. (Tapson and Weinberg, 2023). Absolute and Relative Contraindication to Thrombolysis can be reviewed in [Appendix B](#).

Deep Vein Thrombosis:

Deep vein thrombosis (DVT) is another manifestation of venous thromboembolism (VTE) (Hull and Lip, 2022). The diagnosis of lower extremity DVT should be unequivocal because the adverse effects of

thrombolytic therapy can be severe or life-threatening (e.g., hemorrhage or bleeding in a critical location such as the brain). DVT is typically diagnosed using compression ultrasound (CUS). In patients with acute DVT of the lower extremity, we reserve thrombolytic therapy for patients with severe symptomatic swelling and/or those with limb- or life-threatening extensive proximal or iliofemoral DVT. The goal in this population is to alleviate symptoms and prevent gangrene. In some cases, we also use thrombolysis for patients with persistent, severe symptoms or swelling despite therapeutic anticoagulation, although there are no data to support that practice. The administration of thrombolysis in this population is predicated on symptoms being present for less than 14 days, life expectancy greater than 1 year, good functional status, and low bleeding risk (Rivera-Lebron and Weinberg, 2022).

A thrombolytic agent's mechanism of action involves the conversion of plasminogen to an active thrombolytic enzyme, plasmin, which causes the breakdown of cross-linked fibrin strands. Alteplase, or tissue plasminogen activator (tPA), is the thrombolytic agent typically used for catheter directed thrombolysis. Alteplase (tPA) has a greater affinity for fibrin bound plasminogen than free plasminogen. Alteplase (tPA) is administered directly through the thrombolytic catheter that is placed in radiology and positioned within the clot. The catheter typically has multiple side holes to increase exposure to the surface area of the clot and delivery of alteplase (tPA). In Radiology there may be an initial bolus dose or 'lacing' followed by an infusion of no greater than 2 mg/hour for 8 to 12 hours with a maximum overall dose typically not exceeding 40 mg. Once the alteplase (tPA) infusion is terminated, over 50% of the alteplase (tPA) is cleared from the plasma in 5 minutes and, after 10 minutes, over 80% is cleared. However, fibrinolytic therapy persists for the next couple of hours as the plasmin bound to the fibrin has continued effects at the clot surface.

Heparin should be used carefully with thrombolytic infusions because of the risk of bleeding. Most often, heparin is administered either intravenously or intra-arterially through the sheath to help prevent peri-catheter thrombosis. The products of fibrinogen degradation can increase a patient's sensitivity to heparin, making them more prone to bleeding. For this reason, no heparin bolus dose is given and sub-therapeutic doses are recommended using the heparin low-target protocol.

Follow-up in Interventional Radiology is typically daily or twice-daily until restoration of flow is achieved or until the requirement for surgical intervention is determined for arterial occlusion. Venous occlusion may result in a chronic condition requiring ongoing medical and therapeutic management.

Equipment and Supplies

Alaris Signature Edition CareFusion Pump

Alaris SmartSite infusion set

Pressure monitoring set, single line with 3-way stopcock

Transducer holder

Pressure Infusor bag

Normal Saline (NS) 500 mL bag

Alteplase vial

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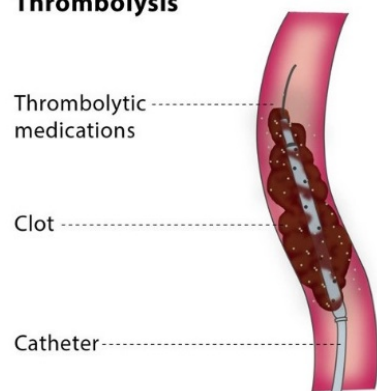
Protocol

Pre-Procedure

The physician will explain to the patient the purpose of thrombolytic (Alteplase (t-PA)) therapy, including possible side effects and complications, the expected duration of treatment and what to expect during the treatment. The radiologist or vascular surgeon will obtain an informed consent prior to commencing the procedure.

Assessment and Interventions	Rationale
1. Absolute and relative contraindications reviewed by radiologist.	
2. Obtain baseline neurovascular assessment of affected limb including swelling and document in PowerChart.	A baseline is important to establish any variances from start of therapy and to report a worsening condition that might require surgical intervention.
3. Obtain baseline vital signs including Glasgow Coma Scale (GCS), pupil size and accommodation to light and document in PowerChart.	
4. Ensure two intravascular access lines size 20 g or 18 g are established	One IV will be dedicated for IV fluid and medications with a second IV dedicated to blood draws. The number of venous punctures should be minimized, as these can bleed as alteplase (tPA) given.
5. Assess need for Foley catheter. If the patient will be unable or has difficulty voiding place Foley catheter, use smallest possible size (usually #12 Fr for female and #14 Fr for male)	The patient will be on strict bedrest and may present difficulties with voiding. Once alteplase (t-PA) infusion is initiated, the patient is at increased risk for bleeding during invasive procedures such as Foley catheter insertion.
6. Confirm that: <ul style="list-style-type: none"> A physician-to-physician (vascular surgeon/MRP to anesthesiologist) consult or request is completed and approved. A discussion with PACU CNL/CN to ensure staff and bed availability for post procedure care. 	Both of these items need to be in place prior to commencing the procedure to ensure staff and space availability for post procedure care.
7. Patients are admitted to PACU or HAU under a vascular surgeon following procedure and will remain on unit until 5 hours following sheath removal.	Patient requires frequent assessments following procedure and will remain in radiology department until space on receiving unit is confirmed.

Intra-Procedure/Immediately following Procedure in Radiology

Assessment and Interventions	Rationale
<p>1. Reconstitute alteplase (t-PA) vial as per directions in PDTM. (50 mg vial with 50 mL sterile water for injection for a final concentration of 1 mg/mL)</p> <p>Complete an independent double check (IDC) with another clinician</p>	
<p>2. Monitor vital signs every 15 minutes and PRN during procedure.</p>	
<p>3. An introducer sheath is inserted either intravenously or intra-arterially. In radiology use pressure set-up, when patient is transferred to critical care or HAU the unit will have ready for the patients arrival pressurized tubing to a pressure bag of normal saline at 300 mmHg.</p> <p>When disconnecting from pressure set up in radiology cap side arm with a positive pressure cap or MaxZero™ Needleless connector. Do not use red Port Cap.</p>	<p>The side arm is a large bore catheter and can occlude easily. This will help prevent back flow and additional clots from forming within the catheter.</p> <p>The set up in radiology when disconnected from transducer cable will bolus the patient through the sheath when under pressurized bag.</p>
<p>4. A thrombolysis catheter will be inserted through the sheath and positioned to lie within the clot. There are multiple side holes for increased contact with the surface area of the clot.</p> <p>5. The alteplase (t-PA) will infuse through the thrombolysis catheter and infuse directly into the clot. Prior to infusion multiple bolus doses will be given (approx. 5 mg at a time) to 'lace' the clot.</p>	<p>Allows alteplase (t-PA) to bind with the fibrin bound plasminogen more readily.</p> <p>'Lacing' the clot with alteplase (t-PA) can accelerate thrombolysis time.</p> <p>Thrombolysis</p>  <p>The diagram illustrates a cross-section of a blood vessel. A catheter is inserted into the vessel, positioned against a dark red, irregularly shaped mass representing a blood clot. Dashed lines with labels point to the catheter, the clot, and the area where thrombolytic medications are being infused into the clot.</p>

Assessment and Interventions	Rationale
6. Further dilute alteplase (t-PA) 12.5 mg in 500 mL NS for a final concentration of 25 mcg/mL as per the PDTM. Typically the infusion will run at 0.5 mg to 2 mg/hr. Confirm dose rate against PDTM monograph and physician order.	
7. Following final placement of the thrombolytic catheter via the introducer sheath the catheter is secured with a transparent, occlusive dressing such as Tegaderm. Independent loops of the catheter may be used to help with accidental movement of the catheter during patient transfers.	
8. Instruct the patient to keep affected limb straight and maintain complete bedrest.	A bent limb can impede peripheral circulation.
9. Continue to assess vital signs Q15 minutes and PRN until transfer.	
10. Assess for bleeding with each vital sign check at catheter insertion site and any other wounds or catheters (Peripheral IVs). Include more generalized signs of bleeding in your assessment such as a change in GCS, restlessness, headaches, pupil changes, dyspnea, hematuria, hematemesis, epistaxis, lower back pain, abdominal distension, or a change in blood pressure and heart rate.	
11. When patient is ready for transfer to unit accompany patient and provide a detailed report at the bedside to the accepting RN. Ensure medication rates and doses are reviewed during handover.	

Post Procedure Care in PACU/SHAU/ICU

Assessment and Interventions	Rationale
1. Prior to patient's arrival to unit, set up pressure tubing with 500 mL NS on pressure bag. Prime pressure tubing with NS. Have ready for patient on an IV pole with a transducer holder.	This will need to be connected as soon as patient arrives to unit to the side arm of the introducer sheath.
2. Review catheter directed thrombolysis set up with IR Nurse as follows: <ul style="list-style-type: none"> • Catheter site secure and dressing dry and intact and free of signs of bleeding (oozing, hematoma etc.). • Thrombolytic catheter infusing alteplase (t-PA) via infusion pump at ordered concentration, dose and rate. Connections secure. • Side arm of introducer sheath connected to pressure tubing with pressure bag at 300 mmHg and normal saline infusing at 3 mL/hr. • The pressure tubing does not need to be transduced. • In cases where there are multiple sheaths/microcatheters used, label each line appropriately. Review each infusion from the site to the bag. NOTE: <ol style="list-style-type: none"> 1. Heparin low target protocol may also be ordered via peripheral IV or via the side arm of the introducer sheath. Ensure heparin is infusing at prescribed concentration, dose and rate, review time for next pTT 2. For patients admitted to ICU, catheter directed thrombolysis set-up review will be done by IR RN and ICU RN immediately after the procedure before the patient is transported back to ICU 	Assess for bleeding and prevent accidental catheter dislodgement. To allow direct contact of thrombolytic with clot. To prevent back flow, particularly with arterial placement. To help prevent peri-catheter thrombosis. ICU team will stay with the patient during the procedure.
3. For PACU/SHAU, Inform anesthesia of patient's arrival on unit.	Anesthesia to review patient and complete PACU/SHAU admission orders.

Assessment and Interventions	Rationale
4. Admit patient to PACU/SHAU/ICU as per unit routine. Complete assessments and documentation requirements.	
5. Monitor and record vital signs every 15 minutes x 8, if stable then every 30 minutes x 4, if stable then every hour and PRN. Report abnormal vital signs to anesthesia.	A drop in blood pressure or rise in heart rate may indicate internal bleeding.
6. Assess and document neurovascular assessment and site check every 15 minutes x 8 then every 30 minutes x 4, if stable then every hour and PRN. Include in neurovascular assessment colour, warmth, movement, sensation, swelling, pulse strength and pain (The 6 Ps).	If assessment findings worsen i.e. increased numbness, unable to move extremity, etc. from baseline notify vascular surgeon and peri-op Anesthesiologist immediately. Deterioration of neurovascular assessment may require surgical intervention. Increase in pain may be related to reperfusion of blood supply after period of ischemia due to muscular swelling and oxidative injury.
7. Assess and record neuro vital signs (GCS, pupil size and reactivity), presence of angioedema and generalized signs of bleeding every 1 hour for the first 6 hours and if no changes then every 4 hours and PRN. General signs of bleeding may include, bleeding of any other wounds or catheters (peripheral IVs), dyspnea, hematuria, hematemesis, epistaxis, lower back pain or abdominal distension.	Changes in level of consciousness, pupil changes may indicate a cerebral bleed, if this occurs, thrombolytic therapy would need to be stopped. Angioedema a side effect of alteplase (t-PA) can be potentially life threatening if not treated promptly.
8. Monitor ordered lab values and notify ordering physician of any abnormal results not within expected parameters. Draw bloodwork as ordered through dedicated IV. If dedicated IV is not working, venipuncture should be performed carefully; upper extremity vessels are preferable	Report fibrinogen results for levels less than 1 g/L to vascular surgeon as lower levels have been linked to an increased risk of bleeding.
9. With any alteplase (t-PA) infusion bag change, confirm concentration and infusion rate by doing an independent double check (IDC) with another RN.	Ensure concentrations are the same and dose rates do not require changing.

Assessment and Interventions	Rationale
10. Patients will return to interventional radiology typically within 12 hours, be aware of this time. Review if alteplase (t-PA) or heparin is to be stopped 4 hours prior to scheduled time.	
11. RN to accompany patient to radiology and provide handover to receiving RN. If patient is unstable or requiring frequent interventions, RN will be required to stay with patient. Prior to returning to unit, check with IR nurse to ensure you are not required to stay.	

Post Sheath Removal

Assessment and Interventions
1. The sheath is to be removed by vascular team physician once the heparin and alteplase (t-PA) have been discontinued for 4 hours.
2. Following sheath removal and completion of thrombolytic therapy, maintain strict bedrest with affected limb straight at all times for 5 hours and closely monitor the site for bleeding. Patient may be repositioned with assistance.
3. Vital signs, neurovascular assessment and site check are to be completed and documented every 15 minutes for 1 hour, every 30 minutes for 1 hour and then every 1 hour until discharge from unit (at minimum 3 hours).
4. For PACU/SHAU, the patient will require a documented clearance from both anesthesia and vascular surgery to go to ward. Prior to transfer, the medication reconciliation on transfer (MROT) will need to be completed by vascular surgery MD.

Precautions

- Avoid venipunctures during alteplase (t-PA) infusion and for 4 hours following. Use a designated IV catheter for blood sampling. If venipuncture is absolutely necessary ensure small gauge needle is used and pressure is applied to puncture site until bleeding has stopped.
- Avoid traumatic procedures such as nasogastric tube or urinary catheter insertion. Prior to initiation of treatment a Foley catheter should be placed if there is any question as to whether the patient will be able to void. The catheter should be removed as soon as possible and routine use avoided.
- When possible avoid central venous and arterial punctures during alteplase (t-PA) infusion and for 4 hours following. If arterial puncture is necessary use an upper extremity artery that is accessible to manual compression.

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- Avoid IM injections while on alteplase (t-PA) infusion and 4 hours after.
- Cap any blocked IV catheters and mark as not working. Do not remove until after 4 hour completion of alteplase (t-PA) infusion. Do not remove arterial catheters until specified by physician.

Documentation

Document all assessments and interventions in PowerChart as follows:

- Sheath Insertion and Assessment
 - In IR: Interactive View and I&O > Adult Critical Lines-Devices > Arterial and Venous Sheaths
 - In PACU/SHAU: Interactive View and I&O > Periop Lines and devices > Artrial and Venous Sheath
- Medications going through the sheath and microcatheters
 - MAR
- Recording Intake and output
 - Interactive View and I&O > Intake and Output
- Documenting PE Thrombolysis Catheter
 - Interactive View and I&O > Adult Critical Lines-Devices > Pulmonary Artery Line > PE Thrombolysis Catheter

Patient and Family Education

- In interventional radiology, ensure patients questions are answered prior to commencement of treatment. If unable to answer questions, redirect to either radiologist or vascular surgeon.
- On arrival to unit, orientate patient and family to unit, provide family member with contact information when appropriate.
- Provide the patient and family with teaching in regards to expectations, e.g. frequency of vital signs, length of treatment, return to radiology, risk for bleeding and to alert a nurse if bleeding is noted by the patient or a family member.
- Instruct the patient to keep the affected limb straight and that they will be required to remain on bedrest for duration of treatment.

Related Documents

1. Heparin Infusions: [Self-directed Learning Module](#)
2. [B-00-13-10105](#) – High Acuity Care; Protocol for (SPH)
3. [B-00-12-10099](#) – Urinary Catheterization
4. Parenteral Drug Therapy Manual – Monograph for [alteplase](#)

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Appendices

- [Appendix A](#): Clinical features and diagnosis of acute lower extremity ischemia
- [Appendix B](#): Contraindications to fibrinolytic therapy for deep venous thrombosis or acute pulmonary embolism

Appendix A: Clinical Categories of Acute Limb Ischemia

	Viable (I)*	Marginally threatened (IIa)*	Immediately threatened (IIb)*	Nonviable (III)*
Pain	Mild	Moderate	Severe	Variable
Capillary refill	Intact	Delayed	Delayed	Absent
Motor deficit	None	None	Partial	Complete, paralysis (rigor)
Sensory deficit	None	None or minimal (toes)	More than toes	Complete, anesthetic
Arterial Doppler	Audible	Inaudible	Inaudible	Inaudible
Venous Doppler	Audible	Audible	Audible	Inaudible
Treatment	Urgent evaluation	Urgent revascularization	Emergency revascularization	Amputation

Adapted from UpToDate: Carpenter, J.P., & Mitchell, M.E. (2022). *Clinical features and diagnosis of acute lower extremity ischemia*. Collins, K. (ed). In UpToDate. Waltham, MA

Appendix B: Contraindications to fibrinolytic therapy for deep venous thrombosis or acute pulmonary embolism

Absolute Contraindications

- Prior intracranial hemorrhage
- Known structural cerebral vascular lesion
- Known malignant intracranial neoplasm
- Ischemic stroke within previous three months (excluding stroke within 4.5 hours of symptom onset)
- Suspected aortic dissection
- Active bleeding or bleeding diathesis (excluding menses)
- Significant closed head trauma or facial trauma within previous 3 months

Relative Contraindications

- History of chronic, severe, poorly controlled hypertension
- Sever uncontrolled hypertension on presentation (SBP more than 180 mmHg or DBP more than 110 mmHg)
- History of ischemic stroke more than three months prior
- Traumatic or prolonged (more than 10 minute) CPR or major surgery less than three weeks ago
- Recent (within two to four weeks) internal bleeding
- Noncompressible vascular punctures
- Recent invasive procedure
- Streptokinase/anistreplase- prior exposure (more than five days ago) or prior allergic reaction to these agents
- Pregnancy
- Active peptic ulcer
- Pericarditis or pericardial fluid
- Current use of anticoagulant (e.g. warfarin) that has produced an elevated INR, more than 1.7 or PT more than 15 seconds
- Age more than 75 years
- Diabetic retinopathy

Adapted from UpToDate: Rivera-Lebron, B., & Weinberg, A.S. (2023). *Approach to thrombolytic (fibrinolytic) therapy in acute pulmonary embolism: Patient selection and administration*. Mandel, J. (ed). In UpToDate. Waltham, MA.

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