Medtronic

Raising the bar

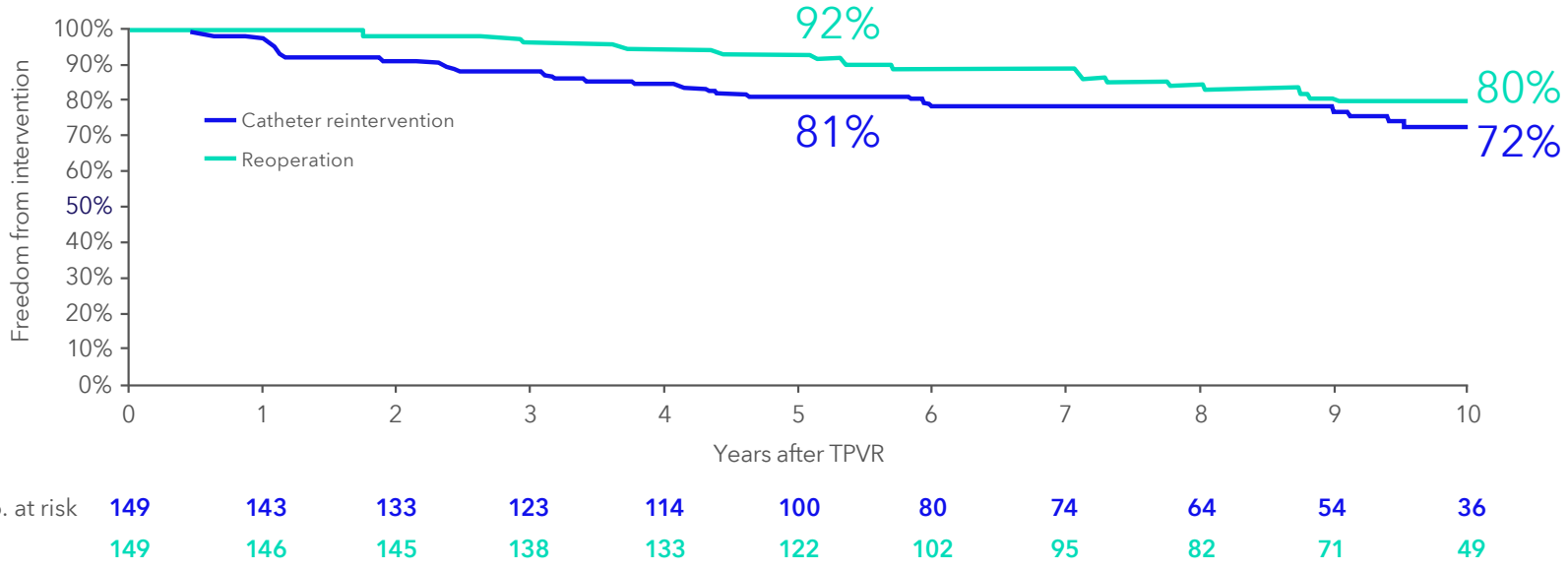
Unmatched clinical evidence by any other transcatheter valve on long-term durability and stable hemodynamic performance.

- Excellent valve durability
- Excellent hemodynamics
- Evolution of procedure
- Why we do what we do

Excellent valve durability

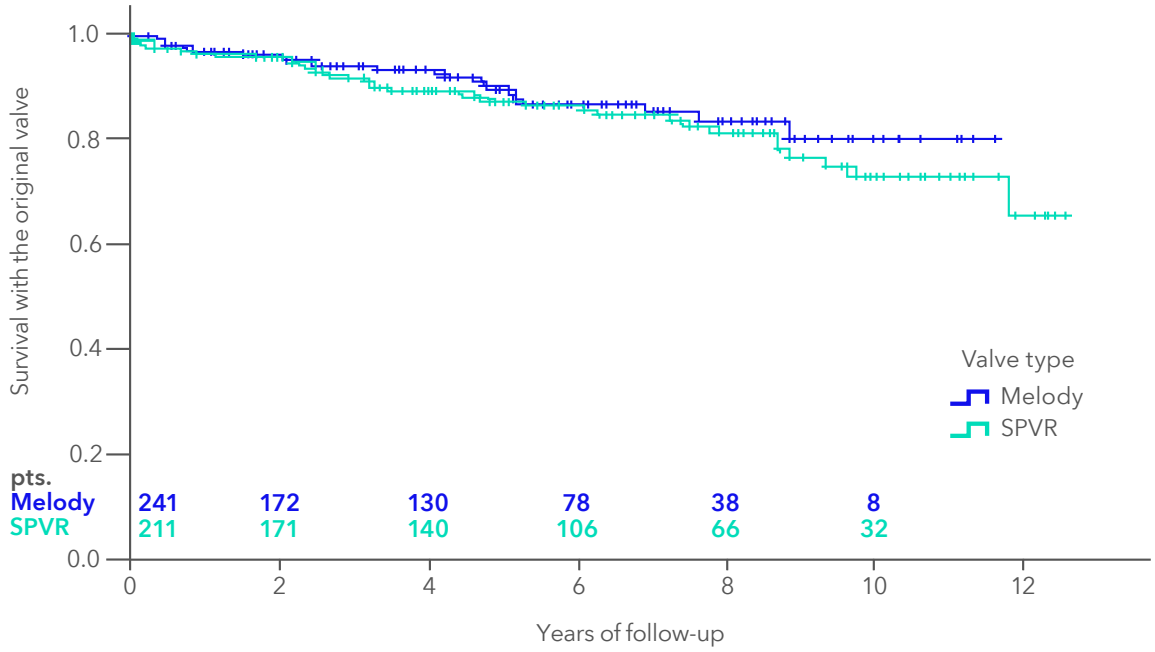
and a survival without reoperation rate comparable to surgery

Freedom from re-intervention[1]



No. at risk											
	149	143	133	123	114	100	80	74	64	54	36
	149	146	145	138	133	122	102	95	82	71	49

Survival: Melody™ versus SPVR[2]



Exceptional durability

Survival without reoperation. Compares favorably to surgery.

[1] Melody Transcatheter Pulmonary Valve Study: Post Approval at Study of the Original IDE Cohort.

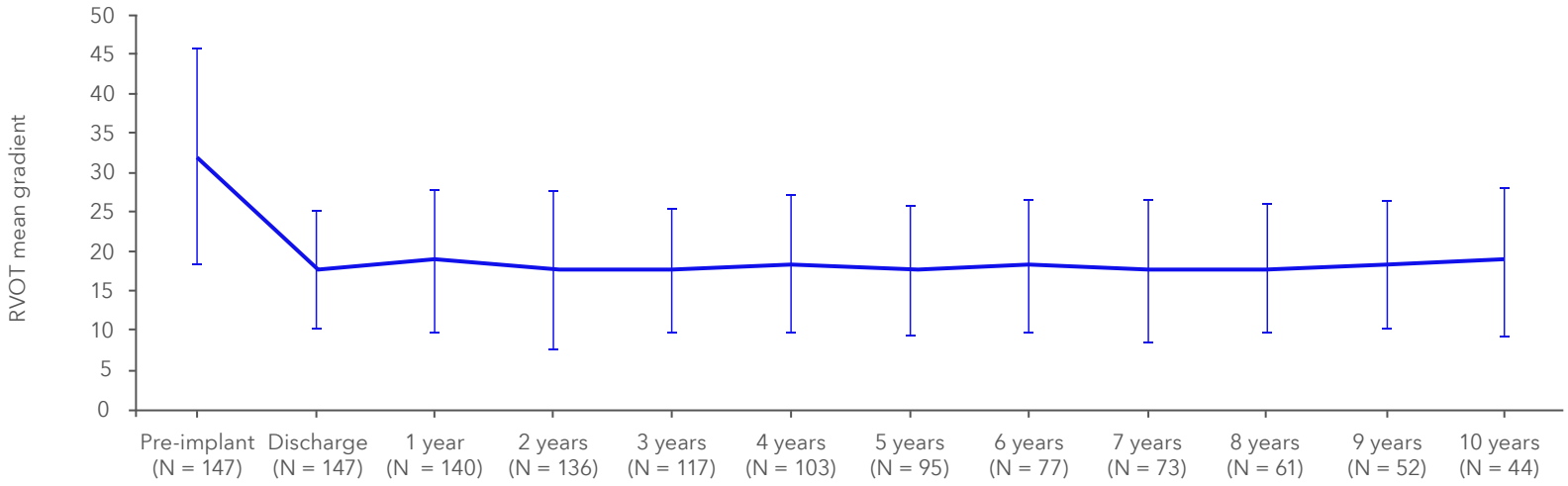
[2] Georgiev S, Ewert P, Eicken A, et al. Munich Comparative Study: Prospective Long-Term Outcome of the Transcatheter Melody Valve Versus Surgical Pulmonary Bioprosthesis With Up to 12 Years of Follow-Up. *Circ Cardiovasc Interv*. July 2020;13(7):e008963.

Medtronic

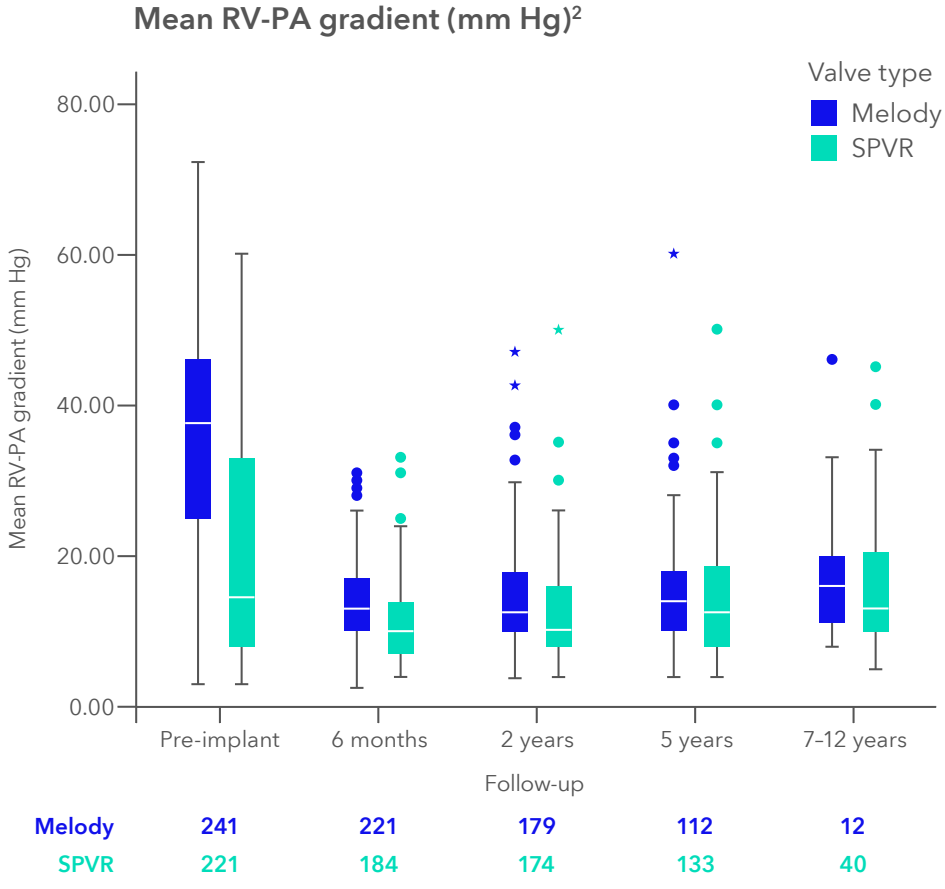
Excellent hemodynamics

comparable to surgery

RVOT mean gradient (mm Hg)[1]



Mean RV-PA gradient (mm Hg)[2]



Melody	241	221	179	112	12
SPVR	221	184	174	133	40

Stable valve hemodynamics help delay future intervention in majority of patients

Consistent long term stable valve function through 10 years (mean RVOT gradient <20 mm Hg)

[1] Melody Transcatheter Pulmonary Valve Study: Post Approval at Study of the Original IDE Cohort.

[2] 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.

Medtronic

Evolution of procedure

what we have learned over the past 10 years on risk management

Studies have shown that **EVOLUTIONS IN IMPLANTATION PRACTICES** are associated with lower rates of valve intervention over time and with lower rates of endocarditis requiring TPV intervention.[1]

Year 2000

First

Transcatheter valve

2011

Pre-stenting

was tied to a lower risk of both stent fracture and reintervention[4,5]

2016

Residual post-implant gradient

is highly associated with risk of IE[1-3]

2018

Patient education

has demonstrated a positive impact on long term outcomes[6]

2020

Longest

Transcatheter valve follow-up at **10 years**

2021

Valve type is not an IE risk factor

First of its kind comprehensive risk factor analysis[7]

[1] Georgiev S, Ewert P, Tanase D, et al. A low residual pressure gradient yields excellent long-term outcomes after percutanous pulmonary valve implantation. *JACC Cardiovasc Interv*. August 2019;12(16):1594-1603.

[2] McElhinney DB. Reflection and Rationalization: Making Sense of the Literature on Endocarditis After Transcatheter Pulmonary Valve Replacement. *Circ Cardiovasc Interv*. February 2017;10(2):e004983.

[3] McElhinney D, Sondergaard L, Armstrong A, et al. Endocarditis After Transcatheter Pulmonary Valve Replacement. *J Am Coll Cardiol*. December 4, 2018;72(22):2717-2728.

[4] Cabalka A, Asnes J, Balzer D, et al. Transcatheter pulmonary valve replacement using the melody valve treatment of dysfunctional surgical bioprostheses: A multicenter study. *J Thorac Cardiovasc Surg*. April 2018;155(4):1712-1724.e1.

[5] McElhinney D, Cheatham J, Jones T, et al. Stent fracture, valve dysfunction, and right ventricular outflow tract reintervention after transcatheter pulmonary valve implantation: patient-related and procedural risk factors in the US Melody Valve Trial. *Circ Cardiovasc Interv*. December 1, 2011;4(6):602-614.

[6] Cools B, Brown S, Budts W, et al. Up to 11 years of experience with the Melody valved stent in the right ventricular outflow tract. *EuroIntervention*. October 12, 2018;14(9):e988-e994.

[7] McElhinney D, Zhang Y, Aboulhosn J, et al. Multicenter Study of Endocarditis After Transcatheter Pulmonary Valve Replacement. *J Am Coll Cardiol*. August 2021;78(6):575-589.

Medtronic

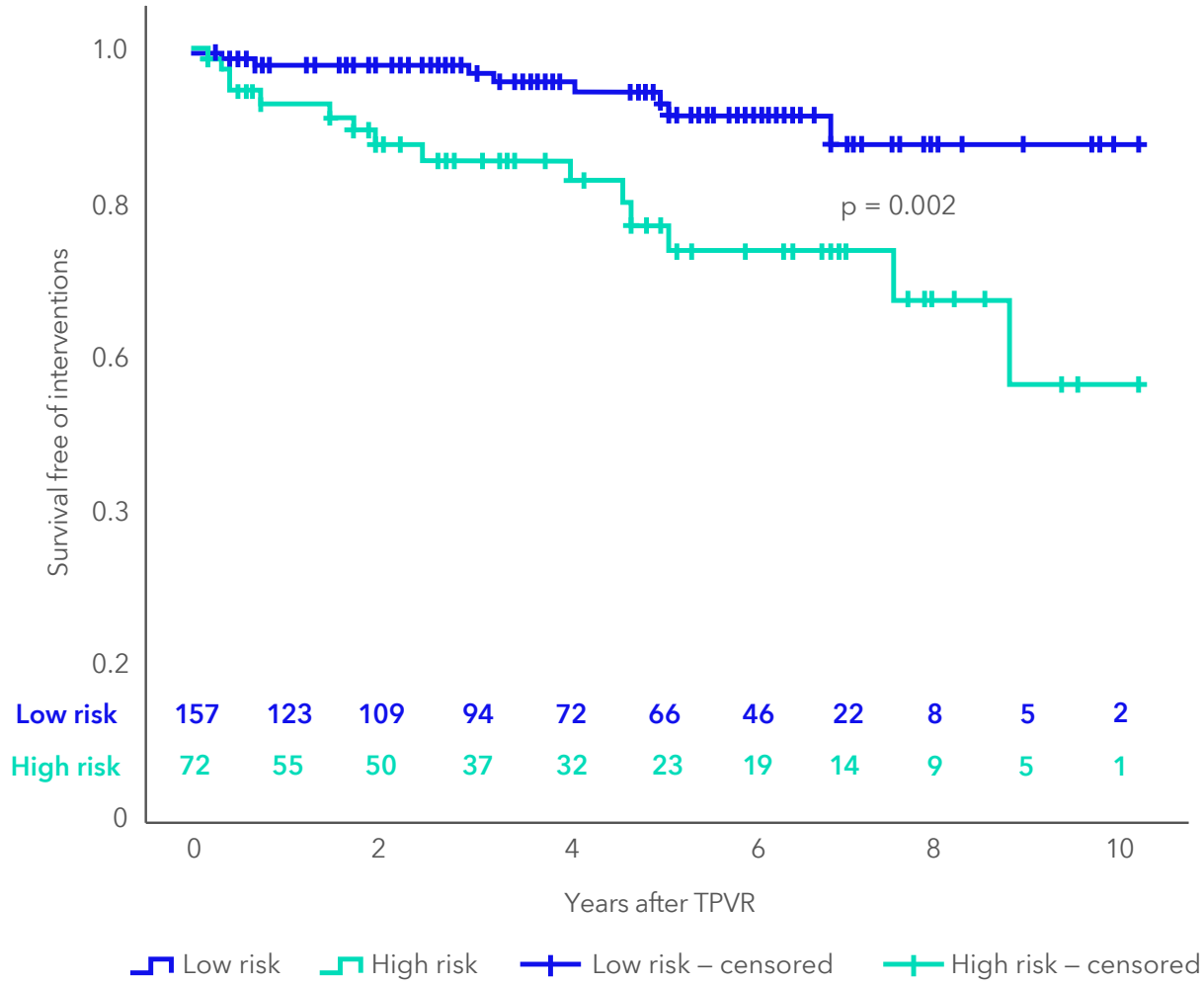
Evolution of procedure

what we have learned over the past 10 years on risk management

Managing the residual pressure gradient and conduit preparation

yields excellent outcomes long-term after percutaneous pulmonary valve implantation, and could further reduce the risk of infective endocarditis

Better survival after percutaneous pulmonary valve implant[1]



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

[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.

Medtronic

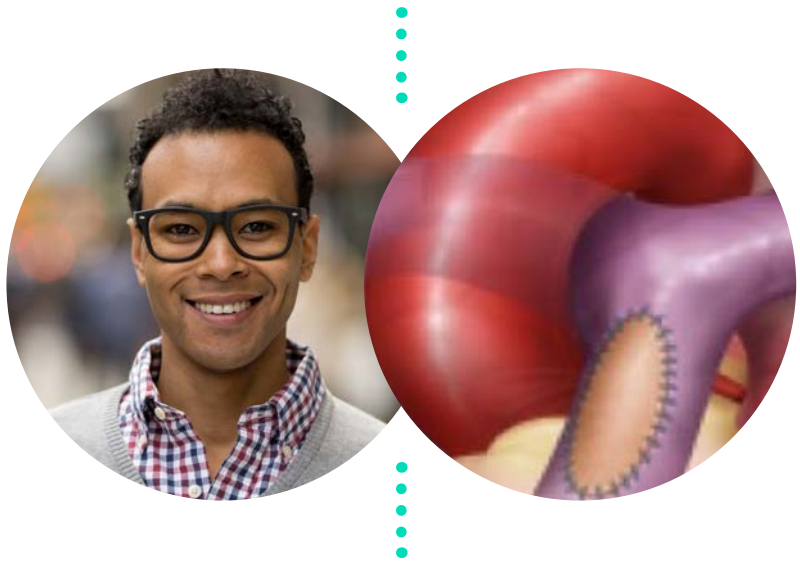
Evolution of procedure

what we have learned over the past 10 years on risk management

Results of a recent large multicenter study of 2,476 patients, equal to 8,475 patient-years and 15 international centers.

Valves were used in different environments

Numerous patient- and procedure- related differences between patients who received Melody™ TPV versus SAPIEN[4]



Patients who received Melody were more likely to be RVOT conduit patients (almost 70%) and younger

Number of patients	Age	Substrate
2038	19 (13, 29)	Native: 10% Conduit: 67% BPV, pre-stent, ViV: 23%

Patients who received Sapien were significantly older and more likely to be native RVOT patch

Number of patients	Age	Substrate
438	28 (19, 40)	Native: 46% Conduit: 31% BPV, pre-stent, ViV: 23%

Source: McElhinney D, Zhang Y, Aboulhosn J, et al. Multicenter Study of Endocarditis After Transcatheter Pulmonary Valve Replacement. *J Am Coll Cardiol*. August 2021;78(6):575-589.

Medtronic

Evolution of procedure

what we have learned over the past 10 years on risk management

Risk management

Let's assess the IE risk holistically

Procedure

- Pre-stenting
- Residual gradient

Valve

- Valve type

Patient

- Personal care
- Patient history of IE
- Conduit type
- Patient age

Multivariable analysis

Age, **history of IE**, and **higher residual gradient** are all risk factors

but valve type is not!

Source: McElhinney D, Zhang Y, Aboulhosn J, et al. Multicenter Study of Endocarditis After Transcatheter Pulmonary Valve Replacement. *J Am Coll Cardiol*. August 2021;78(6):575-589.

Medtronic

Evolution of procedure

what we have learned over the past 10 years on risk management

Those with p < 0.05 identified as relevant in **Univariate Analysis**

Those with p < 0.05 identified as relevant in **Multivariate Analysis**

TABLE 2 Results of Univariable and Multivariable Cox Regression Analysis for Factors Associated With Endocarditis

	Univariable Cox Regression		Multivariable Cox Regression	
	HR (95% CI)	*P* Value	HR (95% CI)	*P* Value
Demographic and historical data				
Female	0.79 (0.58-1.08)	0.13		
Age at TPVR, y	0.98 (0.97-0.99)	0.003	0.98 (0.96-0.99)	<0.001
Weight, kg	1.00 (0.99-1.00)	0.30		
Underlying cardiac diagnosis		0.002		
Tetralogy of Fallot	-			
Truncus arteriosus/DORV/TGA	1.80 (1.28-2.53)		1.67 (1.18-2.35)	0.004
Prior Ross procedure	1.59 (1.06-2.38)		1.83 (1.21-2.77)	0.006
Valvar PS or PAIVS	0.61 (0.27-1.41)			
Other	0.94 (0.35-2.57)			
RVOT conduit/valve type		0.030		
Homograft conduit	-			
Stented bioprosthetic valve	1.18 (0.82-1.69)		1.53 (1.07-2.19)	0.025
Other conduit/SPV/unknown	0.79 (0.40-1.56)			
Native/augmented RVOT	0.46 (0.23-0.91)			
Contegra conduit	1.19 (0.73-1.95)			
Prior TPV	2.77 (1.02-7.54)			
Existing RVOT conduit stent	1.46 (0.96-2.22)	0.10		
Other prosthetic valve(s)	0.86 (0.38-1.94)	0.71		
Prior transvenous pacemaker/ICD	0.90 (0.53-1.52)	0.68		
Known history of endocarditis	1.98 (1.26-3.12)	0.007	2.19 (1.38-3.49)	0.003
Multiple prior endocarditis episodes	1.48 (0.21-10.61)	0.71		
Hemodynamic indication for TPVR		<0.001		
Obstruction	-			
Mixed obstruction and regurgitation	1.45 (1.06-1.99)			
Pulmonary regurgitation	0.66 (0.43-1.02)			
TPVR indication regurgitation vs other	0.55 (0.37-0.83)	0.002		
Procedural data				
Melody valve	2.73 (1.28-5.83)	0.002		
Valve or delivery system diameter, mm	0.88 (0.82-0.95)	<0.001		
Delivery system diameter, mm		0.007		
≤18	-			
20	0.65 (0.42-1.00)			
22-24	0.60 (0.42-0.86)			
25-26	0.23 (0.07-0.74)			
29	0.29 (0.07-1.19)			
Pre-stenting performed	0.98 (0.70-1.37)	0.91		
Multiple pre-stents placed	1.29 (0.94-1.77)	0.12		
Covered pre-stent placed	0.89 (0.61-1.30)	0.55		
TPV post-dilated	1.26 (0.94-1.69)	0.13		
Concomitant procedures performed	1.09 (0.66-1.80)	0.74		
Peak RVOT gradient				
Pre-implant (per 10 mm Hg)	1.16 (1.08-1.25)	<0.001		
Post-implant (per 10 mm Hg)	1.38 (1.15-1.65)	<0.001	1.30 (1.08-1.57)	0.008
Post-implant >15 mm Hg	1.63 (1.18-2.26)	0.005		

for endocarditis was constant over time. Univariable Cox regression analysis revealed a number of factors to be significantly associated with development of endocarditis (Table 2). On stepwise multivariable Cox regression, only younger age at TPVR (as a continuous variable), a known prior history of endocarditis, certain underlying diagnoses, a bioprosthetic valve in the RVOT, and higher post-implant peak RVOT gradient were significant (Table 2). The estimated hazard for developing endocarditis was higher for patients who received a Melody valve on univariable analysis, but there was no significant difference between valve types when other patient-related and procedural factors were taken into consideration with multivariable analysis. On subgroup analysis by RVOT conduit/valve type, there were no significant differences in the hazard for endocarditis between patients with Melody and Sapien valves either on unadjusted or age- and post-implant RVOT gradient-adjusted Cox regression. Exploratory analysis aimed at identifying an age threshold associated with

Source: McElhinney D, Zhang Y, Aboulhosn J, et al. Multicenter Study of Endocarditis After Transcatheter Pulmonary Valve Replacement. *J Am Coll Cardiol*. August 2021;78(6):575-589.

Medtronic

Why we do what we do

putting patients first

"After the Melody valve, I felt 20 years younger. And it only took one stitch."

– **David Scott**
Melody patient since 2018

"The Melody valve has saved me; it has brought me back to life."

– **Juan Fernando**
Melody patient since 2010

Medtronic

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

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.eu.

For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

Important Reminder: This information is intended only for users in markets where Medtronic products and therapies are approved or available for use as indicated within the respective product manuals. Content on specific Medtronic products and therapies is not intended for users in markets that do not have authorisation for use.

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. Melody TPV is not suitable for all patients and ease of use, outcomes, and performance may vary. See the instructions for use for indications, contraindications, precautions, warnings, and adverse events.

Medtronic

Europe
Medtronic International Trading Sàrl.
Route du Molliau 31
Case postale
CH-1131 Tolochenaz
Tel: +41 (0)21 802 70 00
Fax: +41 (0)21 802 79 00

medtronic.eu