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Original Article

Post-market surveillance to detect adverse events associated with Melody® valve implantation

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Abstract *Objective:* The aim of this study was to describe previously unrecognised or under-recognised adverse events associated with Melody® valve implantation. *Background:* In rare diseases and conditions, it is typically not feasible to conduct large-scale safety trials before drug or device approval. Therefore, post-market surveillance mechanisms are necessary to detect rare but potentially serious adverse events. *Methods:* We reviewed the United States Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database and conducted a structured literature review to evaluate adverse events associated with on- and off-label Melody® valve implantation. Adverse events were compared with those described in the prospective Investigational Device Exemption and Post-Market Approval Melody® transcatheter pulmonary valve trials. *Results:* We identified 631 adverse events associated with "on-label" Melody® valve implants and 84 adverse events associated with "off-label" implants. The most frequent "on-label" adverse events were similar to those described in the prospective trials including stent fracture (n = 210) and endocarditis (n = 104). Previously unrecognised or under-recognised adverse events included stent fragment embolisation (n = 5), device erosion (n = 4), immediate post-implant severe valvar insufficiency (n = 2), and late coronary compression (n = 2 cases at 5 days and 3 months after implantation). Under-recognised adverse events associated with off-label implantation included early valve failure due to insufficiency when implanted in the tricuspid position (n = 7) and embolisation with percutaneous implantation in the mitral position (n = 5). *Conclusion:* Post-market passive surveillance does not demonstrate a high frequency of previously unrecognised serious adverse events with "on-label" Melody® valve implantation. Further study is needed to evaluate safety of "off-label" uses.

Keywords: MAUDE database; device safety; transcatheter pulmonary valve

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The Melody® transcatheter pulmonary valve (Medtronic Inc., Plymouth, Minnesota, United States of America) was the first United States Food and Drug Administration-approved transcatheter heart valve.[1] Similar to many other invasive devices, prospective clinical trials evaluating safety and feasibility of Melody® valve implantation enrolled a relatively small number of patients; the combined United States Melody® trials, including the Investigational Device Exemption and post-market approval trials, and the European experience included 379 patients with 255 of them enrolled prospectively.[2–5] Although adverse event rates from these initial experiences were low, the collective experiences were inadequate to detect rare but potentially serious adverse events. Since the Food and Drug Administration's approval, the Melody® valve has gained rapid clinical acceptance and is now in widespread use.[6] Moreover, case reports document that the Melody® valve is increasingly being used clinically in an off-label manner.

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After widespread uptake and with increased off-label use, we sought to determine whether there might be reports of previously unrecognised or under-recognised adverse events associated with Melody® valve implantation. To this end, we queried the United States Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database, a mandatory – for industry – and voluntary – for providers and patients – reporting mechanism designed to facilitate capture of rare device-related adverse events.[7] In addition, we conducted a structured literature review to capture additional reported adverse events and to evaluate whether there might be previously unrecognised or under-recognised adverse events associated with off-label Melody® valve implantation.

Methods

MAUDE database query

The MAUDE database is a searchable, online database of medical device reports received by the Food and Drug Administration. Manufacturers and user facilities – hospitals, outpatient diagnostic or treatment facilities, nursing homes, and ambulatory surgical facilities – are required to report device-related death, serious injury, or malfunction, whereas individual clinicians or patients can submit voluntary reports through the Food and Drug Administration's "MedWatch" programme. This database serves as a passive surveillance tool to monitor device performance and potentially detect adverse events associated with device use. We queried the online MAUDE database[8] using the keywords "MELODY" or "TRANSCATHETER PULMONARY VALVE" in the brand name field. We also performed separate searches using the keywords "MEDTRONIC", "MEDTRONIC INC.", "MEDTRONIC HEART VALVES", or "HEART VALVES SANTA ANA" in the manufacturer field. A start date of 1 January, 2010 was specified to correspond with the Food and Drug Administration's approval of the Melody® valve (25 January, 2010). Device reports were collected through 1 July, 2015. All other query fields were left blank. Figure 1 summarises results of the MAUDE database search and included studies.

Literature review

Embase and Medline searches were conducted with the aid of a professional librarian from Duke University Medical Center. An initial review demonstrated no Medical Subject Headings terms associated with the Melody® valve; therefore, we searched for any of the following search terms alone or in combination: "MELODY", "MELODY VALVE", "MELODY DEVICE", "MELODY TPV", "MELODY TRANSCATHETER HEART VALVE", "MELODY TRANSCATHETER PULMONARY VALVE", and "TRANSCATHETER PULMONARY VALVE". All citations were downloaded into an EndNote library, and abstracts were reviewed for relevance. Articles reporting adverse events or off-label use of the Melody® valve were included; a total of 206 abstracts and/or manuscripts were identified, and 97 were included in the final analysis (Fig 1, eTable 1 and 2). When adverse events were reported in multiple manuscripts describing the same study, and it was feasible to identify duplicated events, we preferentially compiled adverse events from the manuscript documenting the latest patient follow-up for the particular complication.

MAUDE data collection and classification of complications

Medical device reports from the MAUDE database and from the medical literature were reviewed independently by two board-certified paediatric interventional cardiologists (G.A.F and K.D.H). All device reports documenting adverse events that were considered medically significant – that is, consistent with a grade II or greater adverse event in a clinical trial – were included. Device reports for medically insignificant adverse events – that is, resulting in no symptoms and warranting no intervention including no need for ongoing follow-up – and reports that were judged by both reviewers not to represent specific Melody® valve-related adverse events were excluded. Abstract/manuscript case details were cross-referenced with MAUDE device reports. Adverse events judged to represent duplicated reports on the basis of the event description, date, or any other relevant case detail were only included once in the analysis. Complications and relevant outcomes data were extracted and entered into a database. Adverse events were classified in two ways: as procedural or post-procedural adverse events based on the event description and reported timing; and as on-label or off-label complications based on the Food and Drug Administration's labelled indication for the Melody® valve; although the Food and Drug Administration's instructions for use do not provide a specific weight limit for Melody® implantation, we considered implantations in children <30 kg to be off-label indications on the basis of the weight limit for the United States Investigational Device Exemption trial.

Statistical analysis

Complications were identified as discrete events and reported as absolute numbers. A primary

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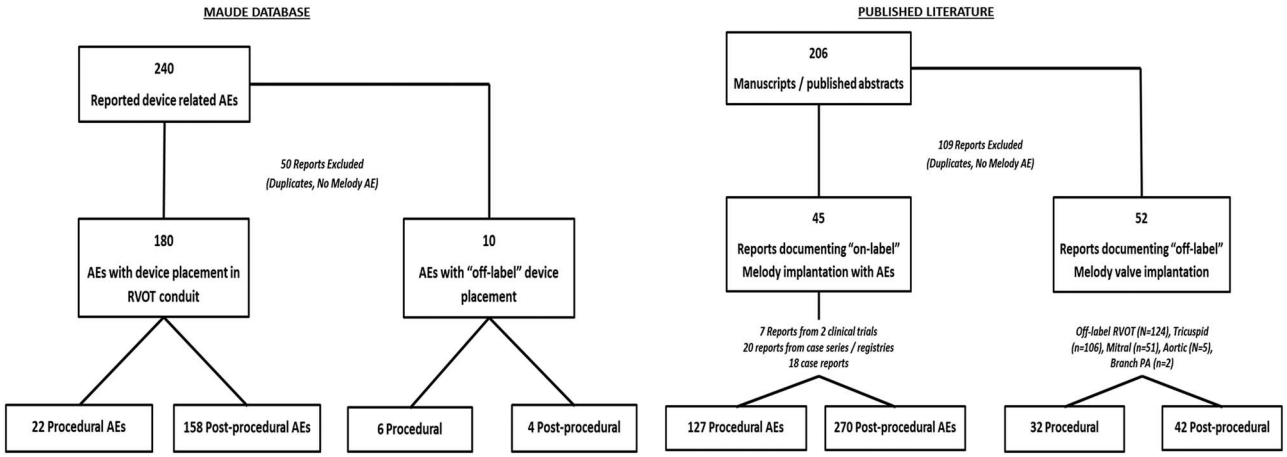

Figure 1.
Melody® valve medical device reports identified from the United States Food and Drug Administration database and Melody® valve adverse event reports identified from the published literature.

complication categorisation was assigned to each medical device report. Standard summary statistics (median, range) were used to describe time to event following implantation. All statistical analyses were conducted using SPSS 22.0 (IBM, Chicago, Illinois, United States of America).

Results

Reports in the literature documenting adverse events associated with "on-label" Melody® valve implantation included seven reports from two prospective clinical trials (248 implants, 70 adverse events), 20 retrospective and/or registry-based case series (2123 implants, 301 adverse events), and 18 case reports (26 implants, 26 adverse events) (eTable 1). The MAUDE database included 240 "on-label" Melody® valve medical device reports submitted between 1 January, 2010 and 7 January, 2015. Upon manual review, 50 of these reports were excluded as non-Melody®-related adverse events or reports duplicated in the medical literature, leaving 190 MAUDE adverse event reports.

Procedural adverse events

Table 1 summarises procedural adverse events reported in the literature and the MAUDE database, as well as adverse events reported in the United States Investigational Device Exemption trial and the post-approval study. Combined, these two studies, both with active surveillance protocols, reported procedural adverse events for 9.2% (23/248) of implants including conduit rupture/tear (n = 8, 3.2%), access site complications (n = 5, 2.0%), guidewire-induced distal pulmonary artery perforation (n = 3, 1.2%), coronary compression (n = 2, 0.8%), ventricular tachycardia (n = 1, 0.4%), and paravalvar leak (n = 1, 0.4%). There were no procedural deaths reported.

Review of passive surveillance mechanisms including the MAUDE device reports and non-trial literature identified additional complications including device embolisation (n = 11), immediate post-implant device failure requiring intervention due to insufficiency (n = 2) or stenosis (n = 5), complete heart block (n = 3), complete branch pulmonary artery obstruction (n = 3), development of an aorto-pulmonary fistula immediately after valve deployment requiring intervention (n = 3), and accidental unsheathing in the right ventricle (n = 2). A total of four procedural mortalities were reported in case series in the literature with a single procedural mortality reported in the MAUDE database. Causes of death were reported for four patients and included coronary compression (n = 2), right pulmonary artery obstruction, and ventricular arrhythmia.

Post-procedural device-related adverse events

Table 2 summarises post-procedural device-related adverse events from the literature review and MAUDE database, as well as adverse events reported in the prospective Investigational Device Exemption trial (n = 144 patients with a median follow-up of 4.5 years) and the post-approval study (n = 100 patients with 1-year follow-up). Combined, these two studies, both with active surveillance protocols, reported 74 post-procedural adverse events, all representing either stent fracture (n = 57) or endocarditis (n = 17). Stent fracture was less frequent in the post-approval study (n = 7/100 implants, 7%) than in the earlier Investigational Device Exemption trial (n = 50/144 implants, 35%), likely reflecting more frequent adoption of conduit pre-stenting in the later

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post-approval study – in fact, pre-stenting was not permitted in the early patients enrolled in the Investigational Device Exemption trial – and a longer duration of follow-up in the Investigational Device Exemption trial.

Similar to the clinical trials, stent fracture and endocarditis were the most commonly reported non-procedural adverse events in the non-trial literature (median follow-up 20 months, range 3–30 months for case series) and in the MAUDE database (median follow-up 18 months, range 1 week to 74 months). There were 76 reports of endocarditis in the non-trial literature and 28 in the MAUDE database. Infectious organisms were documented in 65 of these cases with the most common including *Staphylococcus aureus* (n = 18, 28%), the viridans streptococci (n = 17, 26%), coagulase-negative staphylococcus (n = 14, 22%), and the HACEK (Haemophillus, Aggregatibacter, Actinobacillus, Cardiobacter, Eikenella, Kingella) organisms (n = 4, 6%). Median time to diagnosis of endocarditis was 12 months (range 1 week to 5 years) with only three cases documented within 1 month of implantation.

Additional adverse events in the MAUDE database/non-trial literature that were not well described in the prospective trials included five reports of complete stent fracture with stent fragment embolisation, four cases of device "erosion" into the aorta or aortopulmonary fistula development,[9–11] and two cases of late coronary compression that were identified at 5 days and 3-months after implantation, respectively.[12,13] Case details for these adverse events are summarised in Table 3.

Table 1. Melody® valve procedural adverse events.

	US prospective studies (n = 248)	Registry and case series	MAUDE medical device reports	Case reports
Conduit rupture/tear	8 (3.2%)	41	1	–
Access site complications	5 (2.0%)	13	–	–
Guidewire PA perforation	3 (1.2%)	4	–	–
Haemodynamic change	3 (1.2%)	–	–	2
Coronary compression	2 (0.8%)	5	5	1
Ventricular arrhythmia	1 (0.4%)	1	–	–
Paravalvar leak	1 (0.4%)	–	–	–
Malposition/ embolisation	–	5	5	1
Acute device failure	–	3	4	–
Complete heart block	–	2	–	1
PA obstruction	–	1	2	–
Inappropriate unsheathing	–	–	2	–
Aortopulmonary fistula	–	–	2	1
Major AE NOS	–	19	–	–
Peri-procedural mortality	0 (0%)	4	1	–

AE = adverse event; MAUDE = Manufacturer and User Facility Device Experience; NOS = not otherwise specified; PA = pulmonary atresia

Off-label reports

From the literature, we identified 52 case reports/case series describing 342 "off-label" implantations including implants in the tricuspid (n = 108), mitral (n = 51), and aortic position (n = 6) or "off label" uses in the right ventricular outflow tract (n = 124), branch pulmonary arteries (n = 2), or in children under 30kg (n = 26) (eTable 2). A total of 32 procedural and 42 post-procedural adverse events were described with an additional 10 "off-label" adverse events extracted from the MAUDE database. Table 4 summarises these adverse events by "off-label" indication. Notable events included seven descriptions of early valve failure following implantation in the tricuspid position. In all cases, there was acute success with no significant

Table 2. Melody® valve post-procedural adverse events.

	US Melody® valve trials (n = 244 implants)	Retrospective literature reports	Case reports	MAUDE medical device reports
Stent fracture	57 (23.4%)	116	–	94
Type II (loss of structural integrity)	26 (10.6%)	22	–	35
Type III (with particle embolisation)	1 (0.4%)	–	–	5
Endocarditis	17 (7%)	63	13	28
Valve dysfunction without stent fracture*	–	–	–	37
Device erosion	–	–	2	2
Late coronary compression**	–	–	2	–

MAUDE = Manufacturer and User Facility Device Experience

*Including stenosis or insufficiency

**Right coronary artery compression identified 5 days and 3 months after implant when patients presented with myocardial infarction

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Table 3. Case descriptions for previously under-recognised Melody® valve post-procedural adverse events.

	Time after implant (mos)	Event description and circumstances	Outcome	Source
Type III stent fracture (complete fracture with stent fragment embolisation)	7	Location of fragment not noted	Surgical valve removal	MAUDE
	35	Fragment embolised to the right ventricular apex	Details not provided	MAUDE
	12	Fragment embolised to the right ventricular apex	Fragment left in place, second transcatheter valve implanted	MAUDE
	24	Fragment embolised to the branch pulmonary artery	Fragment retrieved, second transcatheter valve implanted	MAUDE
	98	Fragment embolised to the left lung	No intervention required	MAUDE
Device erosion/ aortopulmonary fistula	0.75	Valve erosion into the ascending aorta in a patient with history of Ross procedure, who presented with heart failure	Surgical valve removal	Taggart et al[10] Congenital Heart Disease
	0.75	Fistula between the aortic root and the conduit in a patient with history of interrupted aortic arch repair	Surgical valve removal	Peer and Sinha[11] Journal of Thoracic and Cardiovascular Surgery
	16	Valve erosion into the ascending aorta with shunt causing "severe" heart failure	Surgical valve removal	MAUDE
	36	Valve erosion into the ascending aorta in a patient with a history of Ross–Konno operation, presented with heart failure	Surgical valve removal	MAUDE
Late coronary obstruction	0.2	LAD obstruction presenting 5 days after implant; intra-procedural coronary compression resolved with nitroglycerin administration and was attributed to vasospasm	Surgical valve removal	Biermann et al[12] Thoracic and Cardiovascular Surgeon
	3	Late right coronary artery dissection and obstruction after exercise, felt to be related to increased cardiac output	Surgical valve removal and right coronary artery re-implantation	Dehghani et al[13] Catheterisation and Cardiovascular Interventions

MAUDE = Manufacturer and User Facility Device Experience; LAD = left anterior descending coronary artery

immediate post-procedural tricuspid regurgitation but with early development (<3 months in 6/7cases) of severe regurgitation requiring intervention. There were also adverse events reported for mitral implants, including embolisation in five reported cases implanted using a percutaneous approach. Notably, mitral implants were largely performed in high-risk patients with 6/9 reports documenting an average age at implant of ⩾ 65 years and one report using a surgical approach in infants (average age at implant of 7 months). There was also a single study describing procedural complications with right ventricular outflow tract conduit implantation in children <30 kg and documenting a serious intra-procedural adverse event rate of 26% (7/26 implants).[14] Most of these adverse events (n = 5) represented contained conduit tears during conduit balloon sizing with two of them considered as major and requiring covered stent placement.

Discussion

In this analysis, we demonstrated that the most commonly reported adverse events associated with Melody® valve implantation in post-market surveillance mirror those reported in the prospective United States Melody® valve Investigational Device Exemption and Post-Market Approval trials, as well as in the initial European experience;[2,4,5,15–18] however, we also identified several rare adverse events, including possible device erosion, device fracture with stent fragment embolisation, acute-onset valvar insufficiency, and late coronary obstruction that were not well documented in the trial literature and are not included on the Food and Drug Administration device label.[19] In addition, reports of acute valvar insufficiency with placement of the Melody® valve in the tricuspid position, embolisation with mitral implantation, and risk of procedural adverse events with

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Table 4. Adverse events associated with "off-label" Melody® valve implantation.

	Native RVOT (n = 124)	Tricuspid (n = 108)	Mitral (n = 51)	RVOT in children <30 kg (n = 26)
Procedural				
Vascular complication	–	1	5	1
Conduit tear	1	–	–	5
AP fistula	1	–	–	–
Guidewire perforation	–	–	1	1
Haemo/ pneumothorax			3	
Embolisation	–	–	5	–
Complete AV block	–	3	1	–
Procedural mortality	–	–	1	1*
Post-procedural	–	–	–	–
Stent fracture	6	2	–	2
Endocarditis	3	1	–	2
Early valve failure	1	7	–	–
Paravalvar leak	–	–	2	–

AP = aortopulmonary; AV = atrioventricular; RVOT = right ventricular outflow tract

*Melody® valve implantation was performed in a patient on extracorporeal membrane oxygenator following pulmonary atresia laceration during a previous procedure. Mortality was not felt to be directly attributable to the Melody® implantation

implantation in younger children suggest a need for systematic processes to evaluate safety when the Melody® valve is being used outside of its labelled indication and in high-risk, often high-acuity, clinical scenarios.

Post-market approval passive surveillance of medical devices is an important mechanism used to monitor for potentially harmful but under-recognised adverse events, particularly in rare diseases and conditions where large-scale safety trials are typically not feasible. The United States Food and Drug Administration developed the MAUDE database for this specific purpose[20] and it was previously used in the field of interventional paediatric cardiology to highlight the risk of erosion with the Amplatzer Septal Occluder device (St. Jude Medical Inc., Plymouth, Minnesota, United States of America).[21] A limitation of the database is that it does not accurately represent event rates because most adverse events are under-reported and because the total number of device implants is not available.[22] For these reasons, the Food and Drug Administration recommends that the database be used to "detect a signal that might require further investigation". This was the specific objective of our analysis.

Our findings from both the MAUDE database and our literature review are generally reassuring for use of the Melody® valve within the confines of its labelled indication. Most of the intra-procedural and post-procedural adverse events that we report, including coronary compression, conduit disruption, device embolisation, stent fracture, and endocarditis, have been previously well described.[2–5] We did not detect any obvious "signal" suggesting a major safety concern with "on-label" Melody® valve implantation; however, several less well-recognised adverse events perhaps warrant closer monitoring by the interventional community. These events included acute device failure due to insufficiency (n = 2 cases), post-implant device "erosion" (n = 4 cases), and late coronary compression (n = 2 cases). In several of these cases, there were potential extenuating circumstances (described in Table 2). Regardless, these represent important device-related events, and the fact that there were extenuating circumstances should not deter reporting of these events – it is well recognised that post-market adverse events are often under-reported because they are judged to be due to errors in implant technique or clinical judgement.[22] To facilitate passive surveillance mechanisms, implanting physicians can report device-related adverse events relatively easily via the MedWatch reporting form (www.Food and Drug Administration.gov/Safety/MedWatch/default.htm).

Although both Melody® valve endocarditis and stent fracture have been previously well described, our analysis does provide some additive insight regarding these events. With respect to endocarditis, this represents the largest reported collection of Melody® endocarditis cases and confirms findings of previous reports documenting that Melody® endocarditis does not cluster around the acute implant period, and that the most common bacteria – streptococci and staphylococci – represent typical endocarditis bacteria.[17,23,24] These findings suggest that Melody® endocarditis results from de novo post-procedural blood stream infection with seeding of the Melody® apparatus rather than a pre- or peri-procedural event related to sterilisation practices – for example, use of a non-operating room environment – or the implantation protocol – for example, valve manipulation before delivery. With respect to stent fracture, another previously well-documented adverse event, this is the largest report of type III fracture, which is associated with stent fragment embolisation. A single type III fracture was identified in the United States Investigational Device Exemption trial, and we identified five cases from the MAUDE database. None of these reports resulted in adverse patient outcomes; however, they highlight the need for ongoing surveillance after initial identification of a type I or type II

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fracture; in all of these cases, the patients first presented with a lower-grade (type I or II) fracture.

Safety of off-label use

"Off-label" use refers to use outside of the labelled indication and is very common in the field of paediatric interventional catheterisation.[25] We identified an increasing number of reports documenting off-label Melody® implantation. These reports may represent important breakthroughs, leading to rapid advances in clinical applications, particularly in scenarios where clinical trials might be prohibitively expensive. Safety tracking, however, is difficult when off-label uses occur sporadically at a large number of different centres. Our limited analysis is not sufficient to appropriately evaluate safety or efficacy of these off-label indications. Large multi-centre registries will be best positioned to address the safety or efficacy of infrequent off-label uses. In lieu of these data, providers should be aware of the potential complications that we identified, including heart block and acute valvar insufficiency with implantation in the tricuspid position and valve embolisation with implantation in the mitral position. Although implantation in smaller children is not technically an off-label application, the original Melody® valve trials restricted enrolment to those >30 kg. It is notable, although perhaps not unexpected, that the adverse event rate is somewhat higher in these smaller patients.[14]

There are several important limitations to the present analysis. Despite using a structured approach to our literature review, it is possible that we missed some published reports or that some of our published cases are duplicated and reported in both the literature and the MAUDE database. Moreover, there are inherent biases in the published literature; positive findings are more likely to be published, whereas negative outcomes and safety events often go unpublished. Similarly, the MAUDE database may under-represent adverse events as it was designed for passive surveillance. The information submitted by reporters has limitations, including the possibility of inaccurate or incomplete data. In addition, most reports are not verified through objective, independent assessment mechanisms, and the prevalence and incidence of adverse events cannot be determined through the MAUDE database because adverse events are under-reported, may in some cases be reported in duplicate, and the total number of devices implanted is not known.

Conclusion

The data presented in this study are relatively reassuring that Melody® valve-related adverse events have been defined through prospective clinical trials. With the notable exception of two reports of acute valvar insufficiency, intra-procedural adverse events have all either been previously reported or could be anticipated. We also did not find any evidence of previously unrecognised post-procedural adverse events occurring at a high incidence. Closer surveillance may be warranted for patients at increased risk for device erosion – for example, after arterial switch, Ross procedure, or in those with a dilated aortic root[26] – and after identification of an initial type I stent fracture due to risk of progression in the degree of stent fracture. Finally, although off-label Melody® valve applications are increasingly being reported, our data suggest that there may be unique safety complications that warrant consideration. Specific clinical trials are unlikely for most of these off-label usages, further emphasising the need for systematic monitoring of these implantations either via large multi-centre registries or by restricting these applications to a select subset of centres to facilitate close safety surveillance.

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Ethical Standards

This work was conducted in accordance with the ethical standards outlined in the Declaration of Helsinki.

Supplementary materials

For supplementary material referred to in this article, please visit https://doi.org/10.1017/S1047951116002092

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