INFECTIVE ENDOCARDITIS (IE) AFTER PERCUTANEOUS PULMONARY VALVE IMPLANTATION (PPVI)

Definition and Diagnosis

An infection of the endocardial surface(s) of the heart, which may include one or more heart valves, the mural endocardium, or a septal defect.

Diagnosis may be difficult, thus the development of diagnostic criteria.

The Duke criteria were developed for native valve endocarditis. Applicability to prosthetic valve endocarditis (including transcatheter valves) is questionable.

Patients with fever and a change of valve function (increased gradient or new Pulmonary Regurgitation (PR)) should be considered and treated as potential IE, even in the presence of negative blood cultures.

In the setting of Melody™ TPV IE, valve dysfunction can typically present as stenosis but regurgitation can also occur.

Diagnostics:

a. Blood cultures
b. TTE (not ideal for adult patients, patients with multiple operations, or multiple stents)
c. TEE (limited RVOT imaging)
d. Thoracic CT may be more specific/sensitive
e. ICE is most specific/sensitive
Minimizing Risk

Pre-implant

• Evaluation of all potential IE sources
  a. Skin
  b. Teeth and gums
  c. Other sources (i.e., ear, nose, and throat)
• Successfully treat any infections and complete any dental work prior to implant
• Educate patients appropriately regarding lifestyle risk factors and improve prior to implantation
  a. Personal hygiene
  b. Nail biting
  c. Piercing/tattoos
  d. IV drug abuse
  e. Chronic skin infection and/or scratch lesions (skin disease, neurosis)
• Educate patient appropriately on these possible increased risk factors:
  a. Congenital Heart Disease
  b. History of endocarditis
  c. Comorbidities
  d. Complex RVOT
  e. Male sex

Procedurally

• Catheter laboratories sterility must be appropriately maintained to the OR level.
• Ensure appropriate sterile attire of catheter laboratory staff (caps covering all hair, masks, shoe covers, etc.) during the entire procedure, from before the patient enters the room (as in OR setting).
• Always prepare valve on sterile table, just prior to implant (not in advance) and consider limiting the number of staff in the catheter laboratory during valve preparation.
• Meticulous preparation of the conduit/landing zone, prior to valve implantation (pre-dilation with high pressure balloons and/or pre-stenting, until conduit recoil is eliminated) in order to achieve the lowest possible residual RV-PA gradient.
• Utilize prophylactic IV antibiotics during and after the procedure.

Post-implant

• Educate patients, parents, guardians, referring physicians, and dentists on the risk of Endocarditis with implantation of a bioprosthetic valve.
  a. Best dental care post-PPVI
  b. Infection in skin lesions (acne, bug bites, ingrown toenails, etc.) should be avoided, if at all possible.
     If infections develop, they should be treated as quickly as possible.
  c. Lifelong antibiotic prophylaxis prior to any dental and invasive medical procedures
• Currently there is no consensus on aspirin protocol (various protocols are in use: from none given, to 6 months regimen, to lifelong)
Treatment Strategies

Management of patients with suspected IE after PPVI

Admit to hospital

Determine which presentation type

Hemodynamically stable

Early institution of appropriate broad spectrum IV antibiotics (4-6 weeks)\(^1\)

Close in-patient observation (serial evaluation of RVOT for obstruction as needed)

Antibiotic resistance: II
- Surgical RVOT replacement

Sterilization of blood

If residual valve dysfunction

Balloon dilation or stenting III

Valve-in-valve (second TPV) III

Early institution of appropriate broad spectrum IV antibiotics

Fulminant disease RVOT obstruction

Emergency relief of RVOT obstruction

Surgical RVOT replacement

If urgent surgery unavailable, catheter intervention: dilation and/or stent

Surgical RVOT replacement or valve-in-valve (second TPV)

\(^1\) Indications for urgent treatment in active phase:
- Heart failure
- Periannular complications (abcess, fistula)
- Persistent infection despite adequate antibiotics
- Prevention of pulmonary emboli when vegetation > 20 mm in adults

\(^2\) Antibiotic Resistance:
- Persisting fever
- Pulmonary emboli
- Septic
- Progression of obstruction

\(^3\) There is currently no consensus on treatment timing and various timing are in clinical use:
- Perform balloon dilation or stenting within 1 month of sterilization of blood
- Perform balloon dilation or stenting 3-6 months after sterilization; following an additional 2-3 months proceed to second TPV
- Perform balloon dilation within 1 year of initial IE followed by a second TPV over 1 year after complete sterilization of blood
- Some centers only consider surgery (versus catheter intervention) when replacement is indicated

Note: IE more aggressive with staph aureus infection
Caution

This information is provided as an educational resource based on an identified need, but is not intended to constitute medical advice or in any way replace the independent medical judgment of a trained and licensed physician with respect to any patient needs or circumstances. The physician is solely responsible for all decisions and medical judgments relating to the treatment of their patients. Factors, treatment, use, risks, and outcomes may vary. Please see the complete Instructions for Use for products discussed, including all product indications, contraindications, precautions, warnings, and adverse events.

References


**Melody™ Transcatheter Pulmonary Valve, Ensemble™ Transcatheter Valve Delivery System**

**Important Labeling Information for United States.**

**Indications:** The Melody TPV is indicated for use in the management of pediatric and adult patients who have a clinical indication for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic pulmonary valve that has ≥ moderate regurgitation, and/or a mean RVOT gradient ≥ 35 mm Hg.

**Contraindications:** None known.

**Warnings/Precautions/Side Effects**

- **DO NOT** implant in the aortic or mitral position. Preclinical bench testing of the Melody valve suggests that valve function and durability will be extremely limited when used in these locations.
- **DO NOT** use if patient’s anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22 Fr size introducer, or if there is significant obstruction of the central veins.
- **DO NOT** use if there are clinical or biological signs of infection, including active endocarditis. Standard medical and surgical care should be strongly considered in these circumstances.
- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.
- To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% of the nominal diameter (original implant size) of the conduit for pre-dilation of the intended site of deployment, or for deployment of the TPV.
- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV.
- If a stent fracture is detected, continued monitoring of the stent should be performed in conjunction with clinically appropriate hemodynamic assessment. In patients with stent fracture and significant associated RVOT obstruction or regurgitation, reintervention should be considered in accordance with usual clinical practice.

Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, blistering, or peeling of skin, pain, swelling, or bruising at the catheterization site.

Potential device-related adverse events that may occur following device implantation include the following: stent fracture,* stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

*The term “stent fracture” refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

For additional information, please refer to the Instructions for Use provided with the product.

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.
Indications: The Melody Transcatheter Pulmonary Valve is indicated for use in patients with the following clinical conditions:

- Patients with regurgitant prosthetic right ventricular outflow tract (RVOT) conduits or bioprostheses with a clinical indication for invasive or surgical intervention, OR
- Patients with stenotic prosthetic RVOT conduits or bioprostheses where the risk of worsening regurgitation is a relative contraindication to balloon dilatation or stenting.

Contraindications:

- Venous anatomy unable to accommodate a 22 Fr size introducer sheath
- Implantation of the TPV in the left heart
- RVOT unfavorable for good stent anchorage
- Severe RVOT obstruction, which cannot be dilated by balloon
- Obstruction of the central veins
- Clinical or biological signs of infection
- Active endocarditis
- Known allergy to aspirin or heparin
- Pregnancy

Potential Complications/Adverse Events:

Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, pain, swelling or bruising at the catheterization site.

Potential device-related adverse events that may occur following device implantation include the following: stent fracture, stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

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For additional information, please refer to the Instructions for Use provided with the product or available on http://manuals.medtronic.com.

The Melody Transcatheter Pulmonary Valve and Ensemble II Transcatheter Delivery System has received CE Mark approval and is available for distribution in Europe.