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In-hospital outcomes of patients undergoing concomitant aortic and mitral valve replacement in Germany

Maximilian Kreibich [a,b,*], Klaus Kaier [b,c], Constantin von zur Mühlen[b,d,e], Matthias Siepe [a,b], Manfred Zehender[b,d,e], Christoph Bode[b,d], Friedhelm Beyersdorf[a,b], Peter Stachon[b,d,e] and Wolfgang Bothe[a,b]

[a] Department of Cardiovascular Surgery, University Heart Center Freiburg, Freiburg, Germany
[b] Faculty of Medicine, University of Freiburg, Freiburg, Germany
[c] Institute of Medical Biometry and Statistics, Faculty of Medicine and Medical Center, University of Freiburg, Freiburg, Germany
[d] Departments of Cardiology and Angiology I, University Heart Center Freiburg, Freiburg, Germany
[e] Department of Cardiology and Angiology I, Faculty of Medicine, Center of Big Data Analysis in Cardiology (CeBAC), Heart Center Freiburg University, University of Freiburg, Freiburg, Germany

* Corresponding author. Department of Cardiovascular Surgery, University Heart Center Freiburg, Hugstetter Str. 55, 79106 Freiburg, Germany. Tel: +49-761-270-28180; fax: +49-761-270-25500; e-mail: maximilian.kreibich@uniklinik-freiburg.de (M. Kreibich).

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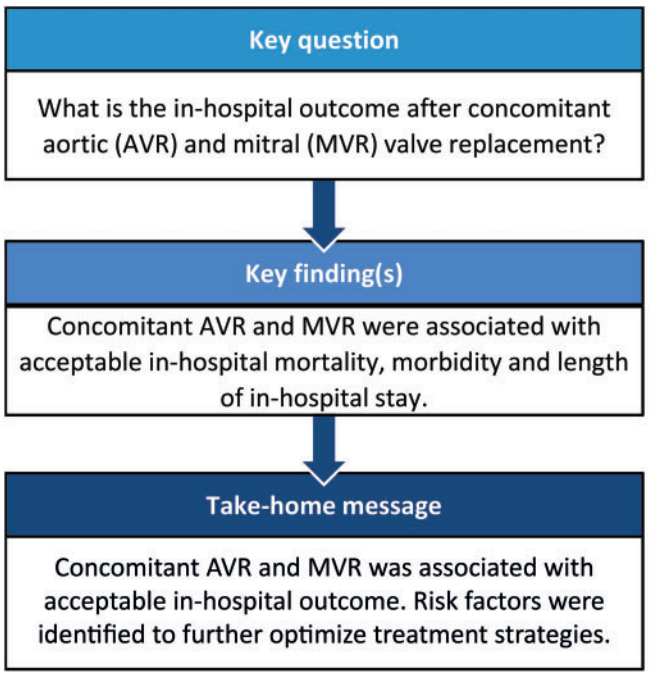

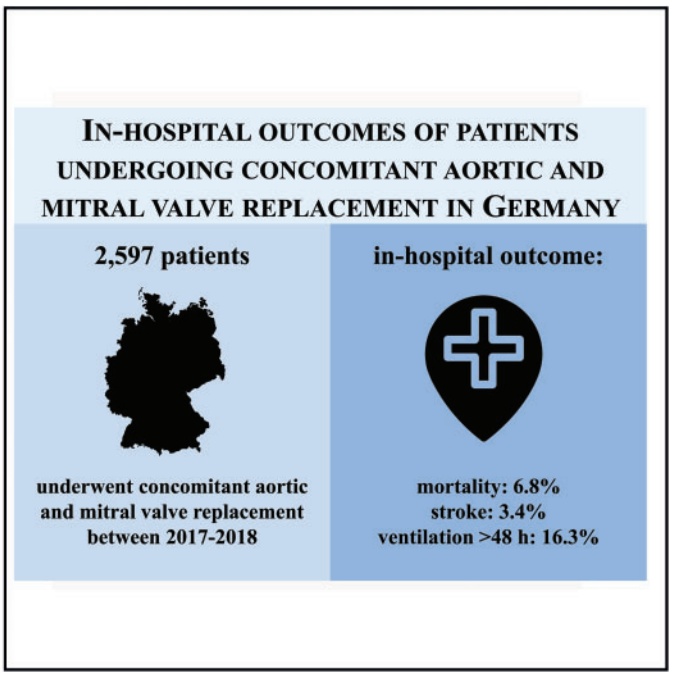

Abstract

OBJECTIVES: To evaluate in-hospital outcomes of concomitant mitral valve replacement (MVR) in patients undergoing conventional aortic valve replacement due to aortic stenosis in a nationwide cohort.

METHODS: Administrative data from all patients with aortic stenosis undergoing conventional aortic and concomitant MVR (reason for MVR not specified) between 2017 and 2018 in Germany were analysed.

RESULTS: A total of 2597 patients with a preoperative logistic EuroScore of 9.81 (standard deviation: 8.56) were identified. In-hospital mortality was 6.8%. An in-hospital stroke occurred in 3.4%, acute kidney injury in 16.3%, prolonged mechanical ventilation of more than 48 h in 16.3%, postoperative delirium in 15.8% and postoperative pacemaker implantation in 7.6% of the patients. Mean hospital stay was 16.5 (standard deviation: 12.1) days. Age [odds ratio (OR): 1.03; $P = 0.019$], New York Heart Association class III or IV (OR: 1.63; $P = 0.012$), previous cardiac surgery (OR: 2.85, $P = 0.002$), peripheral vascular disease (OR: 2.01, $P = 0.031$), pulmonary hypertension (OR: 1.63, $P = 0.042$) and impaired renal function (glomerular filtration rate <15, OR: 3.58, $P = 0.001$; glomerular filtration rate <30, OR: 2.51, $P = 0.037$) were identified as independent predictors for in-hospital mortality.

CONCLUSIONS: In this nationwide analysis, concomitant aortic and MVR was associated with acceptable in-hospital mortality, morbidity and length of in-hospital stay. The regression analyses may help to identify high-risk patients and further optimize treatment strategies.

Keywords: Mitral valve replacement • Aortic valve replacement • Concomitant valve replacement • Double-valve replacement • Outcome

ABBREVIATIONS

AVR	Aortic valve replacement
GFR	Glomerular filtration rate
MVR	Mitral valve replacement
NYHA	New York Health Association
OR	Odds ratio

INTRODUCTION

Aortic valve stenosis is the most prevalent valvular heart disease often necessitating aortic valve replacement (AVR). Yet, patients undergoing AVR often suffer mitral valve pathologies in addition to severe aortic valve stenosis [1]. While most of them are candidates for concomitant AVR and mitral valve repair, some still need concomitant AVR and mitral valve replacement (AVR + MVR) [2–4]. In this case, surgery is the treatment of choice, but as the procedure is more invasive, it may increase perioperative mortality and morbidity [1–4]. In fact, European guidelines have been calling for more data on the impact of interventions on outcomes of patients requiring AVR and MVR treatment [1].

Therefore, in this study, we analysed in-hospital outcomes and risk factors to assess the perioperative complications of patients with aortic stenosis undergoing concomitant AVR + MVR in a large nationwide database.

PATIENTS AND METHODS

Ethics statement

In study, only summarized data from a research data centre were accessed and we had no access to individual patient data. Hence, both the need for institutional review committee approval and informed consent were waived in accordance with national law [5].

Patients and data protocol

We analysed the in-hospital data on all concomitant AVR + MVRs performed in Germany in 2017 and 2018 combined. These analyses were done on our behalf by the Research Data Center of the Federal Bureau of Statistics, in Wiesbaden, Germany, and aggregated statistics were provided based on SAS codes (SAS software, version 9.2; SAS Institute) that we had supplied to the Research Data Center as previously described [5, 6].

Table 1: Baseline characteristics ($n = 2597$)

Logistic EuroSCORE, mean (SD)	9.8 (8.6)
Age in years, mean (SD)	68.4 (9.9)
Female, *n* (%)	867 (33.4)
NYHA class II, *n* (%)	366 (14.1)
NYHA class III or IV, *n* (%)	1070 (41.2)
Coronary artery disease, *n* (%)	561 (21.6)
Arterial hypertension, *n* (%)	1389 (53.5)
Previous MI within 4 months, *n* (%)	18 (0.7)
Previous MI within 1 year, *n* (%)	10 (0.4)
Previous MI after 1 year, *n* (%)	57 (2.2)
Previous CABG, *n* (%)	39 (1.5)
Previous cardiac surgery, *n* (%)	166 (6.4)
Peripheral vascular disease, *n* (%)	114 (4.4)
Carotid artery disease, *n* (%)	106 (4.1)
COPD, *n* (%)	236 (9.1)
Pulmonary hypertension, *n* (%)	535 (20.6)
Renal disease, GFR <15%, *n* (%)	65 (2.5)
Renal disease, GFR <30%, *n* (%)	44 (1.7)
Atrial fibrillation, *n* (%)	1363 (52.5)
Diabetes, *n* (%)	654 (25.2)

CABG: coronary artery bypass grafting; COPD: chronic obstructive pulmonary disease; GFR: glomerular filtration rate; MI: myocardial infarction; NYHA: New York Heart Association.

Diagnoses, procedural codes and definitions

Details on patient identification and code classification have been described [5, 6]. The German Procedure Classification (OPS) codes were used to identify all patient admissions relevant for this investigation. Patients undergoing other concomitant cardiac operations were excluded from this analysis. Data on coexisting conditions and complications were collected via diagnostic and procedural codes for acute and chronic conditions [OPS and International Statistical Classification of Diseases and Related Health Problems, 10th revision, German modification (ICD-10-GM)]. Hence, coexisting conditions and complications are based on administrative hospital coding and are based on ICD-10-GM. Diagnosis and procedure codes used for this analysis are listed in Supplementary Material, Table S1.

Statistical analysis

Data are presented as mean and standard deviation or as relative frequencies. Multivariable logistic and linear regression analyses

Table 2: In-hospital outcomes ($n = 2597$)

In-hospital mortality, *n* (%)	177 (6.8)
In-hospital stroke, *n* (%)	88 (3.4)
Acute kidney injury, *n* (%)	423 (16.3)
Permanent pacemaker implantation, *n* (%)	197 (7.6)
Delirium, *n* (%)	410 (15.8)
Mechanical ventilation >48 hours, *n* (%)	423 (16.3)
Length of stay in days, mean (SD)	16.5 (12.1)

CABG: coronary artery bypass grafting; COPD: chronic obstructive pulmonary disease; GFR: glomerular filtration rate; MI: myocardial infarction; NYHA: New York Heart Association.

were performed to identify independent predictors for in-hospital mortality, postoperative acute kidney injury, permanent pacemaker implantation, delirium, prolonged mechanical ventilation (>48 h) and in-hospital stroke. Due to the high number of patients available, we were able to include all patient characteristics as potential confounders in the regression models.

RESULTS

Baseline characteristics

Table 1 displays the baseline characteristics of the patients included. A total of 2597 patients underwent AVR + MVR in 2017 and 2018 combined. The logistic EuroScore was 9.8 (standard deviation: 8.6%). The mean age was 68 (standard deviation: 10) years and 33.4% were female. Preoperative atrial fibrillation was common with an incidence of 52.5%.

Outcome characteristics

In-hospital mortality was 6.8% in this collective. An in-hospital stroke occurred in 3.4%, acute kidney injury occurred in 16.3% and prolonged mechanical ventilation of more than 48 h in 16.3%. The complete postoperative outcome including length of hospital stay is summarized in Table 2.

Multivariable logistic and linear regression analyses

Age in years [odds ratio (OR): 1.03; $P = 0.019$], New York Heart Association (NYHA) class III or IV (OR: 1.63; $P = 0.012$), previous cardiac surgery (OR: 2.85, $P = 0.002$), peripheral vascular disease (OR: 2.01, $P = 0.031$), pulmonary hypertension (OR: 1.63, $P = 0.042$) and impaired renal function [glomerular filtration rate (GFR) < 15, OR: 3.58, $P = 0.001$; GFR < 30, OR: 2.51, $P = 0.037$) were identified as independent predictors for in-hospital mortality, while a lower NYHA class of II (OR: 0.33, $P = 0.008$) and arterial hypertension (OR: 0.67, $P = 0.033$) were identified as protective variables. The full regression analyses for in-hospital mortality and postoperative morbidity (acute kidney injury, permanent pacemaker implantation, postoperative delirium and mechanical ventilation >48 h, and in-hospital stroke) including all variables of the models are listed in Table 3.

DISCUSSION

Our investigation's main findings are that undergoing concomitant AVR and MVR are associated with acceptable in-hospital mortality and morbidity. In addition, age, advanced NYHA class, previous cardiac surgery, peripheral vascular disease, pulmonary hypertension and impaired renal function were identified as independent predictors for in-hospital mortality.

European guidelines have been calling for more data on the natural history and impact of interventions on the outcomes of patients requiring AVR and MVR in order to identify the indications for intervention [1]. We therefore analysed a nationwide dataset in this study containing data on over 2500 patients in 2017 and 2018 combined to evaluate the outcome of AVR + MVR and more accurately determine the risk factors for in-hospital morbidity and mortality. With the present data, we provide evidence of acceptable outcomes in a patient cohort requiring concomitant AVR and MVR surgery. While this study adds valuable knowledge on the outcome of such patients, its main limitation is that we were unable to analyse the indication for concomitant MVR. Nevertheless, according to our experience, the two main pathologies accounting for concomitant replacement of the mitral valve in patients undergoing AVR are functional mitral regurgitation or mitral valve stenosis.

For patients with functional mitral regurgitation undergoing cardiac surgery, MVR has become the procedure of choice because of a high recurrence rate of mitral regurgitation following isolated mitral ring annuloplasty [7, 8]. In the small subset of patients with severe mitral valve calcification, MVR is also the treatment of choice, but the procedure is challenging and associated with a risk for perioperative complications [1, 9, 10].

This study identified several risk factors for in-hospital mortality, namely age, advanced NYHA class, previous cardiac surgery, peripheral vascular disease, pulmonary hypertension and impaired renal function. Note that we observed that conventional risk scores such as the logistic EuroScore were not predictive of in-hospital mortality and that the calculated logistic EuroScore was higher compared to the actual postoperative in-hospital mortality. Other risk scores, like the Society of Thoracic Surgeons (STS) risk score do not even allow the calculation of AVR + MVR surgery. Hence, conventional risk scores do not suffice to predict the outcome in patients presenting both aortic and mitral valve pathologies and it remains unclear (due to the available data) if the EuroSCORE II would be more accurate in predicting the mortality risks. With the data available we are able to adequately calculate the EuroSCORE as previously described [5], but we are unable to provide EuroSCORE II data for this analysis. Nevertheless, this study also confirms that patients whose kidney function is impaired carry a significant risk of in-hospital mortality (in this study, patients with a GFR under 15 had the highest odds of in-hospital mortality) [3, 11–13].

In patients with the above-mentioned risk profile suffering from combined aortic and mitral valve stenosis, alternative treatment options for the mitral valve may include balloon dilatation or transcatheter valve replacement, but results after balloon dilatations are mostly unsatisfactory, while currently, no established options for endovascular MVR exist [14].

In patients with the above-mentioned risk profile suffering from combined aortic stenosis and functional mitral regurgitation, alternative treatment options for the mitral valve may include the implantation of a MitraClip™ (Abbott Vascular,

Table 3: Multivariable logistic regression analyses (*N* = 2597)

	In-hospital mortality				Acute kidney injury				Permanent pacemaker insertion			
	OR	*P-value*	95% CI		OR	*P-value*	95% CI		OR	*P-value*	95% CI	
Logistic EuroSCORE	1.02	0.146	0.99	1.05	1.04	0.003	1.01	1.06	1.00	0.962	0.97	1.03
Age in years	1.03	0.019	1.01	1.06	1.02	0.017	1.00	1.04	1.00	0.882	0.98	1.02
Female	1.33	0.124	0.92	1.92	0.73	0.026	0.56	0.96	1.21	0.262	0.87	1.69
NYHA class II	0.33	0.008	0.15	0.75	0.72	0.133	0.47	1.10	0.78	0.330	0.48	1.28
NYHA class III or IV	1.63	0.012	1.11	2.38	1.92	<0.001	1.45	2.53	1.15	0.425	0.82	1.61
CAD	1.22	0.318	0.82	1.81	1.29	0.081	0.97	1.72	1.36	0.091	0.95	1.96
Arterial hypertension	0.67	0.033	0.47	0.97	0.84	0.189	0.65	1.09	0.79	0.147	0.58	1.09
Previous MI within 4 months	2.32	0.223	0.60	8.96	0.31	0.082	0.09	1.16	1.00			
Previous MI within 1 year	4.80	0.083	0.82	28.27	4.65	0.065	0.91	23.90	0.99	0.992	0.12	8.47
Previous MI after 1 year	0.96	0.941	0.33	2.78	1.39	0.360	0.69	2.80	1.32	0.533	0.55	3.15
Previous CABG	0.59	0.375	0.18	1.90	0.70	0.495	0.26	1.93	0.79	0.698	0.25	2.56
Previous cardiac surgery	2.85	0.002	1.48	5.49	1.36	0.275	0.78	2.36	1.69	0.135	0.85	3.36
Peripheral vascular disease	2.01	0.031	1.06	3.78	1.50	0.124	0.89	2.53	1.43	0.279	0.75	2.74
Carotid artery disease	0.65	0.326	0.28	1.53	0.56	0.076	0.30	1.06	1.67	0.123	0.87	3.22
COPD	1.02	0.953	0.59	1.77	0.77	0.232	0.50	1.18	0.67	0.192	0.37	1.22
Pulmonary hypertension	1.63	0.042	1.02	2.61	1.29	0.157	0.91	1.83	1.16	0.514	0.74	1.82
GFR <15	3.58	0.001	1.71	7.46	0.71	0.379	0.33	1.52	1.09	0.848	0.44	2.74
GFR <30	2.51	0.037	1.06	5.98	3.31	0.001	1.58	6.92	1.04	0.940	0.35	3.14
Atrial fibrillation	1.15	0.456	0.80	1.65	1.98	<0.001	1.52	2.57	1.51	0.014	1.09	2.09
Diabetes	0.97	0.885	0.67	1.41	1.18	0.219	0.91	1.54	1.11	0.537	0.79	1.55

	Delirium				Mechanical ventilation >48 h				Stroke			
	OR	*P-value*	95% CI		OR	*P-value*	95% CI		OR	*P-value*	95% CI	
Logistic EuroSCORE	1.03	0.027	1.00	1.05	1.05	<0.001	1.03	1.08	1.14	<0.001	1.10	1.18
Age in years	1.03	<0.001	1.02	1.05	1.01	0.119	1.00	1.03	0.96	0.002	0.94	0.99
Female	0.72	0.015	0.55	0.94	0.86	0.257	0.65	1.12	0.81	0.414	0.49	1.35
NYHA class II	0.63	0.022	0.43	0.94	0.66	0.058	0.43	1.01	0.36	0.038	0.13	0.94
NYHA class III or IV	1.17	0.252	0.89	1.53	1.61	0.001	1.22	2.12	0.99	0.973	0.60	1.63
CAD	1.08	0.607	0.81	1.43	1.10	0.509	0.82	1.48	1.09	0.774	0.62	1.92
Arterial hypertension	0.84	0.193	0.66	1.09	0.77	0.051	0.59	1.00	0.98	0.936	0.61	1.59
Previous MI within 4 months	0.51	0.350	0.13	2.07	0.90	0.879	0.24	3.39	0.10	0.096	0.01	1.52
Previous MI within 1 year	1.96	0.399	0.41	9.31	7.10	0.025	1.28	39.43	(omitted)			
Previous MI after 1 year	1.06	0.886	0.48	2.32	1.01	0.985	0.47	2.16	1.57	0.522	0.40	6.16
Previous CABG	0.50	0.243	0.15	1.61	0.59	0.309	0.21	1.63	0.06	0.032	0.00	0.78
Previous cardiac surgery	0.82	0.531	0.45	1.51	1.81	0.026	1.07	3.05	0.83	0.636	0.37	1.83
Peripheral vascular disease	1.13	0.645	0.66	1.93	0.86	0.579	0.49	1.49	0.68	0.442	0.26	1.80
Carotid artery disease	1.10	0.734	0.63	1.94	0.47	0.026	0.24	0.92	0.36	0.087	0.11	1.16
COPD	1.22	0.313	0.83	1.79	1.19	0.368	0.81	1.75	0.24	0.005	0.09	0.66
Pulmonary hypertension	0.85	0.372	0.59	1.21	1.36	0.077	0.97	1.93	0.27	<0.001	0.13	0.55
GFR <15	1.75	0.103	0.89	3.42	2.63	0.003	1.39	4.99	0.75	0.633	0.24	2.40
GFR <30	1.54	0.261	0.72	3.29	1.14	0.738	0.53	2.43	0.59	0.459	0.15	2.38
Atrial fibrillation	1.46	0.003	1.14	1.88	2.16	<0.001	1.66	2.81	1.26	0.373	0.76	2.08
Diabetes	1.39	0.010	1.08	1.79	1.14	0.346	0.87	1.48	1.06	0.816	0.63	1.78

CAD: coronary artery disease; CI: confidence interval; COPD: chronic obstructive pulmonary disease; GFR:glomerular filtration rate; MI: myocardial infarction; CABG: coronary artery bypass grafting; NYHA: New York Heart Association; OR: odds ratio.

Menlo Park, CA, USA) or the use of Tendyne™ (Abbott Vascular, Menlo Park, CA, USA). However, even the percutaneous treatment of isolated functional regurgitation is discussed controversially and solid long-term data are unavailable [15–17]. Hence, the role of endovascular options for the treatment of patients with combined aortic and mitral pathologies remains a non-evidence-based case-to-case decision by the heart team due to the lack of long-term data. More studies are therefore needed to clearly delineate the characteristics of patients with aortic valve stenosis requiring concomitant MVR, and how postoperative outcomes in these patients may be improved further.

Lastly, this study shows that AVR + MVR surgery is a frequently performed procedure in Germany with acceptable in-hospital results. The advances in cardiac surgery and postoperative care are well reflected in this analysis considering that the in-hospital mortality associated with this double-valve replacement procedure is lower in this nationwide cohort compared to older single-centre reports [11, 18]. Of note, the number of combined AVR + MVR cases seems to be increasing over the time from 2158 in 2007 and 2008 compared to 2597 in this study period (2017–18) underlying the value of this analysis.

Limitations and strengths

Although our retrospective data analysis assessed a nationwide dataset encompassing over 2500 patients, there are several limitations. First, administrative data were used for this analysis and coding errors may be present. In addition, these administrative data solely provide in-hospital data and we are unable to provide any long-term data on

these patients. Second, we were able to analyse outcomes in a large patient collective, but we were unable to analyse the indications for MVR and intraoperative data cannot adequately be analysed and interpreted (e.g. valve type). Also, using these administrative data, we are able to adequately calculate the EuroSCORE, which has to be interpreted carefully since we are unable to calculate more advanced scores using these data source such as the EuroSCORE II. Although that is our main study limitation, this study clearly highlights the need for further research in this field. Lastly, as this is a national dataset, and despite the large patient numbers, results in other countries may not be entirely comparable.

CONCLUSIONS

Patients undergoing concomitant AVR and MVR surgery have an acceptable in-hospital mortality, morbidity and length of in-hospital stay. Age, advanced NYHA class, previous cardiac surgery, peripheral vascular disease, pulmonary hypertension and impaired renal function were identified as independent predictors for in-hospital mortality.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *ICVTS* online.

Conflict of interest: none declared.

Data availability statement

This study analysed summarized data from the Research Data Center of the Federal Bureau of Statistics, in Wiesbaden, Germany and no access to individual data occurred. All, summarized data are provided within this manuscript.

Author contributions

Maximilian Kreibich: Conceptualization; Formal analysis; Visualization; Writing—original draft. **Klaus Kaier:** Conceptualization; Data curation; Formal analysis; Investigation; Writing—review & editing. **Constantin von zur Mühlen:** Conceptualization; Investigation; Methodology; Resources; Validation; Writing—review & editing. **Matthias Siepe:** Formal analysis; Project administration; Resources; Supervision; Writing—review & editing. **Manfred Zehender:** Conceptualization; Methodology; Project administration; Resources; Validation; Writing—review & editing. **Christoph Bode:** Conceptualization; Methodology; Project administration; Resources; Supervision; Validation; Writing—review & editing. **Friedhelm Beyersdorf:** Methodology; Project administration; Resources; Supervision; Writing—review & editing. **Peter Stachon:** Conceptualization; Data curation; Formal analysis; Methodology; Resources; Validation; Writing—review & editing. **Wolfgang Bothe:** Conceptualization; Data curation; Formal analysis; Methodology; Supervision; Validation; Writing—review & editing.

Reviewer information

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