

# Anticoagulation Considerations for Choosing a Tissue or Mechanical Heart Valve



**Vitamin K antagonists such as warfarin are the recommended anticoagulation therapy for patients who have mechanical valves<sup>1</sup>**

- Non-vitamin K oral anticoagulants are not approved for patients who have mechanical valves<sup>1,2</sup>
- All major valvular heart disease (VHD) societal guidelines recommend lifelong therapy with vitamin K antagonists (VKAs), which, to be successful, require patient education and patient adherence to attain and maintain a therapeutic international normalized ratio (INR)<sup>1-4</sup>
- Vitamin K antagonists may not be appropriate for specific patient populations, as shown in the tables below

## Chronic warfarin therapy may not be appropriate for<sup>5</sup>:

- Women who are pregnant
- Noncompliant patients
- Patients undergoing or expecting procedures with the potential for uncontrolled bleeding
- Patients with lifestyles prone to injury or at high risk for falls
- Patients with cerebrovascular disease, gastrointestinal injury, or severe renal impairment

## Predictors of nonadherence to VKA therapy, such as warfarin, include<sup>6-7</sup>:

- Being single
- Education beyond high school
- Being disabled and 55 years of age or older
- Having to adhere to a drug regimen
- Not owning a vehicle for transportation
- Lower level of mental health functioning
- Poor cognitive functioning

The challenges of lifetime anticoagulant therapy for mechanical valve patients may include<sup>1</sup>:



more frequent physician visits



monitoring of INR with routine blood tests



dietary restrictions



medication interactions



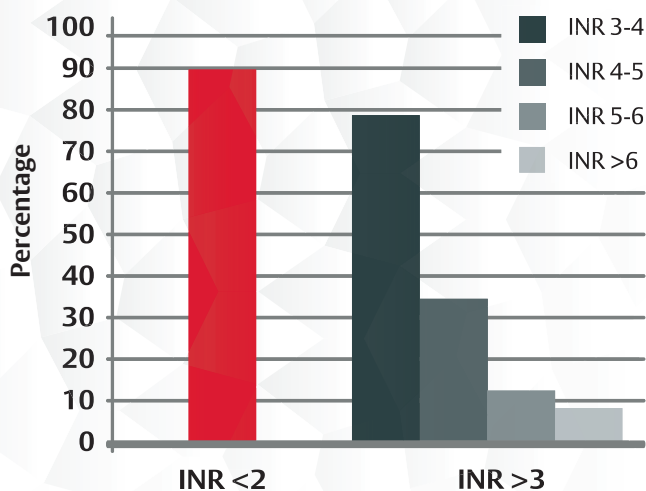
lifestyle and activity limitations

## Difficulty in achieving and sustaining goal INR<sup>1,5</sup>

The 2020 ACC/AHA VHD guidelines recommend an INR goal of 3.0 (2.5-3.5) for patients who have a mitral mechanical valve and for those who have an aortic mechanical valve and higher thromboembolic risk. For current-generation mechanical valves in the aortic position, an INR of 2.5 (2.0-3.0) is recommended. Maintaining a stable INR, however, is challenging for patients on VKA therapy. When the INR value is above the therapeutic range, patients are at a higher risk of major bleeding events, and when the INR value is below the therapeutic range, patients are at a higher risk of thrombotic events, such as stroke.

In a retrospective analysis of 9433 patients who had been using warfarin for more than 6 months (for a target INR of 2-3), 90% had at least one INR measurement lower than 2 and approximately 8% to 79% had at least one in the range of 3 to 6 or higher (Figure).

Figure: Percentage of patients with one or more INR values outside the normal therapeutic range\*



\*Analysis of CoagClinic™ database showing patients outside of the therapeutic range with either INR <2 or INR >3. Note that some patients could be represented in multiple categories depending on the INR levels achieved over time.

## However, tissue valves do not require lifelong anticoagulation<sup>1,2,4</sup>

United States and EU VHD guidelines recommend implantation of a tissue valve in patients who have a desire to avoid anticoagulation therapy, regardless of age.<sup>1-2</sup>

In addition, all major VHD societal guidelines recommend tissue valves when good-quality anticoagulation is unlikely to be achieved, owing to factors such as patient adherence, availability, previous major bleeding, comorbidities, unwillingness, lifestyle, and occupation.<sup>1,2,4</sup>

### Important Safety Information

#### Carpentier-Edwards PERIMOUNT Aortic Bioprostheses

**Indications:** For use in patients whose aortic valvular disease warrants replacement of their natural or previously placed prosthetic aortic valve.

**Contraindications:** Do not use if surgeon believes such would be contrary to the patient's best interests.

**Complications and Side Effects:** Stenosis, regurgitation, endocarditis, hemolysis, thromboembolism, valve thrombosis, nonstructural dysfunction, structural valve deterioration, anemia, arrhythmia, hemorrhage, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, angina, any of which could lead to reoperation, explantation, permanent disability, and death.

**CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician. See instructions for use for full prescribing information.**

#### References

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