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Comparison of the Clinical Outcomes and Hemodynamic Performance between the 19-Mm Mosaic® and 19-Mm TrifectaTM Bioprosthesis

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Abstract

Background: We evaluated and compared short- (≤ 3 months) and mid-term (≥ 4 months) clinical outcomes and hemodynamic performances of the 19-mm Mosaic® and 19-mm Trifecta™ bioprostheses for aortic valve replacement.

Methods: 193 patients underwent aortic valve replacement: 37 received the 19-mm Mosaic® prosthesis (Group M) and 12 received the 19-mm Trifecta™ prosthesis (Group T). Pre- and postoperative echocardiographic parameters and New York Heart Association classes were evaluated in both groups.

Results: Baseline characteristics and preoperative echocardiographic parameters were similar between the groups. The New York Heart Association class improved in both groups. The mean left ventricular-aortic pressure gradient was 22.6 mmHg ± 8.4 mmHg in Group M and 15.0 mmHg ± 6.2 mmHg in Group T. The left ventricular mass index was 99.6 ± 27.6 g/m^2 and 99.0 ± 20.0 g/m^2 respectively, with significant improvements in both groups. Left ventricular mass index regression during the mid-term period showed no significant difference between the groups, despite a higher-pressure gradient and smaller effective orifice area index in the Mosaic® group. Patient-prosthesis mismatch occurred in 20 patients in the Mosaic® group, with no significant differences in the postoperative left ventricular mass indices and New York Heart Association classes between the patient-prosthesis mismatch and no patient-prosthesis mismatch subgroups in the Mosaic® group.

Conclusion: Compared with the 19-mm Trifecta™ bioprosthesis, the 19-mm Mosaic® bioprosthesis showed similar satisfactory improvement in the New York Heart Association class grade and reduction in the left ventricular mass index, despite a higher-pressure gradient and smaller effective orifice area index.

Keywords: Aortic valve; 19-mm Mosaic bioprosthesis; Aortic valve stenosis; Retrospective study

Introduction

The Mosaic® bioprosthesis is one of the most commonly used valves in aortic valve replacement (AVR). When a 19-mm perimount bioprosthesis cannot be implanted in a small aortic annulus, the 19-mm Mosaic® bioprosthesis is used because of its stent flexibility and maneuverability as well as because its outer diameter is smaller than that of tissue valves of the same size. The Mosaic® bioprosthesis has satisfactory long-term clinical outcomes; however, it tends to have a higher-pressure gradient on postoperative cardiac ultrasonography. Clinical outcomes and hemodynamic performance of the 19-mm Mosaic® bioprosthesis have been reported; however, to the best of our knowledge, this study is the first to compare the 19-mm Mosaic® bioprosthesis with the 19-mm Trifecta™ bioprosthesis by reviewing short- and mid-term results and evaluating the effects of AVR.

Patients and Methods

We retrospectively reviewed data collected from Shonan Kamakura General Hospital. From April 2009 to March 2014, 193 patients underwent AVR, of whom 37 received a 19-mm porcine aortic valve bioprosthesis (Mosaic®; Mosaic Porcine Bioprosthesis, Ultra (Aortic); Medtronic Heart Valves, Santa Ana, CA, USA; Group M) and 12 received a 19-mm bovine three-leaflet stented pericardial valve bioprosthesis (Trifecta™; St. Jude Medical® Trifecta™ Valve; St. Jude Medical, St. Paul, MN, USA; Group T). The indication for surgery was severe aortic stenosis. We followed the Japanese guidelines for selection of prosthesis, which indicate patients >65 years old or intolerant to warfarin to be suitable. When we could not implant a 19-mm perimount bioprosthesis in a small aortic annulus, we used a 19-mm Mosaic® bioprosthesis. Patients who underwent mitral valve replacement were not included in this study. The patient preoperative characteristics are presented in Table 1. The body surface area (BSA) of each patient was calculated according to the Mosteller formula, and the average BSA in Group M was lesser than that in Group T.

Operative technique

A median sternotomy was performed with ascending aorta cannulation and double venous drainage through the superior and inferior vena cava. A vent tube was inserted from the upper right pulmonary vein, and an artificial heart–lung circulation was established. A cardioplegic solution was antegradely injected from the ascending aorta, and the right atrium was incised to intermittently inject retrograde coronary perfusion from the coronary sinus and maintain cardiac arrest. The aorta was incised, and the leaflets were checked and completely excised. After a thorough washing, a 19-mm Trifecta™ prosthesis sizer was used to determine whether insertion was possible; if it could not be implanted, we used a Mosaic® bioprosthesis. For suturing the prosthetic valve, in all cases, 2-0 braided polyester was used to suture to a supra-annular position by horizontal mattress suturing.

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Clinical and echocardiographic follow-up

Clinical follow-up data were obtained via hospital visit or telephone interview. Postoperative improvement in symptoms was assessed by determining the New York Heart Association (NYHA) class. Follow-up echocardiography data in the mid-term period were obtained from 33 (67%) of 49 patients at 16.7 ± 11.7 (range, 4-60) months postoperatively. The maximum and mean left ventricular-aortic pressure gradient (LVAo-PG), left ventricular mass index (LVMI), and effective orifice area index (EOAI) were measured and comparatively studied using transthoracic echocardiography in the preoperative, short (≤ 3 months) and mid-term (≥ 4 months) postoperative periods. LVAo-PG was measured using the Bernoulli equation and continuous wave Doppler to measure the maximum and mean value. For LVMI, we used an index established by calculating LV mass determined according to the Devereux equation and dividing it by BSA. For EOAI, we used an index calculated using an equation of continuity and dividing the result by BSA.

Statistical analysis

Results are expressed as the mean ± standard deviation, and the chi-square test or unpaired Student t-test was used to compare the groups. Differences between the two groups were analyzed using the chi-square test, unpaired Student's t-test, or 2-way repeated ANOVA, as appropriate. SPSS (Version 10.1; SPSS, Chicago, IL, USA) was used as the statistical software, and differences were determined to be significant at values of $p<0.05$.

Variables	Group M (n=37)	Group T (n=12)	p
Age (years)	78.1 ± 4.4	74.5 ± 4.4	<0.05
Male/female	10:27	06:06	N.S.
BSA (m^2)	1.47 ± 0.13	1.56 ± 0.17	<0.05
NYHA class	1.97 ± 0.60	1.83 ± 0.72	N.S.
NYHA class III or IV No. of patients	6 (16%)	2 (17%)	N.S.
Indication for surgery			
AS	37 (100%)	11 (97%)	N.S.
ASR	0	1 (8%)	N.S.
Procedure			
Isolated AVR	22 (59%)	6 (50%)	N.S.
+ CABG	10 (27%)	3 (25%)	N.S.
+ Graft replacement	2 (5%)	3 (25%)	<0.05
+ Maze	1(3%)	0	N.S.
+ TAP	2 (5%)	0	N.S.
Bicuspid aortic valve	3 (8%)	3 (25%)	<0.05
Hypertension	30 (81%)	8 (67%)	N.S.
Diabetes mellitus	13 (35%)	4 (33%)	N.S.
Follow-up period (months)	17.3 ± 12.5	16.3 ± 10.3	N.S.

BSA: Body Surface Area; NYHA: New York Heart Association; AVR: Aortic Valve Replacement; CABG: Coronary Artery Bypass Grafting; TAP: Tricuspid Annuloplasty

Table 1: Baseline characteristics of patients undergoing aortic valve replacement.

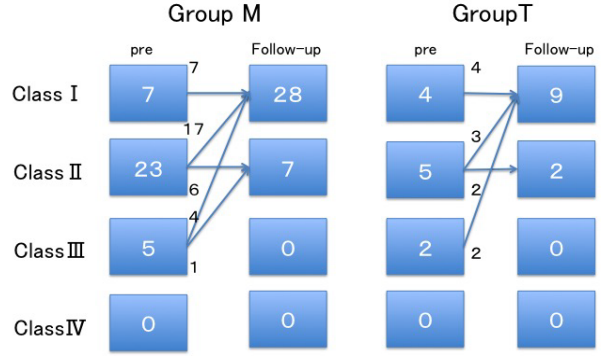

Figure 1: Change in New York Heart Association classification.

Results

Survival

Overall hospital mortality in both groups was 0%. However, in Group M, two (5.4%) patients died during the follow-up period: one from a cerebral hemorrhage 6 months after surgery and the other from gastric cancer 45 months post-surgery. With regard to complications, one (2.7%) patient who developed postoperative sick sinus syndrome had a pacemaker implanted; no other complications were observed, including thrombotic embolism. In Group T, one (8.3%) patient died of an unknown cause 2 months post-surgery, and one (8.3%) patient who developed postoperative sick sinus syndrome had a pacemaker implanted. Paravalvular leakage in both groups was 0%.

New York heart association class

Pre- and postoperative NYHA classes were investigated in the patients, excluding the three patients who died during the follow-up. In Group M, seven patients were preoperative NYHA class I; the classes did not change for any patient post-surgery. Twenty-three patients were NYHA class II preoperatively; of these, 17 were class I and six were class II post-surgery. These results indicate improvement in 17/23 (74%) patients. Five patients were NYHA class III preoperatively; of these four patients were class I and one was class II post-surgery. These results indicate improvement in all patients (Figure 1). In Group T, four patients were NYHA class I preoperatively; all patients were class I post-surgery. Of the five patients who were NYHA class II preoperatively, three were class I and two were class II post-surgery. These results indicate improvement in 3/5 (60%) patients. There were two patients who were NYHA class III preoperatively and were class I post-surgery. The differences between the two groups were insignificant.

Changes in echocardiographic variables

Maximum and mean left ventricular-aortic pressure gradient. In Group M, the maximum and mean LVAo-PG values were 38.3 mmHg ± 13.0 mmHg and 20.1 mmHg ± 6.7 mmHg in the short-term period and 42.6 mmHg ± 13.2 mmHg and 22.6 mmHg ± 8.4 mmHg in the mid-term period, respectively; in Group T, maximum and mean LVAo-PG values were 24.2 mmHg ± 10.1 mmHg and 14.0 mmHg ± 5.7 mmHg in the short-term period and 31.0 mmHg ± 12.7 mmHg and 15.0 mmHg ± 6.2 mmHg in the mid-term period, respectively (Figures 2A and 2B). The pressure gradient was significantly decreased in both groups in the short- and mid-term periods ($p<0.05$); however, the postoperative pressure gradient was higher in Group M than in Group T ($p<0.05$) (Table 2).

Left ventricular mass index

In Group M, LVMI was 126.4 g/m^2 ± 24.1 g/m^2 in the preoperative period, 110.9 g/m^2 ± 30.0 g/m^2 in the short-term period, and 99.6 g/m^2 ± 27.6 g/m^2 in the mid-term period; in Group T, the LVMI was 137.2 g/m^2 ± 39.1 g/m^2 in the preoperative period, 104.3 g/m^2 ± 15.2 g/m^2 in the short-term period, and 99.0 g/m^2 ± 20.0 g/m^2 in the mid-term period. In both groups, significant improvements were observed during both the short- and mid-term periods ($p<0.05$). There were no significant differences in LVMI regression in the short-term period (20.7 g/m^2 ±

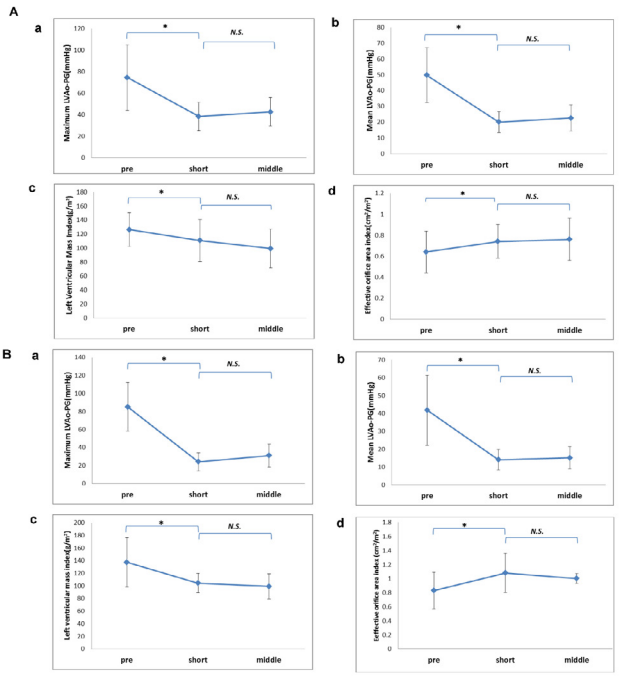

Figure 2: (A) Comparison of echocardiographic data in Group M in the preoperative, short-term, mid-term, and postoperative periods. (B) Comparison of echocardiographic data in Group T in the preoperative, short-term, mid-term, and postoperative periods. In both: a, maximum pressure gradient; b, mean pressure gradient; c, left ventricular mass index; d, effective orifice area index.

Period	Group M (n=37)	Group T (n=12)	p
Maximum LVAo-PG (mmHg)			
Preoperative	74.6 ± 30.4	85.1 ± 26.9	N.S.
Short-term	38.3 ± 13.0	24.2 ± 10.1	<0.05
Mid-term	42.6 ± 13.2	31.0 ± 12.7	<0.05
Mean LVAo-PG (mmHg)			
Preoperative	49.8 ± 17.4	41.7 ± 19.6	N.S.
Short-term	20.1 ± 6.7	14.0 ± 5.7	<0.05
Mid-term	22.6 ± 8.4	15.0 ± 6.2	<0.05
LVMI (g/m²)			
Preoperative	126.4 ± 24.1	137.2 ± 39.1	N.S.
Short-term	110.9 ± 30.0	104.3 ± 15.2	N.S.
Mid-term	99.6 ± 27.6	99.0 ± 20.0	N.S.
EOAI (cm²/m²)			
Preoperative	0.64 ± 0.20	0.83 ± 0.26	<0.05
Short-term	0.74 ± 0.16	1.08 ± 0.28	<0.05
Mid-term	0.76 ± 0.20	1.00 ± 0.07	<0.05

Data given as n (%) or mean ± SD. LVAo-PG: Left Ventricular-Aortic Pressure Gradient; LVMI: Left Ventricular Mass Index; EOAI: Effective Orifice Area Index

Table 2: Comparison of echocardiographic data between Group M and Group T in the preoperative, short-term, mid-term and postoperative periods.

36.1 g/m² vs. 25.1 g/m² ± 20.1 g/m², p=0.68) and mid-term period (30.2 g/m² ± 21.1 g/m² vs. 33.0 g/m² ± 23.7 g/m², p=0.77) between Group M and Group T (Figure 3).

Effective orifice area index and patient-prosthesis mismatch

In Group M, EOAI was 0.64 cm²/m² ± 0.20 cm²/m² in the preoperative period, 0.74 ± 0.16 in the short-term period, and 0.76 cm²/m² ± 0.20 cm²/m² in the mid-term period; in Group T, EOAI was 0.83 cm²/m² ± 0.26 cm²/m² in the preoperative period, 1.06 cm²/m² ± 0.26 cm²/m² in the short-term period, and 1.01 cm²/m² ± 0.08 cm²/m² in the mid-term period. The preoperative EOAI was smaller in Group M than in Group T (p<0.05), and both the short- and mid-term periods EOAI values were significantly better in Group T than in Group M (p<0.05). We divided the patients who received the Mosaic® bioprosthesis into two groups: no patient-prosthesis mismatch (PPM) group and PPM group. EOAI was measured in 28 patients (76%) during the mid-term period. PPM was graded in the short-term period according to EOAI as follows: severe PPM, EOAI<0.65 cm²/m²; moderate PPM, EOAI=0.65 cm²/m²–0.85 cm²/m²; and no mismatch, EOAI>0.85 cm²/m². Severe PPM occurred in nine (32%) patients, moderate PPM occurred in 11 (39%) patients, and no mismatch occurred in eight (30%) patients. There was a tendency for the maximum and mean LVAo-PG to be higher in the PPM group than in the no PPM group; however, the difference was not significant. There were no significant differences in LVMI and NYHA class between the two groups (Figure 4).

Discussion

The Mosaic® bioprosthesis is a third-generation tissue valve that was created to leverage the advantages of free-style tissue in a stented tissue valve. One of its features is that the stent is flexible and returns to its original shape even after deformation; therefore, further cinching during insertion using a ratchet mechanism is believed to make it more useful in cases of a stenotic valve annulus, narrow sinotubular junction, and intense calcification as well as in minimally invasive cardiac surgery. For AVR, 19-mm bioprostheses are used in Japanese patients with a small aortic annulus. Some techniques of aortic root

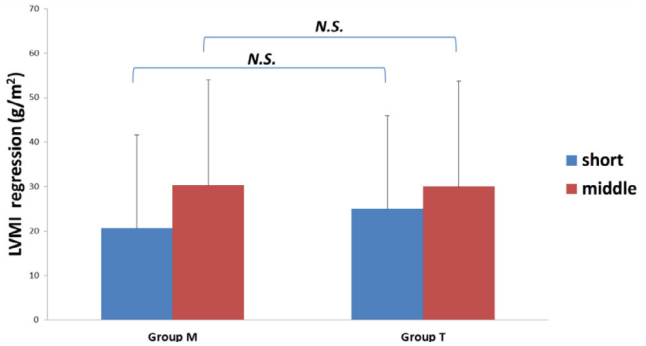

Figure 3: Left ventricular mass index (LVMI) regression compared with preoperative and short- or mid-term LVMI in Groups M and T.

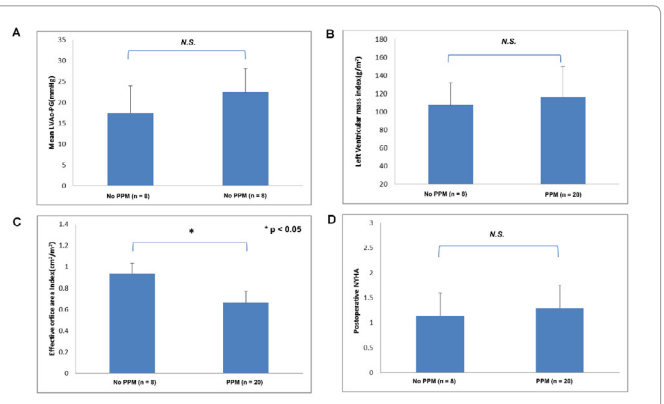

Figure 4: Comparison of the no PPM (n=8) and PPM (n=20) groups in the short-term period in Group M. (a) Comparison of aortic valve mean pressure gradient; (b) comparison of left ventricular mass index; (c) comparison of effective orifice area index; (d) comparison of postoperative NYHA classification.

enlargement have been described that could be used to implant a larger prosthesis; however, these techniques increase postoperative morbidity and mortality [1]. However, 19-mm bioprostheses cause persistent higher-pressure gradients because of the small orifice area. To reduce pressure gradients, the Trifecta™ bioprosthesis with an externally mounted section of pericardium may provide excellent hemodynamic performance [2].

The excellent durability and low incidence of complications in the 19-mm Mosaic® bioprosthesis have been reported as long-term results [3]. However, Kirsch et al. reported a maximum LVAo-PG of 40.8 mmHg ± 12.1 mmHg and mean LVAo-PG of 23.4 mmHg ± 12.1 mmHg, which are high values [4]. Other authors have reported similar results [5,6]. In this study, we found that the maximum (42.6 mmHg ± 13.2 mmHg) and mean (22.6 mmHg ± 8.4 mmHg) LVAo-PG values were high for the Mosaic® bioprosthesis. In contrast, the maximum (31.0 mmHg ± 12.7 mmHg) and mean (15.0 mmHg ± 6.2 mmHg) LVAo-PG values for the 19-mm Trifecta™ bioprosthesis were significantly lower ($p<0.05$). This is because, structurally, the Mosaic® bioprosthesis has reduced turbulence caused by a shape that deflates from the LV outflow tract and produces a pressure recovery phenomenon that has been described as possibly causing the higher-pressure gradients observed on cardiac ultrasonography. Ito et al. [7] reported a case of a high LVAo-PG associated with the use of a Mosaic® bioprosthesis in AVR that was determined to be as high as 60 mmHg by cardiac ultrasonography; however, the peak-to-peak PG measured using a catheter was only 15.1 mmHg. The authors stated that the discrepancy between the Doppler and catheter examinations appeared to be caused by a fluid dynamic pressure recovery phenomenon. The flexible leaflets of the Mosaic® bioprosthesis can be better opened by force than those of the perimount bioprosthesis because of the lower turbulence that enhances pressure recovery.

Despite the higher-pressure gradient observed in Group M, there was no significant difference in LVMI between the two groups (99.6 g/m^2 ± 27.6 g/m^2 vs. 99.0 g/m^2 ± 20.0 g/m^2). LV hypertrophy in aortic stenosis is believed to be a compensatory response to maintain systolic function and is an underlying determinant of patient longevity after AVR. There was no significant difference in LVMI regression in Group M (30.2 g/m^2 ± 21.1 g/m^2) and Group T (33.0 g/m^2 ± 23.7 g/m^2) in the mid-term period and ($p=0.77$; Figure 3). Dalmau et al. [8] compared outcomes after the implantation of Mosaic® and Magna bioprostheses in a randomized study of 86 patients; the Magna bioprosthesis group had a lower mean LVAo-PG (17.1 mmHg vs. 10.2 mmHg) and larger AVA (1.69 cm^2 vs. 1.99 cm^2) after 1 year than the Mosaic® bioprosthesis group; however, no significant difference in LVMI regression was observed. They concluded that small variations in prosthetic hemodynamics may not be important for LVMI regression.

Among the Mosaic® bioprosthesis patients in the present study, severe PPM occurred in nine (32%) patients, moderate PPM occurred in 11 (39%) patients, and no mismatch was observed in eight (30%) patients in this study; the rate of PPM was high. Kirsh et al. [4] reported a very high rate of PPM; the average EOAI among 90 patients who received the Mosaic® bioprosthesis was 0.65 cm^2/m^2 ± 0.07 cm^2/m^2, and 40 (44.4%) patients had moderate PPM and 41 (45.6%) patients had severe PPM. Furthermore, other reports have described high rates of PPM [6]. Despite these high rates, the NYHA class and other echocardiographic parameters have been shown to improve significantly. Because of the potential for the occurrence of an associated pressure recovery phenomenon, evaluation of the Energy Loss Coefficient (ELCo) is required by correcting the pressure recovery according to the following equation:

$$ELCo=(EOA \times AoA)/(AoA - EOA)$$

where AoA is the cross-sectional area of the proximal ascending aorta. In this study, we did not accumulate sufficient ELCo data. Accumulation of more ELCo data is an area of potential future research.

Regarding the association between LVMI and PPM, Roscitano et al. [9] have shown that PPM did not affect the regression of LVMI in patients >65 years old. Some studies have shown that PPM is a strong and independent predictor of mortality among patients with AVR, [10,11] whereas others have shown no effects [12,13]. The association between PPM and mortality and morbidity is yet controversial. In our study, we divided the patients who received the Mosaic® bioprosthesis into the no PPM and PPM groups and compared the echocardiographic parameters in the mid-term period (Figure 4). There was no significant difference in the postoperative LVMI values between the no PPM and PPM groups (107.1 g/m^2 ± 24.4 g/m^2 vs. 115.8 g/m^2 ± 34.0 g/m^2, respectively). There was no significant difference in the NYHA class between the no PPM and PPM groups (1.14 ± 0.35 vs. 1.29 ± 0.46, respectively). Okamura et al. reported that the appropriate EOAI cut-off value for PPM may differ between the types of prosthesis, which would explain the conflicting results between series on the effect of PPM and clinical outcomes [14].

Although the pressure gradient was higher and EOAI was smaller in the 19-mm Mosaic® bioprosthesis group than in the 19-mm Trifecta™ bioprosthesis group, the LMVI values and improvements in the NYHA class were not significantly different. The 19-mm Mosaic® bioprosthesis had similar satisfactory clinical results.

There were several limitations to this study. The number of patients was less, and echocardiographic data was not available for all patients for various reasons; echocardiographic data was obtained for 33 (67%) of 49 patients at 16.7 months ± 11.7 months. We focused on early postoperative hemodynamic performance and did not evaluate the impact of late improvement. Furthermore, it was difficult to accurately evaluate NYHA classification because the level of activity in elderly patients is generally low.

Conclusion

In conclusion, compared with the Trifecta™ bioprosthesis, the Mosaic® bioprosthesis showed similar satisfactory improvement in the NYHA class and LVMI regression. High-pressure gradient formation and a small EOAI influenced pressure recovery in patients who received the Mosaic® bioprosthesis. Further evaluation methods to study these characteristics are required.

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Declaration of Conflicting Interests

The authors declare that there is no conflict of interest.

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