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Original Article

Case Series of Early Structural Valve Deterioration of Trifecta Bioprosthesis – New Zealand Experience

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Purpose: Structural valve deterioration (SVD) remains a limitation on the use of bioprosthetic valves, with patient and valve-related factors contributing to early SVD. The Trifecta valve has been reported to have excellent hemodynamics but studies have highlighted early failure. We present a review and case series at a New Zealand tertiary hospital defining early SVD as failure within 3 years of implant.
Methods: A retrospective review from January 2015 to July 2019 included 525 patients undergoing surgical aortic valve replacement with 263 patients receiving an Abbott Trifecta or Trifecta Glide Technology (GT) valve. Our review found an acceptable safety profile for the valve with excellent hemodynamics, with a low mortality, stroke, and permanent pacemaker rate.
Results: Three patients out of 263 were identified from the study period as having early SVD requiring reintervention within 3 years of valve implantation leading to a 1.14% failure rate. One of the valves that had early SVD was a new generation Trifecta GT. An additional four patients were identified to have valves implanted prior to the study period and had valve failure at greater than 3 years post implantation. Five cases had cusp tears as their mechanism of failure, raising concerns about durability.
Conclusion: The Trifecta valve has an acceptable safety profile and offers good hemodynamics due to the externally mounted leaflets. However, our experience of early SVD and failure is concerning for valve durability. Further comparison to other bioprosthetic valves and longer term follow-up are required to characterize the mechanism of failures.

Keywords: structural valve deterioration, Trifecta, bioprosthesis, aortic valve

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Introduction

There has been an increasing worldwide use of bioprosthetic valves in patients undergoing surgical aortic valve replacement (SAVR). Recent studies have highlighted no difference in 30-day mortality between bioprosthetic and mechanical valves, with a long term-survival benefit of mechanical SAVR only seen in patients until 55 years of age.[1)] These findings are reflected in the recent 2020 AHA/ACC guidelines that favor a bioprosthetic valve in patients over the age of 65 years with further consideration of a bioprosthetic valve for patients between the ages of 50 and 65 years of age on the basis of patient factors and preferences.[2)] This is a further reduction in

age range from the 2017 guidelines that put the upper limit of this recommendation at 70 years of age.[3]

The major limitation of surgical bioprosthetic valves is structural valve deterioration (SVD) and the need for reintervention. An ideal bioprosthesis should provide the patient with excellent hemodynamics with a large effective orifice area (EOA), durability in freedom from SVD, and ease of implantability for the surgeon.[4] The Abbott Trifecta valve (Abbott, St Paul, MN, USA) is a tri-leaflet stented externally mounted bovine pericardial valve that has been described as having superior hemodynamics due to a larger EOA compared to internally mounted valves.[5,6] Like the Sorin/LivaNova Mitroflow, it consists of a polyester fabric covered titanium stent with the addition of a porcine pericardial tissue stent cover to address leaflet abrasion. More recently, an updated version of the Trifecta valve, the Trifecta Glide Technology (GT), has been released with an improved anti-calcification treatment and redesigned valve leaflets and valve holder. Despite the excellent hemodynamic performance, there have been concerns regarding the durability of the Trifecta valve with early valve failure secondary to leaflet tears and SVD. Some international series have reported SVD and early valve failure rates as high as 6.5%.[7]

The high rate of early SVD of Trifecta valves resulted in a medical device alert being issued in the United Kingdom in July 2020 for the Trifecta and Trifecta GT valve.[8] It details 65 cases of Trifecta or Trifecta GT early failure within 8 years, with half of the cases occurring at only 2 to 3 years post implant. The alert from the Medicines and Healthcare products Regulatory Agency recommended that there be an enhanced follow-up as well as caution in sizing and implantation of the valve.

The first Trifecta was inserted in Wellington in 2012 with ongoing use until July 2020. During the 2018 to 2019 period, there was a cluster of seven Trifecta valves that had returned with SVD requiring reintervention raising concerns within the Department about their early failure. This preceded the UK Medical Device Alert. Consequently, we decided to analyze a specific cohort of patients to determine how many valve failures occurred within 3 years of insertion, given the UK cohort had 50% of their cases within the first 2 to 3 years post implantation.

The aims of this retrospective analysis were to identify the baseline characteristics of patients receiving SAVR with a Trifecta bioprosthesis in Wellington, New Zealand, and to outline their safety profile including their operative details and postoperative complications. The secondary aim was to identify cases of early SVD as defined by valve failure requiring reintervention less than 3 years from implantation.

Patients and Methods

Between the period of January 2015 and July 2019, we retrospectively reviewed all patients who underwent a publicly funded SAVR with a bioprosthetic valve at the Capital and Coast District Health Board. Patients were identified through the New Zealand National Cardiac Surgery Database (Dendrite) and clinical records. Only public patients were identified through the Dendrite database. In all, 525 patients at Wellington Public Hospital and Wakefield Private Hospital (public contract cases) were identified as either having a Trifecta, Trifecta GT, or Perimount Magna Ease valve (Edwards, Irvine, CA, USA) inserted. Follow-up data was obtained through the use of regional electronic medical records. The regional Heart Team database was also examined to identify any cases of Trifecta failure that were treated with valve in valve transcatheter aortic valve replacement (TAVR).

Results

Of these 525 patients, 263 patients received either a Trifecta (226) or a Trifecta GT (37) bioprosthetic aortic valve. **Table 1** demonstrates our patient cohort demographics.

Operative details

All patients in the study cohort underwent SAVR via a standard median sternotomy approach utilizing cardiopulmonary bypass. **Table 2** highlights the operative details, with the most common Trifecta size valve used being 23 mm. A total of four surgeons performed these procedures; however, the volume was predominantly by two surgeons inserting 125 (47.5%) and 120 (45%) of the Trifecta valves.

Of the 263 valves, 136 were placed supra-annular with horizontal mattress pledgeted sutures on the ventricular side. The remaining 127 were placed with simple vertical mattress interrupted sutures. All valves were hand tied down after removal of the valve holder with no use of Cor-Knot due to it not being available in our institution. The mean aortic cross clamp time for an isolated aortic valve replacement was 84 minutes. Concomitant procedures were performed in 55% of patients with coronary artery bypass grafting being the most common, occurring in 93 patients (63%).

Table 1 Patient demographics of the 263 patients including age of implant, gender, body mass index, medical history, indication for SAVR, and LVEF

Variable	N = 263
Age at implant (mean), years	72 ± 7.6 years
<49	1.5% (4/263)
50–59	3.8% (10/263)
60–69	23.9% (63/263)
70–79	53.6% (141/263)
>80	17.1% (45/263)
Gender	
Male	63.1% (166/263)
Female	36.9% (97/263)
BMI	
Mean BMI (range)	28.8 (16.9–45.7)
Medical history	
Hypertension	66.8% (177/263)
Hyperlipidemia	59.8% (157/263)
Cerebrovascular disease	11.8% (31/263)
Smoking history	52% (131/263)
Myocardial infarction	11.4% (31/263)
Diabetes	18.9% (49/263)
Severe renal impairment (creatinine clearance <50 mL/min)	17.5% (46/263)
Mean creatinine	94 μmol/L
Indication for SAVR	
Aortic stenosis	85.6% (225/263)
AR	11.0% (29/263)
Endocarditis	3.4% (9/263)
LVEF	
Normal	56.6% (149/263)
Mild	24.2% (90/263)
Moderate	7.6% (20/263)
Severe (<30%)	1.5% (4/263)

AR: aortic regurgitation; BMI: body mass index; LVEF: left ventricle ejection fraction; SAVR: surgical aortic valve replacement

Postoperative outcomes

Four patients had a postoperative stroke (1.5%) and two patients required the insertion of a permanent pacemaker (0.7%). Thirteen out of 263 patients required a return to theatre for bleeding (4.9%). There were two cases of deep sternal wound infection (0.7%). Our 30-day mortality was 2.2% (six patients) with further detail described in **Table 3**. Mortality for isolated aortic valve replacement was 0.7%. An additional 30-day mortality case was not included as it was a patient post coronary artery bypass graft (CABG) with known moderate aortic regurgitation (AR) who developed cardiogenic shock and severe AR postoperatively. An emergency salvage SAVR was performed; however, the patient did not survive the operation.

Hemodynamic performance

An initial postoperative echocardiogram was performed day 3 to day 7 postoperatively in 206 patients. The overall average valve mean gradient across all valves was 9.7 ± 4.0 mmHg. There was no difference in insertion technique with the average mean gradient for non-pledgeted valves being 9.3 mmHg and for pledgeted valves 10.0 mmHg. The Trifecta and Trifecta GT had no difference in valve mean gradients, being 9.7 mmHg and 9.4 mmHg, respectively. AR was moderate in 0.9% of patients (2/206), and there were no cases of severe regurgitation. The average mean gradients per valve size in 206 patients were 13.2 ± 5.2 mmHg for 19 mm (n with documented post-op echo/n per valve size: 17/20), 10.4 ± 3.8 mmHg for 21 mm (51/68), 9.9 ± 3.7 mmHg for 23 mm (79/104), 7.8 ± 3.1 mmHg

Table 2 Operative details of the 263 patients including Trifecta model, implanted valve size, insertion technique, cross-clamp time, cardiopulmonary bypass time, and additional surgical procedures performed at the time of valve surgery

Variable	N = 263
Trifecta model	
Trifecta	85.9% (226/263)
Trifecta GT	14.1% (37/263)
Implanted valve size, mm	
19	7.6% (20/263)
21	25.9% (68/263)
23	39.5% (104/263)
25	20.2% (53/263)
27	5.7% (15/263)
29	1.1% (3/263)
Insertion technique	
Pledgeted sutures	51.7% (136/263)
Non-pledgeted sutures	48.3% (127/263)
Aortic cross-clamp time, min	
All cases (mean)	111 ± 43.4
Isolated SAVR (mean)	84 ± 36.1
Concomitant procedure (mean)	133 ± 44.3
Cardiopulmonary bypass time, min	
All cases (mean)	141 ± 56.8
Isolated SAVR (mean)	109 ± 49.8
Concomitant procedure (mean)	169 ± 58.1
Additional procedure	55% (146/263 patients)
CABG	63% (93/146)
Redo sternotomy	1.5% (4/146)
Aortic surgery	13.7% (19/146)
Mitral surgery	5.7% (15/263)

CABG: coronary artery bypass graft; GT: Glide Technology; SAVR: surgical aortic valve replacement

for 25 mm (46/53), 8.4 ± 2.2 mmHg for 27 mm (10/15), and 7.0 ± 1 mmHg for 29 mm (3/3).

Structural valve deterioration

Three patients out of 263 were identified from the study period as having early SVD requiring reintervention within 3 years of valve implantation leading to a 1.14% failure rate. One of the valves that had early SVD was a new generation Trifecta GT.

An additional four patients were identified who had valves implanted prior to the study period and had valve failure at greater than 3 years post implantation. Their details are included for completeness but have not been included in the overall calculation of the study failure rate.

Of the three patients in the study period, only one patient underwent redo SAVR and the operative findings were of a non-coronary cusp (NCC) leaflet tear as detailed below. The two other patients also had leaflet tears based on transesophageal echocardiogram and underwent valve in valve TAVR.

None of the seven patients had immediate postoperative AR following their SAVR.

Patient 1

This patient was 62 years old when she underwent an SAVR with a 23-mm Trifecta for a congenital bicuspid aortic valve. Her only risk factor was hypertension and she had normal renal function. Her body surface area was 1.78 m^2 with a 23-mm valve resulting in an EOA of 1.01 cm^2. She represented 31 months later to a regional hospital with acute severe AR and heart failure. The patient's preference was for a mechanical valve instead of another bioprosthesis and she came forward for urgent redo SAVR with a 22-mm ATS mechanical aortic valve (ATS Medical Inc; Minneapolis, Minnesota, USA).

The findings intraoperatively were of a torn non-coronary cusp at the junction with the right coronary cusp (RCC) (**Supplementary Fig. 1**; Supplementary figures are available online.). Culture of the valve was negative and the valve was returned to the manufacturer. Further investigation by Abbott showed pannus ingrowth on one leaflet with the hypothesis that this could have induced increased stress on adjacent leaflets leading to leaflet tear and reduced durability.

Patient 2

This patient was 87 years old and underwent an SAVR with a 21-mm Trifecta GT and CABG × 2. Her other significant history includes paroxysmal atrial fibrillation on warfarin and mild renal impairment. Transesophageal echocardiogram (TOE) demonstrated moderate to severe valvular regurgitation presumed secondary to a cusp tear as seen in **Supplementary Fig. 2**. The patient underwent a successful valve in valve TAVR with a 23-mm Evolut R (Medtronic, Minneapolis, Minnesota, USA) 17 months later.

Patient 3

This 79-years-old male underwent an SAVR with a 25-mm Trifecta valve and CABG × 1 in February 2017. His risk factors for SVD were hypertension and Stage 4 chronic kidney disease with a baseline creatinine of 130. He was an ex-smoker, diabetic, and had dyslipidemia. He was identified to have SVD as his renal physician detected a new asymptomatic murmur. His TOE showed two regurgitant jets, one from the NCC and left coronary cusp and another from the NCC and RCC base (**Supplementary Fig. 3**). He was planned for outpatient elective valve in valve TAVR; however, he represented in heart failure and underwent TAVR as an inpatient

Table 3 Patient details, operation, and contributing factors identified of six patients within a 30-day mortality period

30-day mortality	Operation	Factors contributing to mortality
83-year-old male with severe aortic stenosis and blocked LAD with full thickness infarct and non-viable myocardium	Isolated AVR	Found unresponsive on ward in pulseless ventricular tachycardia
32-year-old male with rheumatic heart disease Previously declined surgery twice BMI 43 LVEF 40%	Tissue AVR and tissue MVR	Cardiogenic shock
73-year-old male with culture negative aortic and mitral valve endocarditis Presented with complete heart block, congestive heart failure, and renal failure	Tissue AVR + mitral valve repair + repair of membranous ventricular septal defect	Reinfection of prosthetic valves Heparin-induced thrombocytopenia Toxic epidermal necroylsis
73-year-old female having severe aortic stenosis with chronic atrial fibrillation	Isolated AVR	Postoperative brain stem stroke
65-year-old male with NSTEMI and severe AR and MR LVEF 35% Pulmonary hypertension RVSP 65 mmHg	AVR + MVR + CABG × 3	Cardiogenic shock
81-year-old male with syncope secondary to aortic stenosis and coronary artery disease	AVR + CABG × 2	Ischemic bowel

AR: aortic regurgitation; AVR: aortic valve replacement; BMI: body mass index; CABG: coronary artery bypass graft; LAD: left anterior descending; LVEF: left ventricle ejection fraction; MR: mitral regurgitation; MVR: mitral valve replacement; NSTEMI: non-ST-elevation myocardial infarction; RVSP: right ventricular systolic pressure

Table 4 Classification of PPM within the study cohort identified as zero, moderate, and severe PPM within specific Trifecta valve size cases

Trifecta valve size (total number of patients)	No PPM EOA ≤0.85 cm^2/m^2	Moderate PPM EOA 0.65 to 0.85 cm^2/m^2	Severe PPM EOA <0.65 cm^2/m^2
19 mm (20)	11/20 (55.0%)	9/20 (45.0%)	0/20
21 mm (68)	59/68 (86.8%)	9/68 (13.2%)	0/68
23 mm (104)	99/104 (95.2%)	5/104 (4.8%)	0/104
25 mm (53)	50/53 (94.3%)	3/53 (5.7%)	0/53
27 mm (15)	15/15 (100%)	0/15	0/15
29 mm (3)	3/3 (100%)	0/3	0/3

EOA: effective orifice area; PPM: patient prosthesis mismatch

with a 26-mm Medtronic Evolut R 20 months post initial surgery.

Patients outside study period

Four other patients were identified outside of the study period with SVD. Patient 4 had a 23-mm Trifecta valve inserted in 2018. After 39 months post initial surgery, valve leaflet tear was identified requiring a redo SAVR. Patients 5–7 had Trifecta 2 valves inserted. After more than 5 years, thickened valves and one valve leaflet tear were identified requiring a valve in valve TAVR.

Patient prosthesis mismatch (PPM)

We identified 26 out of our 263 patients (9.8%) with moderate PPM as defined by an indexed effective orifice area (EOAI) between 0.65 and 0.85 cm^2/m^2. The most common prosthesis for patients with moderate PPM was the 19-mm prosthesis with 9 out of 20 patients who received a 19-mm prosthesis having moderate PPM as defined by an EOA between 0.65 and 0.85 cm^2/m^2 (**Table 4**).

None of the patients who had SVD, both those within the study period and those outside, had PPM as defined by an EOAI <0.85 cm^2/m^2 (**Table 5**).

Discussion

Our review of the Trifecta usage in Wellington demonstrated an acceptable safety profile with regards to both postoperative outcomes and hemodynamic performance. Our 30-day mortality rate was 2.2% and our permanent

Table 5 Details of EOAI and mean transvalvular gradients within the identified SVD patients within and outside the study period

ID	Age, years	Sex	Year of implant	Year of reintervention	Durability months	Valve type	Valve size, mm	BSA, m^2	EOAI	Postop mean gradient, mmHg	Reintervention mean gradient	Pathology
1	65	F	2016	2019	31	Trifecta	23	1.78	1.01	4	5	AR
2	89	F	2017	2019	17	Trifecta GT	21	1.52	1.09	5	5	AR
3	80	M	2017	2020	20	Trifecta	25	2.10	0.96	8	17	AR
Cases prior to January 2015 and SVD at >3 years												
4	75	M	2014	2018	39	Trifecta	23	1.97	0.91	11	15	AR
5	75	M	2012	2018	72	Trifecta	23	2.16	0.86	13	16	AR
6	70	F	2013	2019	67	Trifecta	25	1.83	1.12	12	83	Mixed AR/AS
7	82	M	2013	2019	66	Trifecta	25	2.08	0.96	15	22	AR

AR: aortic regurgitation; AS: aortic stenosis; BSA: body surface area; EOAI: indexed effective orifice area; F: female; GT: Glide Technology; M: male; SVD: structural valve deterioration

stroke rate was also 1.5%. The average mean gradient across all valve sizes was 9.7 ± 4.0 mmHg, and for valve sizes greater than 23 mm, the mean gradients were all less than 10 mmHg highlighting the excellent hemodynamics seen in other series.[5] None of our patients had severe PPM and 9.8% of our patients had defined moderate PPM, lower than other series that had rates as high as 22.8%. Two patients had moderate AR post implantation with no patients having severe regurgitation. No valves were required to be explanted within the first 30 days.

We identified three cases of early SVD from our study population as defined by valve failure requiring reintervention at less than 3 years post insertion, resulting in an early SVD rate of 1.14%. All three of these cases had early leaflet cusp tear as the mechanism of failure, with one patient undergoing redo SAVR and two patients successfully undergoing valve in valve TAVR. The patient who had redo SAVR did not want another bioprosthesis and had a mechanical SAVR. Of the four cases identified outside of the study period, two of them had cusp tears and the valve that was explanted shows this clearly at the commissural junction (**Supplementary Fig. 4**). All seven cases had aortic stenosis as their primary indication for SAVR.

There have been a number of reports regarding early Trifecta valve failure, with the primary mechanism being leaflet cusp tears at the commissural junction.[9–12] These patients tend to present acutely with severe dyspnea due to the acute regurgitation. Kaneyuki et al. experienced seven cases of valve failure out of 107 for an SVD of 6.5% at 6 years. Four of these patients had end-stage renal disease with four having PPM, possibly accounting for the high rate of SVD.[7] Of the six patients who had redo SAVR and explant of the valve, four patients had cusp tears. Larger multicenter registry series have identified non-calcified leaflet tear in small numbers, including Goldman et al.'s study from 2017 identifying one and Kilic et al.'s study identifying three patients.[5,13]

The Trifecta GT was produced in response to the cases of early valve failure, with a new protective holder and internal backstops to protect the stent posts. An additional titanium band was introduced to protect the stent base geometry, as well as a softer sewing cuff. We experienced one case of early failure of the Trifecta GT after 17 months requiring a valve in valve TAVR. A case series by Tchouta et al. published in December 2020 highlighted three cases of Trifecta GT failure out of 106 cases, giving a 3.3% valve failure at 3.5 years.[14] Despite the improvements of the 2nd generation Trifecta GT, the mechanism was detachment of the cusp between the

non-coronary and right coronary cusps in all three cases with one valve having pannus formation. The valves were all inserted by different surgeons, with one valve being inserted with the use of Cor-Knot.

Although there are patient-related risk factors for SVD as identified in our review, such as age and PPM, both our experience and that of other series and case reports highlight a trend of early valve failure in the Trifecta valve that may be related to the externally mounting pericardial leaflets. The *in vitro* study of externally mounted vs internally mounted valves identified mechanical abrasion at the commissural region being a trend of the Trifecta valves, as well as the experience of cusp tears with the earlier versions of the Mitroflow.[15,16] This concern regarding the externally mounted valve design has been reinforced by three recent comparative studies published in 2020 of the Trifecta valve with internally mounted valves.

Fukuhara et al. in March 2020 published a retrospective review of 1058 patients, 508 of whom received a Trifecta valve and a non-Trifecta group of 550 patients.[17] The majority of the valves in the non-Trifecta group were internally mounted valves (80.4% Edwards Perimount Magna Ease, Edwards Intuity 13.1%, Medtronic Avalus 2.7%) with 3.8% being the Mitroflow LXA. They found a significantly higher cumulative incidence of SVD in patients with the Trifecta valve compared with other stented valves (13.3% vs 4.6%; P = 0.010), with a more pronounced trend in younger patients <65 years reinforcing younger age as a risk factor for SVD. The mode of failure for Trifecta valves was more likely to be valvular regurgitation, with 31.8% of Trifecta SVD patients presenting with pure regurgitation characterized as partial cusp tear along a stent post.

In September 2020, Biancari et al. compared the Perimount Magna Ease to the Trifecta valve, with 851 Trifecta patients and 1365 Magna Ease patients from the FinnValve registry.[18] They also found a significantly higher rate of repeat aortic valve replacement in Trifecta patients for structural valve failure (3.3% vs 0%). The most recent study by Yongue et al. in the *Annals of Thoracic Surgery* performed a propensity-matched analysis of 2298 Trifecta valves with the Edwards Perimount valve.[19] They also demonstrated better hemodynamics with the Trifecta valve but significantly more severe AR at 5 years. Interestingly, their series found valvular calcification and stenosis as the primary mode of failure rather than cusp tears or regurgitation as seen in the Fukuhara et al.'s series.[17] They also found that gradients increased more rapidly in the Trifecta valve than in the Perimount valve with a lower freedom from explant at 5 years.

Our study was driven by the concern of early valve failures within our unit and preceded many of these large multicenter trials. Although our review of the literature identified patient-related risk factors for SVD such as age and PPM, we were concerned regarding the valve design given the mechanism of the valve failure in early cusp tears. All of our SVD patients were over the age of 65 and none had PPM. The progressive worsening of transvalvular gradients and subsequent calcification is not unexpected in bioprosthetic valves, particularly past 10 years. However, our cluster of three patients all had failures at less than 3 years. We conclude that the design of the externally mounted Trifecta valve has a good safety profile with excellent hemodynamics but at the expense of valve durability, and our experience of an early failure of the newer Trifecta GT at 17 months led to the cessation of Trifecta valves being used in Wellington in July 2020.

The limitations of our study is that it is retrospective in nature and reliant on a national database and medical records. Our follow-up for hemodynamic valve deterioration only consisted of an early echocardiogram at less than 30 days, with further data collection occurring on longer term follow-up. The limitations of this in New Zealand include the availability of regional echocardiography services and funding, as many SAVR patients are discharged from follow-up after 2 years. Expanding our study period to pre January 2015, more detailed midterm and long-term echocardiographic follow-up, as well as a comparison to the Magna Ease cohort, is also planned.

Conclusion

We conclude that the Trifecta valve use in Wellington was associated with excellent hemodynamics including a low rate of PPM and mean gradients. The use of the valve was safe with a low rate of postoperative complications including stroke and permanent pacemaker implantation. Our study rate of 1.14% of early valve failure is low; however, the mechanism of failure is concerning for the durability of the Trifecta valve and included one of the newer generation Trifecta GT valves. Further studies to examine the difference between early, mid-, and late-term Trifecta failures are required, as well as larger multicenter studies on the Trifecta GT.

Informed Consent

The research has been approved by the authors' institution. Informed consent was received.

Author Contributions

TDT and SDG: concept/design, data analysis/interpretation, drafting the article, critical revision of the article, and approval of the article. LK and AM: data collection, interpretation, drafting the article, critical revision of the article, and approval of the article.

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