

Ventricular Assist Device Adverse Events

Pocket Reference Guide



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Adverse Events
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action



Hematologic

Neurological Dysfunction

Timing: Anytime during VAD support

Types:

- Ischemic stroke (with/without hemorrhagic conversion)
- Intracerebral (blood inside brain) hemorrhage
- Extra-axial (blood around the brain) hemorrhage
- Undefined stroke type
- Hypoxic ischemic encephalopathy
- Other encephalopathy or neuropathy

Presentation:

- **Overt:** Clinical symptoms present
- **Covert:** Imaging only findings, no symptoms

Grades:

- 2: No change in management
- 3: Requires ≥ 1 of the following:
 - New antiepileptic medication
 - Holding antithrombotics >24 hrs
 - Change in transplant listing
- 4: Neurosurgical or interventional procedure required

Bleeding

Timing:

- Grade 4: Anytime during VAD support
- Grades 2–3: Identified ≥ 72 hours after VAD procedure

Locations: GI, Oral/Nasal, Pleural, Pericardial, Pulmonary, GU, Cannula, Retroperitoneal, Other

Grades:

- 2: Local packing/cautery/hemostatics
- 3: PRBC transfusion, new drain, or anticoagulation held >24 hrs
- 4: Invasive procedure to control bleed



Hematologic

Hemolysis

Timing: Anytime during VAD support

Criteria: (any on 2 separate labs):

- Plasma Free Hgb >50 mg/dL
- LDH >3 \times upper limit of normal (no other cause)
- Moderate or greater hemolyzed cells (not from transfusion)

Grades:

- 2: Isolated lab criteria without other clinical findings
- 3: Lab findings + PRBC transfusion or external device component exchange
- 4: Lab findings + internal component exchange or AKI requiring RRT



Device Related

Pump Thrombosis

Timing: Anytime during VAD support

Types:

- **Paracorporeal:** External component exchanged due to thrombus/fibrin
- **Intracorporeal:** If pump changed due to two of the following:
 - abnormal device function
 - embolism or confirmed thrombus
 - hemolysis

Grades:

- 2: No embolism; external component replaced
- 3: Embolism (e.g., stroke); external component replaced
- 4: Surgical or transcatheter internal device component replacement with or without embolism

Device Malfunction

Timing: Anytime during VAD support

Definition: Device not functioning to spec (not routine maintenance); include user error or accessory issues

Types: Mechanical, structural, functional, or elective concern-based replacement

Grades:

- 2: Device works; reset, power change, or external component fix (e.g. sound of membrane)
- 3: Not working, no symptoms; external or driveline repair
- 4: Not working + symptoms or internal component surgical replacement



Infection

Device-Specific Infections

Timing: Anytime during VAD support

Types:

- **Superficial site:** Local signs, negative blood culture
- **Deep site:** Superficial + ≥ 2 systemic/infectious signs
- **Device bloodstream infection:** Positive culture + site/circuit involvement or persistent bacteremia
- **Sternal wound with mediastinal extension:** Involves components + local/systemic signs

Grades:

- 1: Dressing/topicals or systemic antibiotics <24 hrs
- 2: Enteral antibiotics >72 hrs, no systemic signs
- 3: IV/IM antibiotics >72 hrs or requires I&D, component exchange, or long-term therapy
- 4: Internal component exchange, invasive procedure, or ≥ 3 positive cultures over 7+ days requiring long-term therapy

Non-Device Related Infections

Timing: Anytime during VAD support

Types: URI/LRI, viral GE, pneumonia, UTI, sternal wound (non-mediastinal), central line, other

Grades:

- 1: Observation or antimicrobials <72 hrs
- 2: Admission or oral antibiotics ≥ 72 hrs
- 3: IV/IM antibiotics >72 hrs or fluids <40 mL/kg
- 4: IV/IM antibiotics + ≥ 40 mL/kg fluids, vasoactives, or surgery



Right Heart Dysfunction (Biventricular Circulation Only)

Timing: Anytime post-op if ECMO or RVAD used.
If medically managed, ≥ 10 days post-op.

Criteria (with functioning LVAD):

One of each:

- **Hemodynamics:** CVP > 14 mmHg, congestion, CO $< 50\%$ (non-responsive to changes)
- **Imaging:** Mod/severe TR, RV dysfunction

OR

ECMO or RVAD placement at anytime

Grades:

- 3: Vasoactives, invasive drainage, or prolonged drain use
- 4: ECMO or RVAD placement

Renal Dysfunction

Timing: Anytime during VAD support

Criteria: Abnormal creatinine or eGFR (Cystatin C, Schwartz, or CKiD) on 2 consecutive labs

Grades:

- 2: Creatinine 2–3 \times baseline* or eGFR 35–60 mL/min
- 3: Creatinine $\geq 3\times$ baseline* or eGFR < 35 mL/min
- 4: New need for RRT

*Baseline = last pre-index creatinine

Hepatic Dysfunction

Timing: Anytime during VAD support

Criteria (≥ 2 on 2 labs):

- Total bili $> 3\times$ upper limit of normal or baseline
- INR > 3 (non-med related)
- AST/ALT $> 3\times$ upper limit of normal or baseline
- Hepatic encephalopathy (neuro dx)

Grades:

- 2: Meets lab criteria
- 3: Lab criteria + encephalopathy or coagulopathy from liver disease
- 4: Encephalopathy requiring ventilation or MARS

Respiratory Dysfunction

Timing: > 10 days post-op. Anytime when ECMO, oxygenator, or trach needed

Definition: New need for PPV (invasive or non-invasive) or MCS (e.g., ECMO, oxygenator) due to impaired respiratory function unrelated to diagnostic/therapeutic procedures

Grades:

- 2: New non-invasive PPV (BiPAP/CPAP, not pre-VAD)
- 3: > 24 hrs invasive PPV (ETT/trach; not procedural)
- 4: ECMO, oxygenator, or new tracheostomy

Vasoplegia

Timing: Within 72 hrs post VAD implant

Definition: Low SVR, normal/high CI (> 2.4), no other cause, + end-organ dysfunction

Grades:

- 3: Requires ≥ 3 vasoconstrictors
- 4: ≥ 3 vasoconstrictors + ECMO or surgery for necrosis

Feeding Intolerance

Timing: > 10 days post VAD procedure

Definition: Inability to meet caloric goals enterally (excludes pre-existing GI issues)

Grades:

- 2: Enteral + TPN/IL to meet goals
- 3: TPN/IL dependent, no enteral intake
- 4: TPN/IL dependent + cholestasis or no viable feeding route

Chylothorax

Timing: Any time post-index procedure

Definition: Pleural/peritoneal effusion with:

- TG > 110 mg/dL, or
- Pleural TG $>$ serum TG, or
- $\geq 80\%$ lymphocytes in pleural fluid

Grades:

- 2: NPO > 72 hrs
- 3: NPO + medical therapy (e.g., Octreotide) and/or chest tube placement
- 4: Requires surgery

Necrotizing Enterocolitis (NEC)

Timing: Anytime during VAD support

Definition: Meets Modified Bell Criteria with:

- **Imaging:** Dilation, pneumatosis, pneumoperitoneum, portal gas
- ≥ 2 **clinical signs:** Temp instability, brady/apnea, bloody stool, distension, or thrombocytopenia

Grades:

- 3: Medical management (e.g., antibiotics, NPO > 72 hrs)
- 4: Requires surgery

Inadequate Hemodynamics After VAD

Timing: ≥ 10 days post-implant or earlier if death due to inadequate support.

Definition: Inadequate perfusion or congestion despite functioning VAD with:

- Continued vasoactives and ≥ 2 organ dysfunctions (respiratory, hepatic, renal, feeding), or

Grades:

- 3: Organ dysfunction (labratory only), stabilized with vasoactive support
- 4: Organ replacement therapy (e.g., RRT, TPN, ventilation)

Fontan Venous Failure After SVAD

Timing: Anytime post-op with ECMO or Fontan VAD or if medically managed only, ≥ 10 days post-op

Criteria (with functioning systemic VAD):

Inadequate SVAD preload (no response to VAD changes):

- Worsening effusions, ascites, lymphatic failure > 10 days post op
- ECMO for RV failure anytime
- Fontan VAD placement anytime

Grades:

- 2: Effusions < 25 mL/kg/day for > 3 days
- 3: Effusions > 25 mL/kg/day for > 3 days
- 4: ECMO or Fontan VAD placed

Arrhythmia

Timing: Anytime during VAD support

Definition: Clinically significant arrhythmia requiring treatment beyond PO meds/temporary pacing

Grades:

- 3: Requires IV therapy
- 4: Requires cardioversion, ICD, pacemaker, or ablation

Vascular Injury

Timing: Anytime during VAD support

Definition: Injury from percutaneous cannulation

Types: Perforation, pneumothorax, pseudoaneurysm, AV fistula, thrombosis, dissection, stenosis, bleeding, limb ischemia

Grades:

- 3: No intervention/surgery required
- 4: Requires intervention or results in limb/digit loss