Medtronic

Melody™ Transcatheter Pulmonary Valve

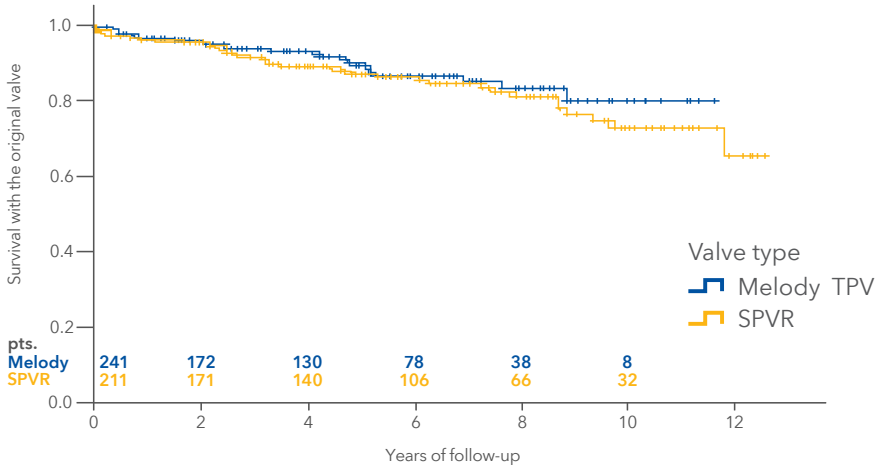
Unmatched Clinical Evidence: 12-Year Experience[1]

Melody™ TPV is clinically unmatched[1] and offers exceptional durability and stable long-term hemodynamic performance when compared to any other transcatheter valve. Backed by the largest body of clinical evidence at 12-years[1] and serving more than 19,000 patients since 2006 – it's the right choice for your patients.

Exceptional durability

Survival without reoperation. Compares favorably to surgery.[1]

Survival: Melody TPV versus SPVR[1]

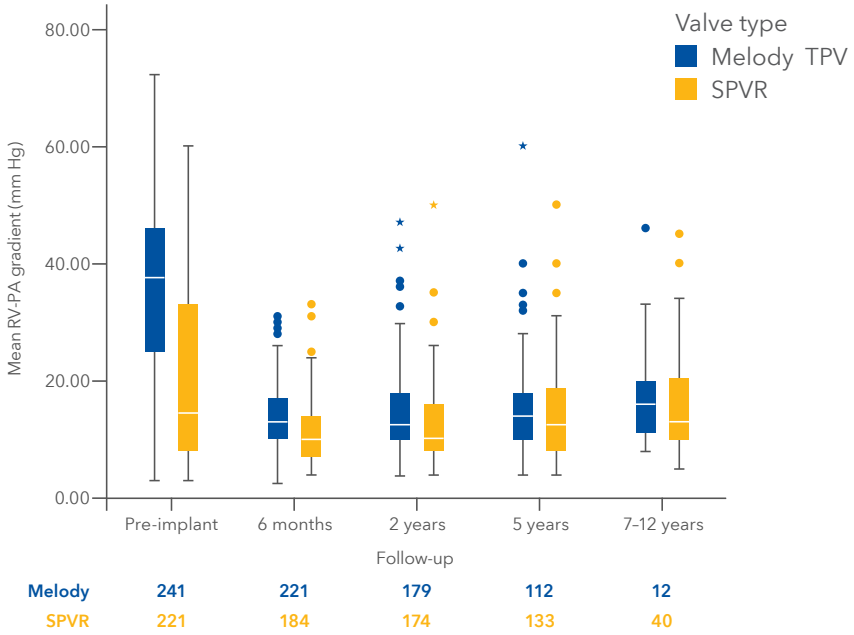


Stable valve dynamics

Helps delay surgical intervention in the majority of patients.

Consistent long-term stable valve function through 12 years (mean RVOT gradient < 20 mmHg)

Mean RV-PA gradient (mmHg)[1]



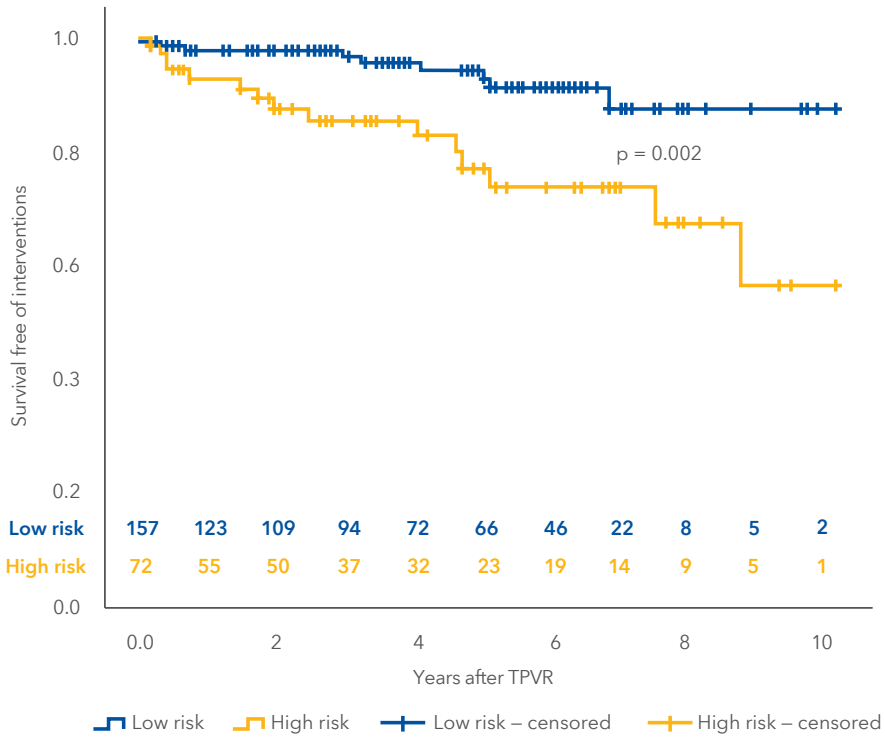
Most medical procedures have risks. The Melody TPV procedure's more serious risks include: valve dysfunction, stent fracture, and endocarditis.

Mitigates risk

Yields excellent outcomes long-term

Conduit preparation and ensuring minimal residual pressure gradient prior to PVI can reduce the risk of infective endocarditis.

Better survival after percutaneous pulmonary valve implant[2]



Low risk = pre-stenting + residual RV-PA gradient < 15 mmHg
High risk = other patients

Catch our new Melody™ TPV Unmatched video series

featuring
Prof. Peter Ewert, M.D.

Most medical procedures have risks. The Melody TPV procedure's more serious risks include: valve dysfunction, stent fracture, and endocarditis.

Reference

[1]Georgiev S, Ewert P, Eicken A, et al. Munich Comparative Study: Prospective Long-Term Outcome of the Transcatheter Melody Valve Versus Surgical Pulmonary Bioprosthesis With Up to 12 Years of Follow-Up. *Circ Cardiovasc Interv.* July 2020;13(7):e008963.

Melody™ Transcatheter Pulmonary Valve, Ensemble™ II Transcatheter Valve Delivery System
Important Labeling Information for the 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. Pre-clinical 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 or available on http://manuals.medtronic.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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