SESLHDMG/106

Medicine Guideline for the Safe Use of

Alteplase to restore Vascular Access Device patency

Health
South Eastern Sydney
Local Health District

ALTEPLASE IS A HIGH RISK MEDICINE **USE WITH CAUTION AND ENSURE THE DIRECTIONS WITHIN THIS PROTOCOL ARE FOLLOWED CAREFULLY**	
Areas where Protocol/Guideline applicable	SESLHD
Areas where Protocol/Guideline is NOT applicable	CVADs used for haemodialysis (vascaths) under the care of the renal team. Refer to local procedures.
Authorised Prescribers:	Medical Officers
Clinicians authorised to instil alteplase:	Appropriate specialty CNC, NP, CNE or RN with a minimum 12-months recent experience in the management of Vascular Access Devices in conjunction with a prescription from the treating Medical Officer or other authorised prescriber. Additional support can be sought from the locally identified specialty resource personnel (e.g., ICU, Vascular Access, Haematology, Oncology CNCs, etc.)
Definitions	• Central Venous Access Device (**CVAD**) – small, flexible tubes placed in large veins, with the tip positioned in the lower third of the Superior Vena Cava (SVC), for people who require frequent access to the blood stream. Placement can be in the neck, chest, arm or groin (tip will be positioned in the inferior vena cava) • Peripherally Inserted Central Catheter (**PICC**) – A catheter inserted through the veins of the upper extremities in adults and children; upper or lower extremities in neonates, catheter tip is located in the superior or inferior vena cava, preferably in the cavo-atrial junction • **TIVAD** (Totally Implantable Venous Access Device) – also referred to as an Implantable Venous Port (IVP) is a device used for long term intermittent central venous access via a port implanted into a subcutaneous pocket, consisting of either a single or double lumen, self-sealing reservoir hub. Most commonly situated in the anterior chest wall with access via the subclavian or internal jugular veins with the catheter tip ideally ending in the distal third of the Superior Vena Cava. • **TC-CICC** (Tunnelled Cuffed Centrally Inserted Central Catheter) and **T-CICC** (Tunnelled Centrally Inserted Central Catheter, non-cuffed) are types of CVAD that are inserted into a vein in the neck and exit out at the chest. A small section of the CVAD sits underneath the skin and is 'tunnelled' through the chest wall. Sometimes other names will be used for this type of CVAD (e.g., Hickman or Powerline).
Important Safety Considerations	Do not delay in completing a comprehensive patient assessment when any signs or symptoms of partial or complete occlusion are evident. **Prompt action is required.**

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Indication for use	1. To restore the function of an occluded Vascular Access Devices (partial or complete) where malfunction is related to a thrombotic cause and when other methods / attempts have failed. 2. Dissolution of fibrin sheath confirmed by linogram
Clinical condition	Occlusion – characterised by the inability to infuse fluids, withdraw blood, or by sluggish flow. Vascular Access Device occlusions may be complete or partial. • **Complete** occlusions prevent any infusion or aspiration of fluid through the Vascular Access Device • **Partial** occlusions often enable infusion but not aspiration of fluid through the Vascular Access Device
Proposed Place in Therapy	Consult with specialty CNC or NP (i.e., ICU, Vascular Access, Haematology, Oncology) for Vascular Access Device that may require alteplase to determine the best method of restoring patency. Consult MUST occur prior to ordering alteplase

Contra-indications	• Known hypersensitivity to Alteplase
	• If there is a known or suspected infection located in the catheter (use of Alteplase may release a localised infection into the systemic circulation)
	• Gentamicin hypersensitivity
	• Any of the below within 48 hours (preceding or following):
	  • Surgery
	  • Percutaneous biopsy of viscera or deep tissues
	  • Obstetric delivery
	  • Puncture of non-compressible vessels

Precautions	Alteplase clearance is mediated primarily by the liver therefore Liver Function Tests (LFTs) need to be checked prior to administration. If the results are not within normal limits please consult with treating medical officer. Indications where thrombolytic therapy such as alteplase increases the risk of bleeding e.g. • Active internal bleeding • Thrombocytopenia • Intracerebral tumour or haemorrhage • Coagulopathy • Recent CVA / TIA
Dosage	**The standard dosing for adults is 2 mg in 2 mL.** **For paediatrics: > 30 kg use 2 mg in 2 mL. < 30 kg use 1.5 mg in 1.5 mL. Alternatively, use volume equal to the 110% internal volume of the catheter if known.** • SINGLE Lumen devices – Instil full dose of Alteplase 2mg into this lumen • MULTI Lumen devices – Where multiple lumens are affected, divide the full dose of Alteplase 2mg between the affected lumens *** Multi lumen devices have a smaller diameter lumen therefore a smaller volume of Alteplase is required. The more lumens the smaller the volume required for each lumen. Instilling Alteplase 2mg into each affected lumen of a multi lumen device would result in SIGNIFICANT systemic administration*

Duration of therapy	If catheter function is not restored after one dose of alteplase, a second dose of equal amount may be instilled after consultation with the appropriate CNC / Medical Officer. If catheter function is not restored after a second instillation of alteplase then consideration may be given to replacing or re-siting the vascular access device. This should be discussed with the appropriate CNC / treating Medical Officer.
Prescribing Instructions	Prescribed on the eMR, eRIC, or in Mosaiq/ARIA, with the indication "to restore function of Vascular Access Device". In the absence of eMM systems, the appropriate paper medication chart may be used.
Administration Instructions	Instillation & subsequent aspiration of alteplase **MUST** occur when appropriate personnel are available (e.g., during **business hours Monday – Friday 0800 – 1600hrs**) to ensure adequate support available. Alteplase should be left insitu for a dwell time of 120 minutes – ensure adequate time available to instil, dwell & aspirate during business hours. Prior to administration: • Chest Xray (within 24hrs of planned instillation) to confirm tip position. • Prior to first dose, notify the appropriate CNC or Medical Officer and confirm that they have documented the indication for alteplase instillation and completion of relevant investigation. • Check patency by gently flushing the affected lumen with 0.9% Sodium Chloride prior to preparing alteplase.
Reconstitution	Aseptic non touch technique must be followed in preparation and administration of alteplase To reconstitute alteplase (Actilyse® Cathflo®) to a final concentration of 1mg/mL, the clinician needs to: 1. Aseptically draw up 2.2 mL of sterile water for injection, using a syringe with suitable measuring accuracy 2. Inject the 2.2 mL of sterile water for injection into the vial with Actilyse® Cathflo® powder. Slight foaming is not unusual; let the vial stand undisturbed to allow large bubbles to dissipate. 3. Mix by gently swirling until contents are completely dissolved. Complete dissolution should occur within 3 minutes. DO NOT SHAKE. The reconstituted solution appears clear and colourless to a slightly yellow solution. Before use, it should be visually checked for colour and the presence of particles. *Note: Alteplase (Actilyse® Cathflo®) contains no antibacterial preservatives. It is stable for 8 hours after reconstitution at temperatures up to 25°C, ideally it should be reconstituted immediately before use.* **No other medication should be added to solutions containing Actilyse® Cathflo®.** If using another formulation of alteplase, refer to the Australian Injectable Drug Handbook for information on reconstitution.

Instillation	Unless specified by the treating Medical Officer, all infusions should be stopped, especially with multi lumen Vascular Access Device to optimise thrombolysis during the dwell time by facilitating maximum contact between the thrombolytic agent and the thrombus on the internal catheter lumen and external catheter surface at or near the tip. Alteplase is incompatible with heparin, bivalirudin or sodium citrate. If these are used as infusions or CVAD locks, the solution must be aspirated from the CVAD and flushed with 10 mL sodium chloride 0.9%. For step-by-step procedure see: eviQ Clinical Procedure – restoring patency to a central venous access device (CVAD) – partial and complete occlusion. An instruction video is also available. When appropriate, staff are to remove the bung on the access device and administer alteplase directly on the clean (disinfected) hub.
Aspiration	1. Using aseptic technique, assess catheter patency after 30mins by attempting to aspirate 3 mL blood from lumen/s. If unable to aspirate after 30 mins, wait a further 90 mins, and then attempt to aspirate blood from lumen/s 2. If catheter function is restored, aspirate 5 mL of blood from each lumen and discard. 3. Gently flush the catheter with 20 mL 0.9% Sodium Chloride using a luer lock syringe and positive pressure lock or 10 mL 0.9% Sodium Chloride followed by a locking solution. Advise the appropriate CNC / Medical Officer of the outcome of the procedure.
Documentation	For **instillation**, documentation should include the following:- • Labelling lumen to note alteplase insitu • Time alteplase instilled into Vascular Access Device • Amount of alteplase instilled into Vascular Access Device lumen/s • Advice NOT TO USE Vascular Access Device for 120 mins • Planned time to aspirate alteplase from Vascular Access Device • Use of asepsis maintained throughout procedure For **aspiration**, documentation should include the following:- • Time of aspiration • Outcome of Vascular Access Device e.g., blood return & flow returned, additional dose required etc • Use of asepsis maintained throughout procedure • Plan for ongoing maintenance of Vascular Access Device
Monitoring requirements	Systemic absorption **may** occur, be alert for:- – Bleeding, including gastrointestinal bleeding and bruising – Hypersensitivity reaction. The patient should be monitored for adverse reactions such as fever, bleeding, bronchospasm, skin rash or changes in their vital signs.

Management of Complications	Should serious bleeding in a critical location (e.g., intracranial, gastrointestinal, retroperitoneal, pericardial) occur, treatment with alteplase should be stopped and the drug should be withdrawn from the catheter. If a severe hypersensitivity reaction occurs, the instillation should be discontinued and appropriate treatment should be promptly initiated.
Storage requirements	Alteplase (Actilyse® Cathflo®) contains no antibacterial preservatives. It is stable for 8 hours after reconstitution at temperatures up to 25°C, ideally it should be reconstituted immediately before use.
Additional Resources	Central venous access device (CVAD) patency algorithm. eviQ. Clinical Procedure – restoring patency to a central venous access device (CVAD) – partial and complete occlusion. eviQ
Basis of Protocol/Guideline: (including sources of evidence, references)	• https://www.cathflo.com/catheter-management/recognizing-occlusions.html • https://www.medicines.org.uk/emc/files/pil.4617.pdf • HNELHN GandP 11_01 Management of Blocked Central Catheters using Alteplase - Adult • ISLHD CLIN PROC 29 Central Venous Access Devices Management • WSYD-PROC201891 The Use of Alteplase for Thrombolysis of Venous Access Devices in Adults
Groups consulted in development of this guideline	Vascular Access, Haematology, Oncology, Intensive Care, Neurosurgery

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GOVERNANCE	
Enactment date *Reviewed* (Version 2) *Reviewed* (Version 3)	October 2024
Expiry date:	31 October 2027
Ratification date by SESLHD DTC	3 October 2024
Chairperson, DTC	Dr John Shephard
Version Number	1.3