Use and Performance of the Melody Transcatheter Pulmonary Valve in Native and Postsurgical, Nonconduit Right Ventricular Outflow Tracts

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Background—Melody Transcatheter Pulmonary Valve (TPV) replacement therapy represents an important advance in congenital cardiovascular interventions. The off-label extension of the Melody TPV to patients with nonconduit outflow tracts (right ventricular outflow tract [RVOT]) has the potential to vastly expand the population of patients eligible to benefit from nonsurgical restoration of RVOT function. However, knowledge on the performance of the Melody TPV in this setting is limited.

Methods and Results—This is a multicenter, retrospective review of the Melody TPV when placed in nonconduit RVOTs, in which at least a portion of the circumference was composed of native tissue. Five centers contributed data on 31 patients. The median age at implantation was 24 years (range, 7–66). At a median follow-up of 15 months, all patients were alive. No patient had greater than mild TPV insufficiency, and the median maximum instantaneous gradients across the RVOT was 23 mm Hg. Stent fracture occurred in 32%. Eight patients developed more than mild TPV obstruction, of whom 6 were associated with identified stent fracture. Three patients developed blood stream infections. There were 5 reinterventions in 3 patients, including 3 repeat TPV implantations and 2 TPV explantations.

Conclusions—Melody TPV implantation is feasible in selected patients with RVOTs comprised solely or predominantly native tissue and has the potential to expand the population of patients eligible to benefit from nonsurgical restoration of RVOT function. In early follow-up, valve competency seems preserved. The dominant mechanism of valve dysfunction seems to be related to stent fracture with recurrent obstruction. Additional data are necessary to better understand how to safely expand TPV therapy to this population. (Circ Cardiovasc Interv. 2014;7:00-00.)

Key Word: pulmonary valve

The advent of the Melody Transcatheter Pulmonary Valve (TPV) has had an indelible impact on the field of congenital cardiovascular interventions. However, the magnitude of this impact has been tempered by limitations inherent to this new technology, including delivery system and valve size, the durability of the stent supporting the valve, and the suitability of current TPVs to complex ventricular outflow tracts. In addition, the Melody TPV is approved exclusively for use in dysfunctional, circumferential, surgically placed right ventricle-to-pulmonary artery conduits that were equal to or greater than 16 mm when originally implanted, an indication present in only a small proportion of the patients who would clinically benefit from restoration of a functional right ventricular outflow tract (RVOT), including many who are either poor or nonsurgical candidates.

The US FDA permits the off-label use of approved medical devices according to physician’s best knowledge and judgment, provided they are well informed about the product, base its use on firm scientific rationale and on sound medical evidence, and maintain records of the product’s use and effects. Under this rubric, Melody TPVs have been placed in a number of off-label clinical situations and anatomic locations. Among these, placement in nonconduit RVOTs likely presents the greatest opportunity to extend this therapy to the largest population and has the potential to significantly modify our approach to postsurgical RVOT dysfunction. Although several investigators have described innovative and potentially useful methods of implanting the Melody valve in unconventional ways in patients with large native RVOTs, these are unlikely to be broadly applicable. Otherwise, there are several small
WHAT IS KNOWN

- Transcatheter pulmonary valve implantation is a safe and effective alternative to surgical pulmonary valve replacement in select populations.
- The Melody Transcatheter Pulmonary Valve is approved exclusively for use in dysfunctional, circumferential, surgically placed right ventricle-to-pulmonary artery conduits.
- The off-label extension of the Melody Transcatheter Pulmonary Valve to patients with nonconduit outflow tracts has the potential to vastly expand the population of patients eligible to benefit from nonsurgical restoration of right ventricular outflow tract function.

WHAT THE STUDY ADDS

- Melody Transcatheter Pulmonary Valve implantation is feasible in selected patients with outflow tracts comprised solely or predominantly native tissue.
- In early follow-up, valve competency seems preserved, and similar to experience in circumferential outflow tract conduits, the dominant mechanism of valve dysfunction seems to be stent fracture with recurrent obstruction.
- Given the differences in the anatomy and dynamic nature of the RVOT in this patient population, more data will be necessary to understand how best to safely expand Transcatheter Pulmonary Valve therapy to this population.

series of Melody valve implantations into the native RVOT, and cases have been included in other large series, but there is limited information on outcomes in this population.

Methods

This is a retrospective review of the multicenter experience of use and performance of the Melody TPV when placed in native or postsurgical, nonconduit RVOTs. Five centers contributed data. Inclusion criterion was Melody TPV implantation in an operated or unoperated RVOT in which at least a portion of the circumference was composed of native in situ tissue (eg, after transannular patch repair of TOF, balloon valvuloplasty of valvar pulmonary stenosis, etc.). Perventricular or other hybrid approaches and implantations outside of the RVOT were not included. In addition, patients brought to the cardiac catheterization laboratory with the intention of placing a valve in this situation, but in whom no valve was placed were not included. The study was approved by each institution’s Committee on Human Research.

All cardiac catheterizations and interventions were performed as a part of routine clinical care, and no aspect of the implantation procedure was specified by this study. As a result, the implant technique and protocol may have varied from institution to institution. Similarly, type and frequency of follow-up data acquisition were at the discretion of the implanting institution. All study data were collected at the performing institution, anonymized, and transferred for central compilation and analysis.

Analysis of fluoroscopic imaging was performed by the implanting institution and included position and movement of the RVOT in relation to the sternum and measurement of initial and postimplant minimal RVOT diameter. In addition, given that RVOT anatomy can vary substantially in this population and may be highly dynamic, we hypothesized that RVOT geometry might be associated with the risk of stent fracture. In an attempt to explore this possibility, we measured RVOT angulation. RVOT angulation was measured on lateral projection as the degree of RVOT deviation from a straight line in the area of Melody implantation (Figure 1) and did not include consideration of right or leftward angulation. Analysis of stent fracture or embolization was obtained from chest films and fluoroscopy, both being recorded as present or absent, with a subsequent description of degree of stent fracture (eg, single or multiple fractures) and affect Melody valve appearance (eg, compression, etc.). Analysis of echocardiographic imaging was performed by the implanting institution and included RVOT mean and maximum instantaneous gradients (MIG), degree of tricuspid regurgitation (none, mild, moderate, or severe), and degree of Melody valve regurgitation (none, mild, moderate, or severe).

Figure 1. Method of calculation of right ventricular outflow tract (RVOT) angulation. The angle of the RVOT was calculated prior to (A) and after (B) Melody valve implantation. Although a greater degree of angulation may have existed between the RVOT and main pulmonary artery (a, inset), only the RVOT in the area of intervention was considered in the calculation.
Statistical Analysis
Descriptive statistics are presented as means±SD or median (range) as appropriate to their characteristics and distributions. Comparison of means and proportions between populations was performed by unpaired $t$ test or Wilcoxon signed-rank test based on distribution and by Fisher exact tests, respectively. Because complete longitudinal follow-up imaging was not available for appropriate time-dependent analysis of factors related to stent fracture, simple logistic regression was used with the addition of follow-up time to the model. Analysis of All predictor (change in minimal RVOT diameter, change in RVOT angulation, substernal location, and prestenting) and outcome (stent fracture, Doppler-derived estimated RVOT gradient at last echocardiogram) variables were prespecified. Echocardiogram-derived RVOT gradients were classified as mild (MIG<35 mm Hg or mean<20 mm Hg), moderate (MIG, 35–50 mm Hg or mean, 20–35 mm Hg), or severe (MIG>50 mm Hg or mean>35 mm Hg). Because higher and particularly early postimplant catheterization and Doppler RVOT gradients are predictive of subsequent Melody valve fracture and dysfunction,11 we chose a relatively low threshold for Melody valve dysfunction as greater than mild obstruction (MIG<35 mm Hg or mean<20 mm Hg) or insufficiency, which differs from the initial investigational device exemption studies.11–13 This threshold was chosen as a point of concern and was not chosen to reflect a threshold for reintervention. More granular data on degree of RVOT obstruction and reintervention are reported separately.

Results
Baseline and Procedural Characteristics
Melody TPVs were placed in native or postsurgical, nonconduit RVOTs in 31 patients. The median age at implantation was 24 years (range, 7–66), and the median weight was 62 kg (range, 23–157). Approximately half of the patients were male. Indications for RVOT intervention included primarily valvular insufficiency in 14 (45%), obstruction in 3 (10%), and mixed obstruction and insufficiency in 14 (45%). The underlying diagnosis was some form of pulmonary stenosis with ventricular septal defect (eg, tetralogy of Fallot, double-outlet right ventricle) in 24 patients (77%), with 3 patients having a history of isolated pulmonary valve stenosis, 2 with carcinoid-related pulmonary valve dysfunction, and one each having transposition with pulmonary stenosis and pulmonary atresia with intact ventricular septum (Figure 2).

Procedural and valve implantation characteristics are presented in Table 1. Twenty-nine of 31 procedures were performed under general anesthesia. Sternal fixation of the RVOT was noted in 2 patients. Preimplantation balloon sizing was performed in the majority of patients. Prestenting, or placement of a bare metal stent in the area of subsequent Melody valve implantation, was performed in 22 of 31 (71%) cases, with a single stent in 21 patients and 2 stents in one. All patients had prestenting and Melody implantation within the RVOT, without unconventional measures to ensure RVOT stent stability (eg, deliberate branch pulmonary artery jailing with extension into the RVOT, implantation of Melody valves into the branch pulmonary arteries, etc.).2,7 The majority of valves were deployed on a 22-mm delivery system. Postdilation of the implanted Melody valve was performed in 5 (16%) patients with balloons ranging from 22 to 24 mm. Additional interventions were performed in 10 (32%) patients.

Immediate Outcomes
Melody valve implantation was successful in all patients with no procedural mortality. After intervention, the median minimal luminal RVOT diameter was increased from 14 to 20 mm, and in those with obstruction there was a significant reduction in right ventricular hypertension, with no patient having greater than a 20 mm Hg peak systolic pressure drop across the area of intervention (Table 2).
Serious complications were reported in 2 (6%) patients. One patient developed a contained RVOT tear during balloon dilation, without hemothorax or hemopericardium, that was treated with covered stent placement prior to Melody valve implantation. One patient developed an iatrogenic aortopulmonary connection during RVOT/pulmonary artery intervention. One patient developed stent fracture and reobstruction 5 months after initial TPV. Although the second valve demonstrated minimal obstruction and no insufficiency, both valves were explanted during a subsequent surgical repair of a complex coarctation of the aorta. One additional patient developed stent fracture and underwent repeat Melody valve implantation +14 months after initial TPV. The first patient developed multiple stent fractures and underwent repeat Melody valve implantation +14 months after initial TPV. The second valve demonstrated minimal obstruction and no insufficiency, both valves were explanted during a subsequent surgical repair of a complex coarctation of the aorta. One additional patient developed stent fracture and underwent repeat Melody valve implantation. The first patient developed multiple stent fractures and underwent repeat Melody valve implantation. The second valve demonstrated minimal obstruction and no insufficiency, both valves were explanted during a subsequent surgical repair of a complex coarctation of the aorta. One additional patient developed stent fracture and underwent repeat Melody valve implantation. The first patient developed multiple stent fractures and underwent repeat Melody valve implantation. The second valve demonstrated minimal obstruction and no insufficiency, both valves were explanted during a subsequent surgical repair of a complex coarctation of the aorta.

Follow-Up
The median duration of follow-up was 15 months (range, 1 month–3.8 years). At last clinical evaluation, all patients were alive. The most recent echocardiogram was performed at a median of 12 months from Melody implant (range, 1–36 months). Excluding patients with explanted valves, no patient had greater than mild TPV insufficiency, and the median MIG across the RVOT was 23 mm Hg (range, 0–70 mm Hg). Table 3. Eight patients developed moderate or greater TPV obstruction, defined as a Doppler-derived MIG of 35 mm Hg or mean gradient of 20 mm Hg or higher, and all 8 patients with MIGs greater than 40 mm Hg were associated with an identified stent fracture. Adequate imaging of stent integrity was obtained in only 19 (61%) patients. Follow-up stent fluoroscopy was more common in those with higher Doppler-derived estimates of RVOT obstruction. Patients who underwent fluoroscopic imaging had median MIGs of 30 mm Hg (range, 0–70), whereas those without adequate imaging had median MIGs of 17.5 (range, 9–34). Among the 19 patients with adequate imaging, 6 (32%) had evidence of stent fracture. Stent fracture was observed in 3/6 (50%) of patients who did not have presenting of their RVOT prior to Melody implantation, whereas it was observed in 3/13 (23%) of patients who underwent presenting (OR, 0.34; 95% CI 0.04–2.97; P=0.34). Similarly, the change in RVOT angulation was 9.7° in those with documented stent fracture versus 0° in those without (OR, 1.1; 95% CI 0.95–1.3; P=0.19), whereas in those without adequate imaging of stent integrity it was 1°. There were no documented stent or stent fragment embolizations. Because documentation of stent integrity was incomplete for the cohort, we were unable to more rigorously assess predictors of stent fracture.

During the follow-up period, there were 5 reinterventions in 3 patients. Three patients underwent repeat Melody valve placement because of stent fracture and recurrent obstruction at 5, 14, and 32 months after initial implant. There were 2 Melody valve explantations, both of whom had undergone a second Melody valve implantation. The first patient developed multiple stent fractures and underwent repeat Melody valve implantation +14 months after initial TPV. Although the second valve demonstrated minimal obstruction and no insufficiency, both valves were explanted during a subsequent surgical repair of a complex coarctation of the aorta. One additional patient developed stent fracture and underwent repeat TPV 5 months after initial TPV implantation. She was brought back to the cardiac catheterization laboratory where additional bare metal stents were placed, followed by an additional Melody valve. However, she subsequently developed ventricular tachycardia and had all stents explanted several days later. The ventricular tachycardia was thought possibly related to the position of the additional bare metal stents.

Three patients were treated for either endocarditis or blood stream infection, 2 of whom had vegetations identified on the Melody valve. Two of these patients were previously reported. All were treated with antibiotics and none required Melody explantation.

Discussion
Potential Utility of TPV Replacement for Native RVOT Dysfunction
The advent of the Melody TPV replacement therapy represents an important advance in congenital cardiovascular interventions. However, there remain substantial limitations to this novel technology. The off-label extension of the Melody TPV

Table 1. Procedural Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Post-Melody</th>
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<tbody>
<tr>
<td>Balloon sizing prior to TPV implant</td>
<td>30/31</td>
<td>97%</td>
</tr>
<tr>
<td>RVOT prestent placed prior to TPV implant</td>
<td>19/22</td>
<td>86.5%</td>
</tr>
<tr>
<td>Prestent type</td>
<td></td>
<td></td>
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<tr>
<td>Palmaz</td>
<td>19/22</td>
<td>86.5%</td>
</tr>
<tr>
<td>Genesis XD</td>
<td>1/22</td>
<td>4.5%</td>
</tr>
<tr>
<td>EV3</td>
<td>1/22</td>
<td>4.5%</td>
</tr>
<tr>
<td>CCPS + Palmaz</td>
<td>1/22</td>
<td>4.5%</td>
</tr>
<tr>
<td>TPV deployment balloon delivery size</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 mm</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td>20 mm</td>
<td>5</td>
<td>16%</td>
</tr>
<tr>
<td>22 mm</td>
<td>24</td>
<td>77%</td>
</tr>
<tr>
<td>24 mm*</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td>Postdilation performed</td>
<td>5/31</td>
<td>16%</td>
</tr>
<tr>
<td>Postdilation balloon size</td>
<td>22–24 mm</td>
<td></td>
</tr>
</tbody>
</table>

Additional interventions
- Pulmonary artery intervention: 7
- Atrial septal defect closure: 2
- Coarctation stent placement: 1

CCPS, Covered Cheatham platinum stent; RVOT, right ventricular outflow tract; and TPV, Transcatheter Pulmonary Valve.

*Cheatham et al.14
isolated pulmonary valve stenosis, at least 2 of whom under- 
ble-outlet right ventricle. The inclusion of 3 patients with 
tricular septal defect, including tetralogy of Fallot and dou-

extended TPV technology. The vast majority were subjects 
range of underlying diagnoses that stand to benefit from 
TPV implantation and follow-up in this setting.

This study presents a more extended evaluation of Melody 
in whom the majority underwent a separate antecedent proce-

reported technical results of TPV implantation in 10 patients, 
early in life, reminds us that pulmonary regurgitation can 
go initial nonsurgical balloon pulmonary valvuloplasty 

Valvuloplasty.16

be an important adverse consequence of balloon pulmonary 

the technical outcomes of using either sequential RVOT stents 
to narrow large RVOTs or intentional pulmonary artery jailing 
as mechanisms of RVOT preparation. Finally, Boshoff et al9 
reported technical results of TPV implantation in 10 patients, 
in whom the majority underwent a separate antecedent proce-
dure for bare metal stent placement prior to TPV implantation. 
This study presents a more extended evaluation of Melody 

The population presented is characteristic of the broader 
range of underlying diagnoses that stand to benefit from 
extended TPV technology. The vast majority were subjects 
with anatomic variation of pulmonary stenosis with ven-
tricular septal defect, including tetralogy of Fallot and dou-
ble-outlet right ventricle. The inclusion of 3 patients with 
isolated pulmonary valve stenosis, at least 2 of whom under-
went initial nonsurgical balloon pulmonary valvuloplasty 
early in life, reminds us that pulmonary regurgitation can 
be an important adverse consequence of balloon pulmonary 
valvuloplasty.16

All procedures were technically successful, with stable 
valve position and no early residual RVOT obstruction. At 
follow-up, 74% of patients in this cohort had RVOT MIGs of 
<35 mm Hg and no important pulmonary insufficiency.

Adverse Events

Serious complications were encountered in 2 patients. The 
first occurred in a young patient with a relatively small 
native RVOT in whom a contained tear occurred during initial 
balloon angioplasty. The successful use of a cov-

ered stent to repair the tear highlights the potential utility 
of large-diameter covered stents in managing RVOT com- 
lications associated with TPV implant procedures. The 
second serious complication was the result of intervention 
unrelated to Melody TPV implantation. The development of 

ventricular tachycardia in 1 patient with RVOT stents is of 
unclear significance. Although the presence of myocardial 
cells in the area of intervention capable of an arrhythmo-

genic focus makes a causal relationship plausible, the exist-
ing literature on RVOT stent placement is not supportive.17–19

Nevertheless, it seems reasonable that, whenever possible, 
RVOT stents should be positioned with as little protrusion 
into areas of contracting muscle as possible, a practice that 
may also reduce the risk of stent fracture, and vigilance for 
arrhythmia must be maintained.

Three patients were treated for blood stream infections or 
resolved endocarditis. There have been several recent reports 
looking at endocarditis after Melody valve implantation.15,20

Although this series is too small to add substantially to that 
discussion, and some of the patients who developed endocar-
ditis in this cohort were included in a prior report, it is impor-
tant to recognize that endocarditis can and does occur after 
Melody valve placement in patients with a native postopera-
tive RVOT as well as those with homograft or bioprosthetic 
 conduits.

Similar to Melody TPV performance under traditional 
indications, valve competency in this cohort seems to be 
relatively well preserved, at least within the time frame 
encompased by this study. Consistent with historical 
observations,11,12 the dominant mechanism of Melody TPV 
dysfunction seems to be stent fracture and reobstruction.

Unfortunately, because the series was relative small and 
documentation of stent integrity was incomplete, we were 
unable to assess predictors of Melody valve stent fracture 
after implant into a native RVOT. However, there was a sug-
gestion of prophylaxis through RVOT preparation with bare 
metal stent placement prior to TPV implantation, 
a technique with clear benefit in more traditional Melody 
implantations.11,21 Nevertheless, in the current population, 
stent fracture occurred in 3 patients despite prestenting. In 2 
of these, there was a residual waist in the Melody stent after 
implant. Without knowing what proportion of patients with-
out stent fracture had residual waists, the significance of 
this must remain uncertain. However, given prior evidence sug-
gesting that multiple pre-Melody stent implantations may be 
more beneficial than a single presten in preventing impor-
tant Melody stent fracture,11 native outflow tract preparation 
with multiple bare metal stents may therefore be appropriate 
in some patients. Keeping this in mind, appropriate caution 
should be taken not to overextend the findings of Melody 
performance from conduits to native outflow tracts. Many of 
the more important risk factors for stent fracture in conduit 
patients (eg, substernal location, dynamic compression, etc.) 
are rarely found in this population, and so the risk factors for 
stent fracture in this situation are likely different. The native 
postoperative RVOT in this population can be highly variable 
anatomically and is frequently subject to significant dynamic 
variability throughout the cardiac cycle.22 This dynamic back-
ground may be one of the important factors contributing to 
fatigue and fracture of the Melody valve frame. If Melody 
valve implantation in the native or augmented postoperative 
RVOT is going to continue, and it likely is, it will be worth- 
while trying to understand risk factors for stent fracture and 
protecting against fracture with prestenting.

| Table 3. Echocardiographic Findings at Follow-Up |
|-----------------|-------|-------|
| Time from Melody placement, months | 12 (1–45) |
| Maximum instantaneous right ventricular outflow tract gradient, n=31 | 23 (0–70) |
| Mean right ventricular outflow tract gradient, n=21 | 12 (0–35) |
| Pulmonary regurgitation, n=30 |
| None—Trivial | 19 |
| Mild | 11 |
| Moderate | 0 |
| Severe | 0 |
Future Directions
TPV therapy has become an important tool in the management of patients with postoperative RVOT dysfunction, but its reach remains relatively limited. The successful extension of TPV therapy has the potential not only to expand the existing candidate population, but also to change fundamentally the management of postsurgical RVOT dysfunction. The deleterious effects of postoperative pulmonary insufficiency on right ventricular mechanics are immediate, and the chronic effects are progressive and, at some point, presumably, irreversible. Prior to the availability of TPV technology, decisions about the timing of RVOT reintervention necessarily weighed the benefits of RVOT restoration against the risks and morbidity of surgical pulmonary valve replacement. As a result, in patients not amenable to TPV implantation, current practice might be characterized as favoring pulmonary valve replacement when it is not too late rather than when it is best for the right ventricle. However, as the risks and morbidity of RVOT intervention decrease, as with TPV therapy, the balance of the equation should change. Based on the evolving understanding of RVOT dysfunction and its implications, along with the shifting balance of risk/morbidity and benefit, it may be reasonably argued that earlier intervention on dysfunctional RVOTs is warranted in some if not all patients. One strategy for extending the reach of currently available TPV technology might be to implant bare metal stents in selected patients with a native postoperative RVOT at a relatively young age, before the degree of RVOT enlargement precludes Melody valve placement. This approach could turn a traditional drawback of stent placement in younger children—that the stents do not grow while children do—into a desirable feature, effectively creating an RVOT dilation limiter that could serve at a landing zone for placement of additional stents and a TPV in the future.

Limitations
There are limitations to the results obtained from this observational cohort. Valve performance is not ideally measured in months, but in years, and limited patient numbers and follow-up constrain extended inference from this study. Also, because we did not have complete longitudinal data on all patients, our ability to fully analyze predictors of important time-dependent outcomes such as stent failure was limited. For example, although we measured RVOT angle, we did not assess the dynamic nature of the RVOT, which may be an important factor in the cause of stent fracture. Similarly, the degree of stent recoil was not routinely captured and may provide additional insight. Finally, because patients who were considered for TPV implant but were found not to be anatomically suitable were not ascertained for this study, we do not have sufficient information to draw clear conclusions about which patients are good candidates for extended use of TPVs. Given that native RVOTs tend to remain highly distensible, it seems likely that RVOTs with diameters $>$22 mm by preparatus imaging are unlikely to be good candidates although this has not been studied systematically. Although the ability to deliver TPVs on 24-mm balloons with apparent reasonable function in the short term may expand the candidate population further, further characterization is clearly desirable.

Conclusions
Melody TPV implantation is feasible in selected patients with outflow tracts comprised solely or predominantly native tissue and has the potential to expand the population of patients eligible to benefit from nonsurgical restoration of RVOT function. In early follow-up, valve competency seems preserved, and similar to experience in circumferential outflow tract conduits, the dominant mechanism of valve dysfunction seems to be stent fracture with recurrent obstruction. Given the differences in the anatomy and dynamic nature of the RVOT in this patient population, more data will be necessary to understand how best to safely expand TPV therapy to this population.

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Disclosures
J.P.C. is a consultant, proctor, and primary investigator for Medtronic. M.J.G. is a consultant for and research support from Medtronic. E.M.Z. and D.B.M. are consultants and proctors for Medtronic. The other authors report no conflicts.

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