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ORIGINAL ARTICLE

Infective endocarditis of a transcatheter pulmonary valve in comparison with surgical implants

Ine Van Dijck,[1] Werner Budts,[2] Bjorn Cools,[1] Benedicte Eyskens,[1] Derize E Boshoff,[1] Ruth Heying,[1] Stefan Frerich,[3] Ward Y Vanagt,[3] Els Troost,[2] Marc Gewillig[1]

ABSTRACT

Background Melody valved stents (Medtronic Inc, Minneapolis, Minnesota, USA) have become a very competitive therapeutic option for pulmonary valve replacement in patients with congenital heart disease. After adequate prestenting of the right ventricular outflow tract (RVOT) Melody valved stents have a good medium term functional result but are exposed to infective endocarditis (IE).

Patients and methods Retrospective study of tertiary centre Congenital Heart Disease database; to compare incidence of IE in three different types of valved conduits in RVOT: Melody valved stent, cryopreserved homograft (European Homograft Bank) and Contegra graft (Medtronic Inc).

Results Between 1989 and 2013, 738 conduits were implanted in 677 patients. 107 Melody valved stents were implanted in 107 patients; IE occurred in 8 (7.5%) patients during a follow-up of 2.0 years (IQR 2.4 years, range 0.3–7.8 years). 577 Homografts were implanted in 517 patients; IE occurred in 14 patients (2.4%) during a median follow-up of 6.5 years (IQR 9.2 years; range 0.1–23.7 years). Finally, 54 Contegra grafts were implanted in 53 patients; 11 patients (20.4%) had IE during a follow-up of 8.8 years (IQR 7.7 years; range 0.2–3.5 years). Survival free of IE by Kaplan–Meier for homografts was 98.7% at 5 years and 97.3% at 10 years; for Contegra 87.8% at 5 years and 77.3% at 10 years and for Melody 84.9% at 5 years (log-rank test; $p<0.001$).

Conclusions The Contegra conduit and Melody valved stents have a significantly higher incidence of IE than homografts. IE is a significant threat for long-term conduit function.

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[1]Department of Pediatric Cardiology, University Hospitals Leuven, Leuven, Belgium
[2]Department of Congenital Cardiology, University Hospitals Leuven, Leuven, Belgium
[3]Department of Pediatric Cardiology, Cardiovascular Research Institute Maastricht, Maastricht University Medical Center, Maastricht, The Netherlands

Correspondence to
Professor Marc Gewillig, University Hospital Gasthuisberg, Herestraat 49, Leuven B-3000, Belgium; marc.gewillig@uzleuven.be

IVD and WB contributed equally to this study.

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INTRODUCTION

Transcatheter (percutaneous) pulmonary valve (TPV) implantation as an alternative to open-heart surgery for right ventricular outflow tract (RVOT) valve implantation was first described in 2000 by Bonhoeffer *et al*.[1] Since then multiple studies have documented the short-term benefits of TPV implantation using the Melody valved stent (Medtronic Inc, Minneapolis, Minnesota, USA) for dysfunctional RV to pulmonary artery (RV–PA) conduits.[2–4] After adequate prestenting, valved stent patency and leaflet function appear to be very competitive to other conduits.[5 6] However, infective endocarditis (IE) of the Melody valve emerges as a potential threat for long-term function.[7–9] The aim of this study is to assess the incidence of IE in Melody valved stents and to compare it with other surgically implanted conduits such as homografts and Contegra conduits.

PATIENTS AND METHODS

Patient selection

This retrospective study includes all patients in the Congenital Heart Disease database of University Hospitals Leuven, a tertiary centre, who underwent a RVOT reconstruction with implantation of either a cryopreserved homograft (European Homograft Bank, Brussels, Belgium), a Contegra graft (VenPro Corporation, Irvine, California, USA, up until 2001; Medtronic Inc) or a Melody valved stent (Medtronic Inc). Implantation was performed according to standard techniques, including perprocedural IE prophylaxis with cephalosporins; none of the patients had anticoagulation or platelet inhibitors prescribed after the implantation.[5] The institutional ethics committee approved the study protocol. Exemption from informed consent was allowed for the homograft and Contegra cohort; all patients (or their parents) of the Melody cohort gave informed consent as part of an observational study imposed by the national health insurance for future reimbursement issues.

Review of records

The database for this study was locked for inclusion on 1 October 2013; follow-up was admitted until 4 March 2014. All hospital survivors of an elective implantation were included. General demographics were recorded, including underlying diagnosis, age at implantation, management prior to valve implantation, dates of the procedures, type and size of the implanted conduit, date of latest follow-up as well as explant date and type of the subsequent conduit. When IE occurred, date of diagnosis, findings preceding infection, microbiological findings, most probable entry point as well as treatment and outcome were recorded. Each IE was scored possible or definite IE according to the modified Duke criteria.[10 11]

Statistical analysis

Data were tested for normal distribution. Descriptive data are presented as medians and IQR and/or minimum to maximal range where applicable. Categorical variables presented as number and percentages were compared using the Pearson's χ^2 test and the Wilcoxon signed-rank test. The Kaplan–Meier method was used to assess the survival time free from IE, whereas log-rank testing was used to compare the three groups. Annualised

event rates were calculated using the total patient follow-up until either most recent cardiac evaluation, conduit explant, death or diagnosis of IE which were censored as event. Univariate and multivariate regression analyses were performed to identify predictors of IE. p Values of <0.05 were considered significant. Statistical analysis was performed using IBM SPSS Statistics, V.22 (IBM, New York, New York, USA).

RESULTS

Patients' characteristics

Between January 1989 and October 2013, 738 conduits were implanted in 582 patients. A total of 107 Melody conduits were implanted between 2006 and 2013 in 107 patients at a median age of 14.3 years (IQR 10.1 years; range 4.5–80.5 years) with a total of 265.1 patient-years of follow-up (median follow-up 2.0 years; IQR 2.4 years; maximum 7.8 years). Landing zone for the Melody valved stent was a homograft in 61 cases, a Contegra graft in 13, a bare stent in 32 and a Freestyle valve in 1 patient. Of the 107 Melody conduits, four were explanted: two because of progressive obstruction due to IE and two because of size issues (restrictive prestent).

Overall, 577 homografts were implanted in 517 patients. Cryopreserved homografts were implanted since the European Homograft Bank was founded in 1989 and are currently still being implanted. The median age at implantation was 13.3 years (IQR 17.6 years; range 0.1–60 years). The median follow-up time of this conduit was 6.5 years (IQR 9.2 years; maximum 23.7 years); 78 valves were explanted, 53 homografts became redundant by stent implantation, 16 patients deceased with a functional homograft in situ and 430 homografts are still in situ.

Of Contegra grafts, 54 were implanted in 53 patients between 2000 and 2002. The median age at implantation was 9.9 years (IQR 13.4 years; range 8 days–47.4 years). Thirty-five Contegra conduits were replaced (64.8%); 19 conduits are still functioning. The median follow-up time was 8.8 years (IQR 7.7 years; a maximum of 13.5 years). Patient data are shown in table 1.

Infective endocarditis

In the Melody group, IE occurred in eight conduits (7.5%) after 1.3 years (IQR 1.2 years; range 1.1–3.6 years); according to the modified Duke criteria six were retrospectively classified as 'definite' IE and two were classified as 'possible' IE. None of the eight patients were previously diagnosed with IE. The details of the Melody patients are summarised in table 2.

Table 1 Demographic and diagnostic details after Melody, Contegra and homograft conduit implantation

Implantation	Melody (n=107)	Contegra (n=54)	Homograft (n=577)
Age, years, median (range)	14.3 (4–80)	9.9 (0–47)	13.3 (0–60)
Men	71 (66.4%)	33 (61.1%)	351 (60.8%)
Primary cardiac diagnosis			
Tetralogy of Fallot	56 (52.3%)	25 (46.3%)	264 (45.8%)
Ross repair	20 (18.7%)	10 (18.5%)	170 (29.5%)
Pulmonary stenosis	8 (7.5%)	1 (1.9%)	49 (8.5%)
Arterial trunk	8 (7.5%)	13 (24.1%)	54 (9.4%)
Miscellaneous	15 (14.0%)	5 (9.3%)	40 (6.9%)
Endocarditis	8 (7.4%)	11 (20.4%)	14 (2.4%)

Table 2 Demographic and diagnostic data as well as outcome details of all patients with infective endocarditis after Melody valve implantation

Patient	Gender	Diagnosis	Age (years)	Size (mm)	FU (months)	Duke*	Bacteria	Previous valve	Treatment	PR	PS (mm Hg)	Presumed entrance	Outcome
1	Male	TF	7	22	14.1	Definite	HACEK	Bare stent	AB 6 weeks	0/4	64	Unprotected dental care	Good
2	Male	TF	17	20	13.4	Possible	*Streptococcus sanguinis*	Homograft	AB 6 weeks	1/4	30	Orthodontics+oral wound	+10 mm Hg in 27 months
3	Male	Rastelli	14	18	15.5	Definite	*Streptococcus viridans*	Homograft	AB 6 weeks	0/4	42	Orthodontics+oral wound	+10 mm Hg in 11 months
4	Male	Trunc	14	20	44.4	Definite	HACEK	Homograft	AB 6 weeks	0/4	62	Unprotected dental care	Melody in 10 months
5	Male	Trunc	15	22	16.4	Possible	*Corynebacterium pseudodiphtheriticum*	Homograft	AB 6 weeks	1/4	22	Cryptogenic	+11 mm Hg in 1 year
6	Male	Rastelli	9	20	27.6	Definite	*Streptococcus viridans*	Homograft	AB 6 weeks	0/4	<5	Unprotected dental care	+10 mm Hg in 9 months
7	Male	TF	17	22	15.5	Definite	HACEK	Homograft	Surgery at D25	1/4	22	Dematophytosis complex	Explant at D25
8	Male	TF	12	22	37.7	Definite	*Staphylococcus aureus*	Bare stent	Surgery at D11	0/4	30	Personal hygiene+nail biting	Explant at D11

*Modified Duke criteria.[9]
AB, antibiotics; FU, follow-up; HACEK, Haemophilus Aggregatibacter Cardiobacterium Eikenella corrodens Kingella; PR, pulmonary valve regurgitation (0–4/4); PS, pulmonary stenosis; TF, Tetralogy of Fallot.

Seven out of eight Melody patients with IE presented with fever; one patient had a progressive gradient and received a bare stent before cultures turned positive. Three patients had a progressive gradient of which two patients needed surgery during hospitalisation because of threatening occlusion. One patient presented in septic shock with renal failure, diffuse intravascular coagulation and elevated liver enzymes. Septic pulmonary embolisms were found in two patients and diagnosed by CT. Vegetations were visualised by transthoracic echocardiography in four out of eight patients; none of the eight patients had significant valve regurgitation. Intracardiac echography was not performed.

Isolated bacteria in the Melody group were *Corynebacterium pseudodiphtheriticum* (1), HACEK (3), *Staphylococcus aureus* (1) (see online supplementary figure A), *Streptococcus viridans* (2) and *Streptococcus sanguinis* (1).

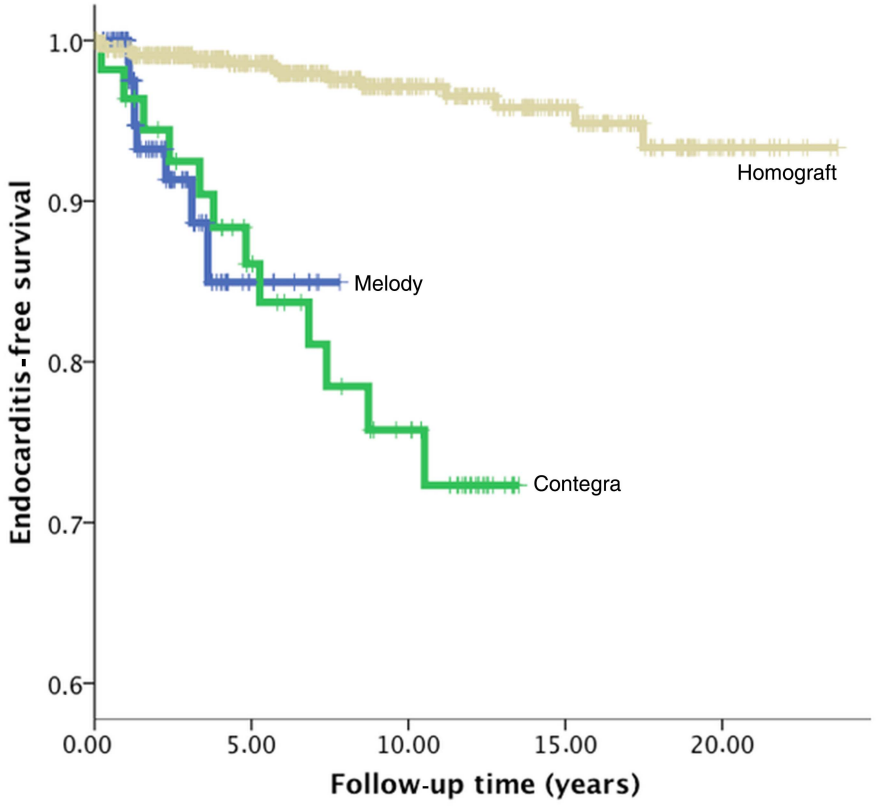
Adequate antibiotic therapy (6 weeks) sterilised the Melody valved stent in six cases. In two patients surgical replacement was needed 11 and 25 days after diagnosis. The patient who was first stented to relieve the stenosis received 6 weeks of antibiotics when cultures turned positive. A second Melody valve was implanted 10 months later and he is doing clinically well with 11 months of additional follow-up.

The most likely point of bacterial entrance was the dental mucosa after inadequate or no IE prophylaxis before dental care in two patients, intraoral wounds as a result of orthodontic intervention in two cases, surinfected tinea pedis in one patient (see online supplementary figure B) and poor personal hygiene and nail biting in one patient. IE in one patient was classified cryptogenic. In this retrospective study, it was not possible to determine the incidence of these risk factors in patients who did not develop IE. Four out of eight patients who developed IE on the Melody valve were known with psychomotor retardation, while this was only present in 19/99 (19.2%) non-IE patients (p=0.063).

IE occurred in 14 patients of the homograft group (2.4%) after 5.7 years (IQR 8.8 years; range 35 days–17.5 years). Two out of the 14 patients treated for IE had suffered IE prior to the homograft implantation.

Of the Contegra conduits, 11 got infected (20.4%) after 4.8 years (IQR 4.3 years; range 76 days–10.5 years). None of the Contegra patients with IE had suffered previously from IE. Six Contegra grafts needed an explantation within 2 months after diagnosis of IE because of conduit failure. Overall, 10 of the 11 conduits with IE were replaced.

Freedom from IE after Melody TPV replacement by Kaplan–Meier analysis was 84.9% at 5 years (then, 11 patients at risk (AR)) (figure 1). For the Contegra subgroup, freedom from IE was 87.8% (37 AR) at 5 years and 77.3% (25 patients AR) at 10 years. The homografts had an overall IE-free survival of



Homograft	AR	577	342	180	101	27
	IE	0	6	10	12	14
Contegra	AR	54	37	25		
	IE	0	6	10		
Melody	AR	106	11			
	IE	0	8			

Figure 1 Survival Kaplan–Meier curves depicting the probability of survival free from IE in the three studied conduits. Homograft: (top line) Contegra: (bottom line); Melody: (middle line). AR, at risk; IE, infective endocarditis.

Table 3 Statistical analysis of significant correlations

	Univariate			*Multivariate*		
	Exp$^{\beta}$	CI	p Value	Exp$^{\beta}$	CI	p Value
Age	0.965	0.931 to 1.001	0.056			
Gender	4.615	1.621 to 13.136	0.004	4.464	1.567 to 12.719	0.005
Melody	10.261	3.896 to 27.023	<0.001	9.738	3.677 to 25.786	<0.001
Homograft			<0.001			<0.001
Contegra	8.664	3.803 to 19.736	<0.001	8.690	3.821 to 19.762	<0.001

98.7% at 5 years (343 patients AR), 97.3% at 10 years (180 AR) and 93.5% at 20 years of follow-up (27 patients AR) (log-rank test; p<0.001) (figure 1).

Regression analysis (table 3) could not withhold correlation between age (p=0.056) or underlying cardiac diagnosis (p=0.283) and IE. Male gender (factor 4.5) and the type of the implanted conduit (Melody factor 9.7 and Contegra factor 8.7) were significantly associated with IE, respectively, p=0.004 and p<0.001. In order to reduce the confounding effect of low age (no Melody was implanted below 4.5 years, endocarditis is very rare in small children), the statistical analysis was repeated after omitting all patients with implantation below 5 years; there was no significant difference with the first analysis.

DISCUSSION

The Melody valved stent has emerged as a valuable alternative for surgical replacement of a pulmonary conduit. Good long-term function of the Melody conduit depends on good stent function (no fracture, no recompression), good fixation of the vein wall to the stent (no hammock effect) and good leaflet function. Up to now, the Melody conduit has been implanted worldwide in over 7000 patients with very low mortality and minimal morbidity during early follow-up.[2 3] As in most treatment strategies, one can expect a gradual shift of indications from symptomatic to more prognostic, provided the valved conduit performs well during (very) long-term follow-up.

IE is a continuous risk for patients with a TPV implant. In our cohort, 8/107 patients (7.5%) developed IE with 85% freedom of IE at 5 years: the incidence was 3.0% per patient-year. Our results go along with the findings of other large series which report similar incidences of IE between 2.4% and 4.2% per patient-year after sufficient follow-up. In detail, Lurz *et al*[12] reported IE in 5/155 (3.2%) patients with a median of 4.93 months (range 2–23 months) after Melody implantation. Cheung *et al*[3] objectified IE in 6/42 patients (14.3%) after TPV implantation during a median follow-up of 27 months (range 2–66 months) with incidence of 3.9% per patient-year. Buber *et al*[8] reported on 14/147 (9.5%) bacteraemia suspected for or diagnostic for IE during a median follow-up of 19 months (range 1–63 months), with 83% freedom of IE at 4 years (4.2%/patient-year). McElhinney *et al*[7] reported on IE in 16/311 (5.1%) patients during a median follow-up of 2.5 years (up to 5.1 years), with an incidence of 2.4% per patient-year.

Incidence of IE in other conduits in RVOT: differences, but why?

All types of conduits are vulnerable for the development of IE and some tissues or RVOT reconstructions may be more prone to infection. This study clearly demonstrates a difference of incidence of IE in RVOT conduits: it varies from 0.8% per patient-year for homografts to 2.7–3.0% per patient-year for Contegra–Melody conduits. Similar differences have been reported in non-comparative studies. Homografts both in aortic position and in RVOT have a very low incidence of IE of less than 1% per patient-year.[13–15] The incidence of IE in Contegra conduits varies. Albanesi *et al*[16] reported IE in Contegra grafts in 12/103 (11.6%) patients during follow-up of 7.6 years (range 1.7–12.7 years) with 88% free of IE at 5 years (incidence IE 1.6% per patient-year). Breymann *et al*[17] reported a 5 year survival free of IE in a cohort of 165 Contegra grafts of 92% (1.6% per patient-year). The relative high incidence of 2.7% per patient-year in our series might be related to suboptimal haemodynamic result with a high incidence of progressive obstruction at the distal anastomosis.[18]

This study was not set up to identify reasons accounting for these differences. An obvious difference may be the leaflet and conduit tissue: homologous human tissue in homografts versus allograft bovine jugular tissue. Other factors such as size, RVOT reconstruction, flow patterns with high shear stress and turbulence, jet lesions or local stress, blood stasis in and around the conduit, surface characteristics, propensity of bacterial adhesion, onset of coagulation and thrombus formation, leaflet motion and redundancy need to be explored by large studies with different conduits.

Over the study period, the dental hygiene and awareness of IE have changed and improved. Although IE prophylaxis was explained to the patient and parents by the same team, patients and/or their family may be differently receptive to the information: the difference in size of the scar and the difference in discomfort after a surgical or percutaneous procedure may create a different degree of awareness and motivation. This argument may explain partially the difference of IE between homografts and Melody valves, but not for the similar high incidence between Contegra and Melody conduits.

Predisposing factors for IE on Melody valved stent

Male sex was identified in our series as a predisposing factor for IE for the whole group, as for the Melody cohort (8/8 (100%)). Men may be less performant in avoiding mucosal and skin lesions. Cheung *et al*[3] also reported in their series male sex as a predisposing factor. Furthermore, Buber *et al*[8] report previous IE, in situ stents in the RVOT and the presence of outflow tract irregularities as emerging additional risk factors.

In this series, we did not observe reactivation of a previous IE. Others have suggested that residual gradient, eccentric turbulence, pockets due to incomplete apposition, thrombus formation, tissue and tissue preparation, asymmetric or incomplete opening with redundancy of leaflet tissue to be of importance.[7 19] This study was not designed to address these issues. For the Melody cohort, only data on last evaluation and prior to IE were available: pulmonary regurgitation was rare in all patients, but an overall peak gradient of more than 40 mm Hg

was present in 4/8 patients with IE and 5/99 without IE ($p<0.05$). However, as gradient is a time-dependant variable, a more comprehensive study involving all annual measurements is required. This observation argues for leaving minimal gradient at the time of valved stent implantation.

An important finding of our study is that IE did not occur within the first year of implantation. This makes an implantation-related infection or colonisation of an early thrombus very unlikely. Nearly all Melody patients with IE had an identifiable point of entry which probably could be avoided: oral wounds in five, one patient had poor personal hygiene with nail biting and one patient had a dermatophytosis complex. Such extenuating circumstances and other predisposing conditions were also reported previously.[7] Psychomotoric retardation was identified as a risk factor in our series. It may have contributed to the development or persistence of chronic skin or mucosa lesions.

The findings of this study strengthen the necessity of adapted strategies to reduce the incidence of IE. Before implantation of a Melody stent, the avoidance of hazardous lifestyle should be implemented, that is, good body hygiene, including good dental care and avoidance of skin lesions within reasonable limits. Antibiotic coverage prior to foreseeable episodes of significant bacteraemia appears indicated.[10 20] Until now, there are no data to support the benefit in this context, but the clinical problem and common sense mandate to emphasise these general concepts.

Outcome of the Melody valve after IE

After identification of the bacteria in several haemocultures, intravenous antibiotic treatment for 6 weeks was started. In this series, no patient needed an emergency operation; two patients had the Melody valve removed during the initial antibiotic treatment after 11 and 25 days because of progressive obstruction and one patient was later restented with repeat Melody. Five patients recovered with adequate valve function. However, the outcome spectrum post Melody implantation has been reported to be broader: an emergency operation at presentation may be required because of severe right heart failure and early and late deaths have been reported.[19 21]

Late percutaneous revalvulation with a second Melody valve was performed in one patient of our series and others in the literature. Apparently, this was not associated with reactivation of IE and a good result in early follow-up.[19]

Limitations

This descriptive study is retrospective with its classic limitations; patients were not randomly selected and treated in a similar but still different time frame. Strengths of the study are the large and complete database and the long follow-up.

Key messages

What is already known on this subject?
Revalvulation of the right ventricular outflow tract by homograft implantation has been described with very good long-time results. As a less invasive alternative, transcatheter implantation of a Melody valved stent is known with a comparable midterm valve function. Despite several studies describing the incidence of infective endocarditis (IE) after Melody valve implantation, the susceptibility of this valved stent compared with surgical conduits is not objectified yet.

What might this study add?
This retrospective report allows the comparison of the incidence of IE after homograft, Contegra graft and Melody valved stent implantation. It confirms that IE after Melody implantation does occur with a worrying incidence. As a pulmonary conduit, the Contegra graft and Melody valved stent have a higher incidence of IE than a homograft in our single centre analysis.

How might this impact on clinical practice?
Given the fact that nearly all Melody patients with IE had an avoidable point of entry, adapted strategies preimplantation and postimplantation with optimal prophylaxis might reduce the incidence of IE to obtain desirable longevity.

CONCLUSIONS

The Contegra conduit and Melody valved stents have a significantly higher incidence of IE than homografts. Nearly all Melody patients with IE had an avoidable point of entry. Adapted strategies preimplantation, perimplantation and postimplantation with optimal prophylaxis might reduce the incidence of IE to obtain desirable longevity.

Contributors MG, WB and ET designed the study. IVD and BC carried out the measurements. BC and IVD performed the statistical analysis. IVD and MG wrote the manuscript. BE and RH helped with the drafting and editing of the manuscript. SF, WYV and DEB helped with the recruitment of the patient and coordinated the study. All authors read and approved the final manuscript.

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Ethics approval Institutional ethics committee.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement We do not have any additional data. All data are included in the study.

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