

**Hospital Clinical Guidelines  
EVIDENCE TABLE**

**GUIDELINE TOPIC: Long Term Ventricular Assist Device (VAD) Anticoagulation.**

Please record all references used in developing the clinical guideline. This form must be filled out electronically and emailed to [Jody.Smith@rch.org.au](mailto:Jody.Smith@rch.org.au)

NB: If you need assistance with completing this table, please contact Jody Smith on x 6956.

<b>Reference (include title, author, journal title, year of publication, volume and issue, pages)</b>	<b>Method</b>	<b>Evidence level (I-V)</b>	<b>Summary of recommendation from this reference (point form)</b>
<p>Hetzer R., Potapov E V., Stiller B., Weng Y., Hubler M., Lemmer J., Alesi-Meskeshvili V., Redlin M., Merkle F., Kaufmann F., &amp; Hennig E. (2006) <u>Improvement in Survival After Mechanical Circulatory Support With Pneumatic Pulsatile Ventricular Assist Devices in Pediatric Patients</u> The Annals of Thoracic Surgery, 82 (3) p.917-925.</p>	Comparative	III-3	<ul style="list-style-type: none"> <li>• Close anticoagulation monitoring with aPTT instead of ACT in the early post-operative period</li> <li>• TEG to identify anticoagulation status</li> <li>• Antithrombin III substituted in &lt; 70%</li> </ul>
<p>Potapov E V., Stiller B., &amp; Hetzer R. (2007) <u>Ventricular assist devices in children: Current achievements and future perspectives</u> Pediatric Transplantation, 11 p. 241-255.</p>	Case series	IV	<ul style="list-style-type: none"> <li>• Anticoagulation monitoring with aPTT instead of ACT</li> <li>• Monitor antithrombin III and substitute if &lt; 70%</li> <li>• After treatment with aspirin and dipyridamole, platelet aggregation tests on a weekly basis with target activation of 30%</li> </ul>

<p>Stiller B., Lemmer J., Schubert S., Ewer P., Schulze-Neick I., Hubler M., Redlin M., Berger F., &amp; Hetzer R. (2006) <u>Management of Pediatric Patients After Implantation of the Berlin Heart EXCOR Ventricular Assist Device</u> American Society of Artificial Internal Organs.</p>	<p>Case series</p>	<p>IV</p>	<ul style="list-style-type: none"> <li>• 0-8 hours post-operative, no anticoagulation</li> <li>• 8-12 hours if still bleeding, no anticoagulation</li> <li>• 8-12 hours if no bleeding, 400-600 units Heparin/kg/day continuous infusion</li> <li>• Aim for aPTT 60-90 seconds</li> <li>• Long-term anticoagulation-if there are no complications and the patient is stable, warfarin administration may be commenced , combined with aspirin plus dipyridamole</li> </ul>
<p>Berlin Heart AG (2004) Berlin Heart Excor VAD with Stationary Driving Unit Iku Instructions for Use, version 4.7</p>	<p>Product Information</p>	<p>V</p>	<ul style="list-style-type: none"> <li>• The patient must be given anti-coagulation treatment. In addition, platelet-aggregation inhibition treatment is required</li> <li>• The Heparin dose would be adjusted with the aid of an aPTT. The aPTT should be between 70s and 90s. Examination intervals should not exceed 6 hours.</li> <li>• Administer aprotinin infusion after conclusion of surgery and in the first 6 hours after the operation</li> <li>• 6 hours after the operation: start administering heparin</li> <li>• IPT: 5 to 15 as determined by thromboelastography</li> </ul>
<p>San Vincenzo Hospital, Taormina, Italy Cardiac Surgery Unit &amp; Intensive Care Unit</p>	<p>VAD anticoagulation regime</p>	<p>V</p>	<ul style="list-style-type: none"> <li>• Check TEG and Antithrombin III levels</li> </ul>
<p>Stollery Children's Hospital, Edmonton, Alberta, Canada <u>Edmonton Anticoagulation and Platelet Inhibition Protocol</u>©</p>	<p>Hospital Protocol</p>	<p>V</p>	<ul style="list-style-type: none"> <li>• If the antithrombin is &lt;70%, administer Antithrombin concentrate</li> <li>• Until the target INR is achieved, simultaneous administration of warfarin and heparin is necessary</li> <li>• If the INR decreases to <math>\leq 2.7</math>, administer LMW heparin</li> </ul>

<p>Thoratec (2006) Instructions for Use</p>	<p>Product Information</p>	<p>V</p>	<ul style="list-style-type: none"> <li>• Once the chest tube drainage falls to about 50ml/hr for 2 to 3 hours, anticoagulants should be considered to minimize the risk of thromboembolism</li> <li>• Heparin infusion on the first or second post-operative day at a dosage of approximately 10 units/kg/hr.</li> </ul>
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Level of Evidence  
Clinical Guidelines  
Royal Children's Hospital

### The Hierarchy of Evidence

**The Hierarchy of evidence is based on the National Health and Medical Research Council (2000) and Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)**

- I** Evidence obtained from a systematic review of all relevant randomised control trials.
- II** Evidence obtained from at least one properly designed randomised control trial.
- III-1** Evidence obtained from well-designed pseudo-randomised controlled trials (alternative allocation or some other method).
- III-2** Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case control studies, or interrupted time series with a control group.
- III-3** Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.
- IV** Evidence obtained from case-series, either post-test or pre-test and post test.
- V** Expert opinion without critical appraisal, or based on physiology, bench research, or historically based clinical principles.

Clinical guidelines are based on reviews of the best available evidence. **Level 1 evidence represents the gold standard for intervention studies;** however it is not available for all areas of practice and for some guidelines it may be appropriate to utilise results from studies with lower levels of evidence. Some clinical guidelines may also be informed by experts in the field, locally (RCH) and internationally (Journal articles) (expert opinion) etc. This NHMRC Hierarchy can be used to grade evidence. Please record details on the evidence table and return to Clinical Quality and Safety (CQS) with guideline draft. The Evidence table can be filled out electronically or printed and used as a hard copy.

*Please contact Jody Smith Clinical Guideline and Path Coordinator on ext 6956 if you have any concerns or require assistance.*