# Anticoagulation of Prosthetic Valves – Guideline

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1. **Overview**  (What is this policy about?)

This guideline is for use by all staff who manage patients with prosthetic heart valves, including information on: target INR; addition of antiplatelet therapy to oral anticoagulation; interruption of oral anticoagulation therapy (OAC) for non-cardiac surgery, invasive procedures or dental care; and management of prosthetic valve thrombosis.

The guideline has been based upon the European Society of Cardiology Guidelines (2007) and American College of Cardiology/American Heart Association Guidelines (2008) on Management of Patients with Valvular Heart Disease.

Clinical judgement should be exercised at all times, however reasons for deviation from the guidelines should be documented fully in patients’ notes.

2. **Scope**  (Where will this document be used?)

Which staff groups need to have a good working knowledge of this policy?

Does the policy apply to all staff or only to specific departments?

- All staff

Does it apply to children as well as adults?

- Yes

Is it relevant to community services as well as hospital services?

- Yes

**Associated Documents**

- Anticoagulation Guidelines: Anticoagulation Prescribing Principles
- Anticoagulation Guidelines: Warfarin Dosing
- Anticoagulation Guidelines: Rapid Reversal of Anticoagulation

3. **Background**  (Why is this document important?)

Important and necessary on order to ensure patients with prosthetic valves have optimal anticoagulation in order to prevent valve thrombosis and to ensure safe perioperative management of anticoagulation in these patients.

4. **What is new in this version?**

No changes made
5. Protocol

5.1 Introduction

Antithrombotic management should encompass the effective management of risk factors for thrombo-embolism in addition to the prescription of antithrombotic drugs.

Type and duration of anticoagulation for patients with prosthetic valves depends on:

- type of prosthesis
- medical comorbidities
- cardiac function
- patient-related factors

Mechanical valves

- all require long-term oral anticoagulation with warfarin or sinthrome (OAC)

Tissue (biological) valves

- less thrombogenic than mechanical valves and do not require long-term anticoagulation unless there are other indications, e.g. persistent atrial fibrillation.

- warfarin or sinthrome for the first 3 months after insertion with target INR of 2.0 – 3.0. Some cardiothoracic centres use aspirin 75 mg od as an alternative to anticoagulation for the first 3 months after bioprosthetic valve implantation.

- warfarin or sinthrome longterm for patients with bioprostheses who have other indications for anticoagulation, e.g. atrial fibrillation

For mechanical or tissue valves, the first postoperative month is a particularly high-risk period for thrombo-embolism, and particular care should be taken to avoid INR being lower than the target value during this period - anticoagulation should be monitored more frequently

5.2 Target INR

The target INR takes into account patient risk factors and the thrombogenicity of the prosthetic valve:

Antithrombotic therapy – mechanical prosthetic valves

<table>
<thead>
<tr>
<th>Valve Type</th>
<th>INR 2.0 – 3.0</th>
<th>INR 2.5 – 3.5</th>
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<tbody>
<tr>
<td>AVR low risk</td>
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<tr>
<td>AVR high risk</td>
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<tr>
<td>MVR</td>
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AVR – aortic valve replacement
MVR – mitral valve replacement
Prosthetic valve thrombogenicity:

**Low thrombogenicity:**

- Carbomedics bileaflet
- Medtronic Hall tilting disc
- Bjork-Shiley tilting disc
- St Jude bileaflet

**High thrombogenicity:**

- Lillehei-Kaster tilting disc
- Omniscience tilting disc
- Starr-Edwards ball & cage

2.2 Patient-related factors increasing risk:

- mitral, tricuspid, or pulmonary valve replacement
- previous thrombo-embolism
- atrial fibrillation
- left atrial diameter >50 mm
- left atrial dense spontaneous echo contrast
- mitral stenosis of any degree
- LVEF <35%
- hypercoagulable state

5.3 Addition of antiplatelet therapy to oral anticoagulation:

- When added to anticoagulation, antiplatelet drugs increase the risk of major bleeding.
- Reserve for specific indications, according to the analysis of the benefit and increased risk of major bleeding
- Usually aspirin not recommended with warfarin even if known CAD. Important exceptions include recent coronary artery stenting.
Indications:

- **concomitant arterial disease** - coronary and other significant atherosclerotic disease e.g. myocardial infarction, thrombotic stroke

- **intracoronary stenting** - dual antiplatelet therapy, DAPT (aspirin + clopidogrel; aspirin + prasugrel; aspirin + ticagrelor) is necessary but increases bleeding risk.
  - Use of drug-eluting stents (DES) should be avoided if possible in patients with mechanical prostheses to allow for a shorter period of triple antiplatelet/antithrombotic therapy.
  - Weekly monitoring of INR
  - Any over-anticoagulation must be avoided
  - Consider PPI and try to avoid NSAIDs.

DES – DAPT required for 12 months

BMS (bare metal stent) – DAPT for at least 1 month

Genous stent – DAPT for at least 1 week

Definite embolic episode with adequate INR:

Options are to increase target INR and/or add antiplatelet therapy as follows:

- **Target INR 2.0 to 3.0**: increase target INR to 2.5 to 3.5
- **Target INR 2.5 to 3.5**: increase target INR to 3.5 to 4.5

  or

- If not taking aspirin: add aspirin 75mg od
- OAC plus aspirin 75mg od: consider increasing aspirin to 300 mg per day if increased target INR has not prevented recurrence of embolic events.
- Aspirin alone: consider increasing to 300 mg od or adding clopidogrel 75 mg od and/or adding OAC.
- Consider looking for other causes of cardioembolism eg PFO/ASD, consider left atrial occluder device if left atrial appendage thrombus found.

Liaise closely with cardiology in all patients who require antiplatelet therapy + OAC

5.4 **Interruption of OAC therapy for non-cardiac surgery, invasive procedures, or dental care**

4.1 **low risk of thrombosis**

- bileaflet mechanical AVR with no risk factors
- stop OAC 48 to 72h before the procedure (until INR falls to <1.5)
• restart within 24h after the procedure
• heparin is unnecessary

4.2 high risk of thrombosis

• mechanical MVR
• mechanical tricuspid valve replacement
• mechanical AVR with any risk factor
• pulmonary valve replacement

• stop OAC 48 to 72h before the procedure (until INR falls to <2.0)
• start therapeutic tinzaparin when INR <2.0, reduce dose as per anticoagulation guideline if renal impairment
• omit tinzaparin 24h before the procedure
• restart tinzaparin as early after surgery as bleeding stability allows, and continued until the INR is again therapeutic with OAC

Antithrombotic therapy should not be stopped for procedures in which bleeding is unlikely or would be inconsequential if it occurred:

e.g. skin surgery
dental cleaning
simple treatment for dental caries

Cardiac catheterisation

• Femoral arterial puncture can be performed with an INR <1.5
• If patient is high risk for thrombosis, give bridging heparin as in 4.2
• If a higher target INR or heparin is needed, radial approach is recommended and the radial artery approach can be used for diagnostic coronary angiography without need for interruption of OAC.

5.5 Management of Valve Thrombosis

5.1 Obstructive valve thrombosis

In all cases of suspected or possible valve thrombosis, liaise closely with cardiology

• Valve thrombosis should be suspected in any patient with any type of prosthetic valve who presents with a recent increase in shortness of breath or embolic event.

• Suspicion should be higher if there has been recent inadequate anticoagulation or a cause for increased coagulability (e.g. dehydration, infection).

• Patient may have stopped hearing valve clicks. On examination the mechanical prosthetic sound may be muffled, absent or intermittent and there may be signs of cardiac failure.

• The diagnosis should be confirmed by transthoracic echocardiography and transoesophageal echocardiography (TOE).
Liaise closely with Cardiology in all cases of suspected or possible prosthetic valve thrombosis.

Algorithm for management of obstructive valve thrombosis:¹

- **Suspicion of thrombosis**
  - Echo (TTE + TEE)/fluoroscopy
  - Obstructive thrombus
  - Critically ill

  **Yes**
  - Surgery immediately available

  **No**
  - Recent inadequate anticoagulation
    - **Yes**
      - Heparin + aspirin
        - Success
          - Fibrinolysis* + Follow-up
        - Failure
          - High risk for surgery
            - **Yes**
              - Surgery*
            - **No**
              - Fibrinolysis*
    - **No**
      - Fibrinolysis*
      - Follow-up

- TTE = transthoracic echocardiography
- TEE = transesophageal echocardiography
- *Risk and benefits of both treatments should be individualized. The presence of a first-generation prosthesis is an incentive to surgery.

In patients with thrombus <10mm who are in NYHA functional class I or II, treatment with short-term LMWH should be considered.

**There should be at least daily clinical and echocardiographic assessment.**

**Fibrinolysis should be considered in:**

- Critically ill patients unlikely to survive surgery because of comorbidities or severely impaired cardiac function prior to developing valve thrombosis.
- Situations in which surgery is not immediately available and the patient cannot be transferred.
- Thrombosis of tricuspid or pulmonary valve replacements, because of the higher success rate and low incidence of embolism.

**Fibrinolysis is less likely to be successful in:**

- mitral prostheses
- chronic thrombosis
- in the presence of pannus, which can be difficult to distinguish from thrombus
Fibrinolysis:

Tenecteplase - intravenous injection over 10 seconds; 30–50 mg according to body-weight.
Consider risk-benefit and warn the patient of the potential risk of intracranial haemorrhage and cerebral/peripheral embolism (12 – 15%).

Factors identifying patients at risk for adverse outcomes of fibrinolytic therapy are:
- active internal bleeding
- history of hemorrhagic stroke
- recent cranial trauma or neoplasm
- diabetic haemorrhagic retinopathy
- large thrombi, mobile thrombi
- hypertension (> 200/120mmHg),
- hypotension or shock
- NYHA functional class III–IV

If fibrinolytic therapy is successful, follow with therapeutic LMWH until OAC achieves
- INR 3.0 to 4.0 for AVR
- INR 3.5 to 4.5 for MVR

If fibrinolytic therapy is *partially* successful, may be followed by a combination of therapeutic LMWH twice daily plus warfarin (INR 2.5 to 3.5) for 3-months.

5.2 Non-obstructive valve thrombosis

- diagnosed with TOE performed after an embolic event
- management depends on the occurrence of thrombo-embolic event and the size of the thrombus.
- Close monitoring by echocardiography is mandatory.

The prognosis is favourable with medical therapy in most cases of small thrombus (<10 mm).

A good response with gradual resolution of the thrombus obviates the need for either surgery or fibrinolysis.

Surgery is recommended for large (≥10 mm) non-obstructive prosthetic thrombus complicated by embolism or which persists despite optimal anticoagulation.
Algorithm for management of non-obstructive valve thrombosis:¹

Fibrinolysis:

May be considered as an alternative if surgery is high risk. Consider the risk – benefit analysis carefully in use of thrombolysis for non-obstructive prosthetic thrombosis.

If fibrinolytic therapy, combined LMWH/fibrinolytic therapy, or combined LMWH/OAC is successful, increase OAC until INR
- 3.0 - 4.0 for AVR
- 3.5 and 4.5 for MVR

If fibrinolytic therapy is unsuccessful, in *haemodynamically stable patients* consider therapeutic LMWH plus OAC (INR 2.5 - 3.5) for 1 to 3 months

Liaise closely with Cardiology in all cases of suspected or possible prosthetic valve thrombosis.
6. Roles & responsibilities

6.1 Role 1
Anaesthetic team – planning of pre-operative anticoagulation

6.2 Role 2
Surgical team – planning of recommencement of anticoagulation post-operatively

7. Monitoring document effectiveness

The policy will be reviewed in Cardiology Clinical Governance. The management prosthetic valve anticoagulation will be audited after the introduction of the guideline.

8. Abbreviations and definitions

OAC – oral anticoagulant (refers to warfarin or sinthrome)
AVR – aortic valve replacement
MVR – mitral valve replacement
Tissue (bioprosthetic) valve – porcine or bovine valve (non-mechanical)
DAPT - (aspirin + clopidogrel; aspirin + prasugrel; aspirin + ticagrelor)
DES – drug-eluting stent
BMS - bare metal stent
Genous stent – bio-engineered coronary stent coated with monoclonal antibodies
PFO – patent foramen ovale
ASD – atrial septal defect
TOE – transoesophageal echocardiogram
NYHA – New York Heart Association

9. References


10. Appendices

- N/A
11. Document Control Information

All sections must be completed by the author prior to submission for approval

<table>
<thead>
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<th>Lead Author:</th>
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<th>Name of person or group</th>
<th>Role / Department / Committee (Care Org)</th>
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<tbody>
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<td>Peter Woolfson</td>
<td>Clinical Lead, Cardiology; Salford Royal Care Organisation</td>
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<td>07/02/2019</td>
</tr>
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<td>Endorsement</td>
<td>Name of person or group</td>
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<tr>
<td>Pete Turkington</td>
<td>Chair Clinical Effective Committee</td>
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<td>13/11/2018</td>
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<td>prosthetic valves, anticoagulation</td>
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<td>Communication plan:</td>
<td>Guideline will be implemented by the Cardiology consultant team, who will take responsibility for informing other doctors in the team. Progress will be reviewed by the Cardiology Clinical Governance meeting. Policy will be available on Synapse, on HCU, L3, EAU, A&amp;E and ITU. New starting medical staff will be informed of the existence of the guideline in their induction packs.</td>
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<td>Clinical Effectiveness Committee</td>
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<td>Chairperson: Pete Turkington</td>
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<td>Approval date: 13/11/2018</td>
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<td>Formal Committee decision</td>
<td>Chairperson’s approval X</td>
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12. **Equality Impact Assessment (EqIA) screening tool**

Legislation requires that our documents consider the potential to affect groups differently, and eliminate or minimise this where possible. This process helps to reduce health inequalities by identifying where steps can be taken to ensure the same access, experience and outcomes are achieved across all groups of people. This may require you to do things differently for some groups to reduce any potential differences.

1a) Have you undertaken any consultation/involvement with service users, staff or other groups in relation to this document? If yes, specify what.

1b) Have any amendments been made as a result? If yes, specify what.

no

2) Does this policy have the potential to affect any of the groups listed below differently?

*Place an X in the appropriate box: Yes, No or Unsure*

This may be linked to access, how the process/procedure is experienced, and/or intended outcomes. Prompts for consideration are provided, but are not an exhaustive list.

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<td><strong>Age</strong> (e.g. are specific age groups excluded? Would the same process affect age groups in different ways?)</td>
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<td><strong>Sex</strong> (e.g. is gender neutral language used in the way the policy or information leaflet is written?)</td>
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<td><strong>Race</strong> (e.g. any specific needs identified for certain groups such as dress, diet, individual care needs? Are interpretation and translation services required and do staff know how to book these?)</td>
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<td><strong>Religion &amp; Belief</strong> (e.g. Jehovah Witness stance on blood transfusions; dietary needs that may conflict with medication offered.)</td>
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<td><strong>Sexual orientation</strong> (e.g. is inclusive language used? Are there different access/prevalence rates?)</td>
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<td><strong>Pregnancy &amp; Maternity</strong> (e.g. are procedures suitable for pregnant and/or breastfeeding women?)</td>
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<td><strong>Socio/economic</strong> (e.g. would there be any requirement or expectation that may not be able to be met by those on low or limited income, such as costs incurred?)</td>
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<td><strong>Disability</strong> (e.g. are information/questionnaires/consent forms available in different formats upon request? Are waiting areas suitable?) Includes hearing and/or visual impairments, physical disability, neurodevelopmental impairments e.g. autism, mental health conditions, and long term conditions e.g. cancer.</td>
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Are there any adjustments that need to be made to ensure that people with disabilities have the same access to and outcomes from the service or employment activities as those without disabilities? (e.g. allow extra time for appointments, allow advocates to be present in the room, having access to visual aids, removing requirement to wait in unsuitable environments, etc.)

| X |

3) Where you have identified that there are potential differences, what steps have you taken to mitigate these?
N/A

4) Where you have identified adjustments would need to be made for those with disabilities, what action has been taken?
N/A

Will this policy require a full impact assessment? No
(a full impact assessment will be required if you are unsure of the potential to affect a group differently, or if you believe there is a potential for it to affect a group differently and do not know how to mitigate against this - Please contact the Inclusion and Equality team for advice on equality@pat.nhs.uk)

Author: Type/sign: Peter Woolfson Date: 07/01/2019
Sign off from Equality Champion: Date: