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Treatment of Severe TRIcuspid Regurgitation in Patients with Advanced Heart Failure with CAval Vein Implantation of the Edwards Sapien XT VALve (TRICAVAL): a controlled prospective randomized trial

--Manuscript Draft--

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Corresponding Author:	Karl Stangl Charite Campus Mitte - Dept. Of Cardiology & Angiology GERMANY
Corresponding Author's Institution:	Charite Campus Mitte - Dept. Of Cardiology & Angiology
First Author:	Henryk Dreger, MD
Order of Authors:	Henryk Dreger, MD
	Isabel Mattig, MD
	Bernd Hewing, MD
	Fabian Knebel, MD
	Alexander Lauten, MD
	Alexander Lembcke, MD
	Martin Thoenes, MD
	Robert Roehle, MSc
	Verena Stangl, MD
	Ulf Landmesser, MD
	Herko Grubitzsch, MD
	Karl Stangl, MD
	Michael Laule, MD
	Christoph Schöbel, MD
	Gert Baumann, MD
Order of Authors Secondary Information:	
Abstract:	Aims: The aim of our study was to compare the impact of implantation of a balloon-expandable transcatheter valve into the inferior vena cava (CAVI) on exercise capacity with optimal medical therapy (OMT) in patients with severe tricuspid regurgitation (TR) and high surgical risk. Methods and Results: 28 patients were randomized to OMT (n = 14) or CAVI (n = 14). Primary endpoint was maximal oxygen uptake at the three months follow-up. Secondary endpoints included six-minute walk test, NYHA class, NT-proBNP levels, right heart function, unscheduled heart failure hospitalization, and quality of life as assessed by the Minnesota Living with Heart Failure Questionnaire (MLHFQ). Patients underwent follow-up examinations one, three, six, and twelve months after randomization. Maximal oxygen uptake did not change significantly in both groups after three months and there was no difference between the OMT and CAVI groups (-0.1±1.8 ml•kg -1 •min -1 vs. -1.0±1.6 ml•kg -1 •min -1 , p = 0.4995). Compared to baseline, CAVI improved NYHA class, dyspnea, and quality of life after three months. However, there were no statistically significant differences in the secondary

	endpoints between both groups. Four periprocedural complications occurred after CAVI resulting in open-heart surgery. Four patients in the OMT group and eight patients (including four after conversion to surgery) in the CAVI group died from right heart failure, sepsis or hemorrhage. Conclusions: CAVI did not result in a superior functional outcome compared to OMT. Due to an unexpectedly high rate of valve dislocations, the study was stopped for safety reasons.
Response to Reviewers:	We have addressed the remaining points by … … adding the names of the collaborators to Editorial Manager, … uploading ICMJE forms for the collaborators, and … changing the order of the figures.
Additional Information:	
Question	**Response**
Please indicate your twitter account so we will be able to "tag" you in twitter when your paper will be pushed in EuroIntervention's social media.	n.a.
If you have submitted this manuscript to another publication please give details below	We recently published the condensed results of the primary endpoint (three months after randomization) as a brief research report (795 words) in the Journal of the American College of Cardiology (Laule et al. J Am Coll Cardiol. 2019 Jul 23;74(3):473-475). In the present manuscript, we provide detailed information on the primary and all secondary endpoints including the extended follow up of 12 months.
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Corresponding Author E-Mail:	karl.stangl@charite.de
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CharitéCentrum für Herz-, Kreislauf- und Gefäßmedizin
Ärztlicher Centrumsleiter: Prof. Dr. med. U. Landmesser

Prof. Dr. H. Dreger | Kardiologie | Charitéplatz 1 | 10117 Berlin

Medizinische Klinik und Poliklinik
Schwerpunkt Kardiologie, Angiologie
Direktor: Prof. Dr. med. Karl Stangl

Prof. Dr. Henryk Dreger
Leitender Oberarzt
Tel.: +49 30 450 613496
Fax: +49 30 450 7613496
E-mail: henryk.dreger@charite.de
Internet: herz.charite.de

Datum:
u. Z.:

Prof. Patrick W. Serruys, MD
Editor-in-Chief
EuroIntervention

Dear Prof. Serruys,

we are grateful to hear that our manuscript entitled “Treatment of Severe TRIcuspid Regurgitation in Patients with Advanced Heart Failure with CAval Vein Implantation of the Edwards Sapien XT VALve (TRICAVAL): a controlled prospective randomized trial” has been accepted for publication in *EuroIntervention*.

We have addressed the remaining points by …
… adding the names of the collaborators to Editorial Manager,
… uploading ICMJE forms for the collaborators, and
… changing the order of the figures.

Thank you very much for accepting our study for publication in EuroIntervention.

Sincerely,

Henryk Dreger, MD Karl Stangl, MD Michael Laule, MD

Treatment of Severe TRIcuspid Regurgitation in Patients with Advanced Heart Failure with CAval Vein Implantation of the Edwards Sapien XT VALve (TRICAVAL): a controlled prospective randomized trial

Henryk Dreger, MD[1,2]; Isabel Mattig, MD[1]; Bernd Hewing, MD[1,2,3]; Fabian Knebel, MD[1,2,3]; Alexander Lauten, MD[4]; Alexander Lembcke, MD[5]; Martin Thoenes, MD[6]; Robert Roehle, MSc[3,7,8]; Verena Stangl, MD[1,2]; Ulf Landmesser, MD[2,3,4]; Herko Grubitzsch, MD[9]; Karl Stangl, MD[1,2]; Michael Laule, MD[1,3]

A list of study collaborators can be found in the appendix

Short title: inferior caval valve implantation for severe tricuspid regurgitation

[1]) Medizinische Klinik für Kardiologie und Angiologie, Campus Charité Mitte, Charité – Universitätsmedizin Berlin, Germany
[2]) DZHK (German Centre for Cardiovascular Research), partner site Berlin, Germany
[3]) Berlin Institute of Health (BIH), Berlin, Germany
[4]) Medizinische Klinik für Kardiologie, Campus Benjamin Franklin, Charité – Universitätsmedizin Berlin, Germany
[5]) Institut für Radiologie, Campus Charité Mitte, Charité – Universitätsmedizin Berlin, Germany
[6]) Edwards Lifesciences, Nyon, Switzerland
[7]) Coordinating Center for Clinical Studies, Charité – Universitätsmedizin Berlin, Germany
[8]) Institute of Biometry and Clinical Epidemiology, Charité – Universitätsmedizin Berlin, Germany
[9]) Klinik für Kardiovaskuläre Chirurgie, Charité – Universitätsmedizin Berlin, Germany

Correspondence to:
Karl Stangl, MD
Medizinische Klinik für Kardiologie und Angiologie, Campus Charité Mitte
Charité – Universitätsmedizin Berlin
Charitéplatz 1
D – 10117 Berlin, Germany

Phone: +49 30 450 513 142
Fax: +49 30 450 513 932
Email: karl.stangl@charite.de

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Abstract

Aims: The aim of our study was to compare the impact of implantation of a balloon-expandable transcatheter valve into the inferior vena cava (CAVI) on exercise capacity with optimal medical therapy (OMT) in patients with severe tricuspid regurgitation (TR) and high surgical risk.

Methods and Results: 28 patients were randomized to OMT (n = 14) or CAVI (n = 14). Primary endpoint was maximal oxygen uptake at the three months follow-up. Secondary endpoints included six-minute walk test, NYHA class, NT-proBNP levels, right heart function, unscheduled heart failure hospitalization, and quality of life as assessed by the Minnesota Living with Heart Failure Questionnaire (MLHFQ). Patients underwent follow-up examinations one, three, six, and twelve months after randomization. Maximal oxygen uptake did not change significantly in both groups after three months and there was no difference between the OMT and CAVI groups (-0.1±1.8 $ml \cdot kg^{-1} \cdot min^{-1}$ vs. -1.0±1.6 $ml \cdot kg^{-1} \cdot min^{-1}$, p = 0.4995). Compared to baseline, CAVI improved NYHA class, dyspnea, and quality of life after three months. However, there were no statistically significant differences in the secondary endpoints between both groups. Four periprocedural complications occurred after CAVI resulting in open-heart surgery. Four patients in the OMT group and eight patients (including four after conversion to surgery) in the CAVI group died from right heart failure, sepsis or hemorrhage.

Conclusions: CAVI did not result in a superior functional outcome compared to OMT. Due to an unexpectedly high rate of valve dislocations, the study was stopped for safety reasons.

Classifications: Tricuspid disease; Femoral; Dyspnea; TTVR

Condensed abstract:

The aim of our study was to compare the safety and efficacy of implantation of a balloon-expandable transcatheter valve into the inferior vena cava (CAVI) with optimal medical therapy (OMT) in patients with severe tricuspid regurgitation.

28 patients were randomized to OMT (n = 14) or CAVI (n = 14). Primary endpoint was maximal oxygen uptake three months after randomization. Secondary endpoints included six-minute walk test, NYHA class, NT-proBNP levels, unscheduled hospitalization for heart failure progression, and quality of life. There were no significant differences between both groups regarding the primary and secondary endpoints. Four periprocedural complications occurred after CAVI resulting in open-heart surgery.

Abbreviations

BMI	body mass index
CAVI	inferior caval valve implantation
EROA	effective regurgitant orifice area
IVC	inferior vena cava
LVEF	left ventricular ejection fraction
MLHFQ	Minnesota Living with Heart Failure Questionnaire
NT-proBNP	N-terminal prohormone of brain natriuretic peptide
NYHA	New York Heart Association
OMT	optimal medical therapy
RA	right atrium
RV	right ventricle
SVC	superior vena cava
TAPSE	tricuspid annular plane systolic excursion
TAVR	transcatheter aortic valve replacement
TEE	transesophageal echocardiography
TR	tricuspid regurgitation
VARC-2	Valve Academic Research Consortium 2
$\dot{V}O_{2max}$	maximal oxygen uptake
VTI	velocity time integral of the liver vein reflux

Introduction

Severe tricuspid regurgitation (TR) is associated with high morbidity and mortality [1,2]. Medical therapy is often insufficient for adequate symptom relief and patients frequently suffer from effort dyspnea and refractory peripheral edema. Despite its high prevalence, isolated surgical repair of TR is rarely performed and perioperative mortality remains high [3]. Encouraged by the success of transcatheter aortic valve replacement (TAVR) and edge-to-edge repair of the mitral valve, a variety of approaches for interventional treatment of TR have been proposed [4]. Due to the size and anatomical complexity of the tricuspid valve, no currently available percutaneous transcatheter valve system is suited for direct implantation into the native tricuspid annulus. Accordingly, most approaches for interventional treatment of TR aim at bicuspidization of the valve or annuloplasty [5]. However, these novel therapies are technically challenging and require excellent intraprocedural visualization of the valve by transesophageal echocardiography (TEE) [6].

As backflow into the inferior vena cava (IVC) leads to congestive hepato- and gastropathy it is a major component of the pathophysiology of severe TR. We have previously shown that inferior caval valve implantation (CAVI) reduces IVC peak pressure [7]. We therefore hypothesized that implantation of a transcatheter valve into the IVC may improve symptoms and exercise capacity of TR patients by reducing abdominal regurgitation and congestion. In addition, CAVI is a comparatively simple procedure and can be performed using commercially available products. Furthermore, it can be guided by fluoroscopy and transthoracic echocardiography and therefore does not require general anesthesia which is usually necessary for TEE guidance [8].

Encouraged by a series of compassionate use cases which suggested both technical feasibility and symptom relief [7,9-11], we designed the randomized TRICAVAL trial to compare optimal medical therapy (OMT) with CAVI. We recently reported the results of the primary endpoint

three months after randomization in a brief research letter [12]. Here, we provide detailed information on the study population, the primary and secondary endpoints as well as on the extended 12 months-follow-up.

Methods

Study Design

TRICAVAL was an investigator initiated, prospective, open-label, single center, randomized trial comparing OMT with CAVI in patients with severe, symptomatic TR (NCT02387697). Inclusion criteria were NYHA class ≥2 despite established OMT, age ≥ 50 years, and high surgical risk (logistic EuroSCORE I ≥15% or other contraindications for conventional valve surgery according to the decision of the local heart team). OMT was adjudicated by heart failure specialists and defined as medical therapy as recommended by current heart failure guidelines. For patients with preserved ejection fraction, OMT was defined as maximum tolerable dose of diuretics controlling edema. Main exclusion criteria included severe left ventricular dysfunction and severe kidney dysfunction (for complete list see online supplement). Patients were further screened for anatomic suitability by 3D echocardiography and (following patient number 12) computed tomography and excluded when the IVC diameter at the landing zone exceeded > 31 mm. Patients were randomized using a computer-generated block randomization. All patients provided written consent. The study complies with the Declaration of Helsinki and was approved by the local ethics committee (LaGeSo, Landesamt für Gesundheit und Soziales Berlin, Germany) and state authorities (BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte, Bonn, Germany).

The primary endpoint was exercise capacity, which was determined by quantifying maximal oxygen uptake by treadmill spiroergometry three months after randomization. Spiroergometry was performed according to the recommendations of the European Association for Cardiovascular Prevention & Rehabilitation [13]. In order to maintain comparability, all patients were supported to reach the anaerobic threshold defined by respiratory rules or the respiratory exchange ratio (RER), respectively [14]. Only tests which fulfilled the criteria of target performance were included in our analysis.

Secondary endpoints included NYHA class, six minute walk test, NT-proBNP levels, right heart function, unscheduled hospitalization for heart failure, and quality of life as assessed by the Minnesota Living with Heart Failure Questionnaire (MLHFQ) three months after randomization. Follow-up visits were scheduled one, three, six and twelve months after implantation. Over the course of the study, three patients from the OMT group declined to undergo further follow up-examinations due to deteriorating health. Safety was evaluated according to the Valve Academic Research Consortium 2 (VARC-2) criteria [15].

Severity of tricuspid regurgitation was graded as recommended by the European Association of Cardiovascular Imaging and the American Society of Echocardiography [16,17] with a special focus on systolic flow reversal in the hepatic veins.

Caval valve implantations

Implantations were performed via a right transfemoral venous access under local anesthesia and guided by transthoracic echocardiography as described previously [9]. Unfractionated heparin was given to reach an activating clotting time >250 seconds. Depending on IVC anatomy, a landing zone was first prepared by implantation of a self-expanding nitinol stent (sinus-XL, Optimed, Ettlingen, Germany) into the IVC protruding approximately 5-10 mm into the right atrium. Subsequently, a 23, 26 or 29 mm Edwards Sapien XT transcatheter valve (Edwards Lifesciences, Irvine, CA) was implanted into the junction of the IVC and the right atrium (Figure 1). After sheath removal, hemostasis was achieved by Z-suture of the skin and manual compression. All patients were put on oral anticoagulation after implantation. Doppler echocardiography was used to determine the extent of the liver vein reflux by measuring the velocity time integral (VTI) by pulsed wave Doppler in a prominent vein in all patients before and after implantation.

Statistics

Sample size calculation was based on the primary endpoint of maximal oxygen uptake after three months. A difference between both groups of 8 $ml \cdot kg^{-1} \cdot min^{-1}$ was considered clinically significant. To detect this difference with a *t*-test at a significance level of 5% (two-tailed) with a power of 80% and an assumed standard deviation of 8 $ml \cdot kg^{-1} \cdot min^{-1}$, a total number of 34 patients was calculated to be required (nQuery Advisor 7.0, Statistical Solutions Ltd, Cork, Ireland). To account for 15% drop-outs, 40 patients were planned to be randomized.

The primary endpoint was primarily evaluated using a linear regression with group assignment and baseline value as independent variables. As a sensitivity analysis, the unadjusted difference was compared using a *t*-test. In order to incorporate the follow-up measurements and to investigate time trends, a linear mixed model with maximal oxygen uptake as dependent variable, time, group, and time-by-group interaction as fixed effects and a random subject intercept was calculated. The same approach was done for the MLHFQ but time was modelled with a quadratic effect due to the structure found in the data. Continuous and normally distributed data are presented as means ± SD and were compared using the student's t-test. Non-normally distributed data are given as median with the interquartile range and were analyzed using the Mann-Whitney U-test. Categorical data are presented as percentages and were compared using the Boschloo-test. Dependent continuous data were compared using paired t-tests or Wilcoxon-tests depending on the distribution while dependent categorical data were compared using the symmetry test. A p-value < 0.05 was considered statistically significant although the results of this study have to be interpreted in an exploratory way. All statistical analyses were performed using the SPSS statistical package, version 23.0 (IBM Corp, New York, NY) and R version 3.4.4 [18].

Results

Study population

Between January 2015 and November 2017, 28 patients (mean age 75.1 ± 8.5 years) were enrolled and randomized to CAVI (*n* = 14) or continuation of OMT (*n* = 14). Details regarding patient enrollment are given in Figure 2. Patient characteristics at baseline are summarized in Table 1. Details on the heart failure classification and medication at baseline are provided in Table 2. According to a recently proposed grading scheme, four patients (14.3%) had severe, four patients (14.3%) had massive, and 20 patients (71.4%) had torrential TR [19].

Valve implantations

Valve implantations were primarily successful with correct valve deployment in the intended landing zones in all patients. Mild paravalvular leakage was present in two patients (14.3%). Doppler echocardiography confirmed significant reduction of the liver vein reflux in all CAVI patients (VTI 15.4 ± 5.0 cm at baseline vs. 5.1 ± 6.6 cm after implantation, $p = 0.004$).

We observed four delayed major complications 7 to 48 hours after primarily successful implantations leading to open heart surgery (two cardiac tamponades due to stent migration and two valve dislocations). Patient recruitment was stopped for safety concerns after the fourth major complication.

Primary and secondary endpoints

The primary endpoint, maximal oxygen uptake at month three, did not differ between the OMT and CAVI groups (10.5 ± 3.4 ml·kg^{-1}·min^{-1} vs. 11.6 ± 2.6 ml·kg^{-1}·min^{-1}, p from baseline adjusted regression = 0.4995; unadjusted p value = 0.299, Table 3). Analyzing all follow-up

examinations, there was also no significant change over time in both the OMT group (slope 0.09 ml·kg^{-1}·min^{-1} per month; 95% CI -0.05-0.23 ml·kg^{-1}·min^{-1} per month; p = 0.225) and in the CAVI group (slope -0.05 ml·kg^{-1}·min^{-1} per month; 95% CI -0.19-0.10 ml·kg^{-1}·min^{-1} per month; p = 0.530). Furthermore, there was no significant difference in the slopes between the two groups (slope difference CAVI vs. OMT -0.13 ml·kg^{-1}·min^{-1} per month; 95% CI -0.33-0.07 ml·kg^{-1}·min^{-1} per month; p = 0.196, Figure 3).

Three months after implantation, CAVI patients with complete follow-up reported a significant improvement of NYHA class (-0.6 ± 0.5, p = 0.025). This is in agreement with the subjective assessment of exertional dyspnea using a Likert scale which showed significant improvement three months after CAVI compared to OMT (1.5 ± 1.1 vs. -0.2 ± 1.3, p = 0.008, Table 3). Regarding the change of NYHA class, however, there was no significant difference between both groups over the entire follow up period (p > 0.05 for all follow-up visits, Figure 4).

For the analysis of quality of life measured with the MLHFQ, both groups showed significant improvement over time (p for quadratic time trend = 0.040, Figure 5) with no significant difference between both groups (p for interaction = 0.680).

In addition, there were no significant differences between both groups regarding the other secondary endpoints with regard to change from baseline (six minute walk test, NT-proBNP levels, and right heart function) at the three months follow-up (Table 3).

Three patients from the CAVI group (21%) died in-hospital after conversion to surgery from hemorrhagic shock due to resuscitation-related splenic rupture, acute-on-chronic right heart failure, or pneumonia. All-cause mortality after 12 months was 57% in the CAVI and 29% in the OMT group (p = 0.159). There were no significant differences in heart failure hospitalizations between both groups (Table 4). Echocardiography showed normal caval valve function in all CAVI patients one, three, six and twelve months after implantation. There were no major vascular complications.

Discussion

Given the high number of patients with severe TR who are unfit for surgery and remain symptomatic under OMT, the development of interventional treatment options represents a pressing unmet clinical need. Driven by the success of established interventions for left heart valve disease, several approaches have been proposed for the treatment of severe TR [5]. However, there is a lack of randomized trials as most published data on these new therapeutic options stem from non-randomized case series. Our study represents the first randomized controlled trial analyzing the effect of CAVI on exercise capacity in patients with severe TR compared to OMT.

CAVI resulted in a significant improvement of exertional dyspnea, which was associated with a significant improvement of quality of life. This is in agreement with previously published data from non-randomized studies [7,9-11] and comparable to the efficacy of other interventional approaches [19-22]. Except for the subjective assessment of dyspnea by the Likert scale, there were, however, no significant differences between both study groups regarding the secondary endpoints – including NYHA class (Table 3, Figures 4 and 5). In addition, we observed no significant improvement of exercise capacity after CAVI (Figure 3). However, the interpretation of these results is clearly limited by the low number of patients. Initially, we planned to enroll 40 patients into our study but stopped patient recruitment after the fourth incidence of delayed valve dislocation or stent migration. This was an unexpected finding, as we did not observe similar complications in our compassionate use cases. Valve dislocations are a well-known TAVR complication and have also been described after CAVI [7]. Nevertheless, the high number of dislocations in our study – despite multi-modal assessment of IVC anatomy by CT and 3D echocardiography – raises safety concerns. In stark contrast to the calcified aortic root in TAVR patients, the smooth luminal surface and the fluid-load dependent, variable diameter of the IVC seem to inhibit stable positioning of balloon expandable

transcatheter valves even after pretreatment of the IVC by implantation of self-expandable stents. In addition, 17% of the screened patients had to be excluded due to an IVC diameter >31 mm (Figure 2). Accordingly, the use of dedicated self-expandable valves or reduction stents suitable for larger IVC diameters should be considered in future studies investigating a possible beneficial effect of CAVI on symptom relief [23]. This would also allow a bicaval approach with implantation of transcatheter valves in both the inferior and superior vena cava (SVC). In advanced severe TR, the SVC frequently shows a tapered dilatation, which is not suited for implantation of balloon-expandable valves. Therefore – and because backflow in the SVC is often smaller than into the IVC due to hydrostatic pressure – our study focused on CAVI into the IVC only. In addition, valve implantation into the SVC is frequently limited by the presence of pacemaker and ICD leads.

Echocardiographic follow-up examinations revealed no significant effects of CAVI on the severity of tricuspid regurgitation. Similarly, there were no measurable differences between both groups regarding right heart morphology and function. Despite a significant increase of the difference between the peak v-wave pressure in the IVC and the right atrium before (1.4 ± 3.1 mmHg) and after implantation (11.0 ± 8.2 mmHg, $p = 0.021$), we did not observe an increase of right heart diameters or an impaired right heart function due to a possible pressure overload after CAVI (Table 3).

An unresolved issue remains the question which patients are good candidates for interventional treatment of TR. As the majority of our patients had torrential TR with severe dilatation of the right heart, CAVI may have failed to improve cardiac function and morphology due to a lack of potential for reverse remodelling in advanced stages of right heart failure. Future studies might therefore need to focus on patients who have a high surgical risk but are still in earlier stages of valvular heart failure.

Limitations

Due to an unexpectedly high rate of complications, the study was stopped for safety reasons resulting in a low number of enrolled patients. Subjective improvement of symptoms caused by the placebo effect cannot be ruled out as patients were not blinded to the procedure.

Conclusions:

Implantation of a balloon-expandable transcatheter valve into the IVC did not result in a superior functional outcome compared to OMT.

Dedicated devices (e.g. TricValve, TriCento) might overcome some of the anatomic challenges observed in our trial [23,24]. In particular, the risk of valve dislocation needs to be minimized as the excess mortality in the CAVI arm was driven by patients who underwent cardiac surgery for removal of dislocated valves.

In summary, further studies using dedicated devices in patients in less advanced stages of chronic right heart failure are be needed to identify patient subgroups who may benefit from heterotopic tricuspid valve replacement. CAVI using a balloon-expandable device can currently not be recommended due to safety concerns.

Impact on daily practice:

"Heterotopic tricuspid valve replacement" by implantation of a transcatheter valve into the inferior vena cava (CAVI) does not result in a superior functional outcome compared to optimal medical therapy in patients with severe tricuspid regurgitation. Therefore, CAVI using a balloon-expandable transcatheter valve cannot be recommend in patients with advanced heart failure. Further studies with dedicated devices may be needed to identify patient subgroups who may benefit from the procedure.

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Appendix – List of collaborators

Prof. Christoph Schöbel, MD
Schlafmedizinisches Zentrum, Universitätsmedizin Essen, Ruhrlandklinik, Essen, Germany

Prof. Gert Baumann, MD
Medizinische Klinik für Kardiologie und Angiologie, Campus Charité Mitte, Charité – Universitätsmedizin Berlin, Germany

Conflicts of interest:

M.L., A.La. and K.S. report speaker and proctor fees from Abbott, Edwards Lifesciences und Medtronic. A.La. is consultant for P&F TricValve. M.T. is an employee of Edwards LifeSciences, Inc. The other authors have no conflicts of interest to declare.

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Figure legends:

Figure 1: Caval valve after implantation as seen by transthoracic echocardiography (A, subcostal view) and fluoroscopy (B, posterior-anterior projection). IVC, inferior vena cava; RA, right atrium.

Figure 2: Overview of patient screening and enrollment.

Figure 3: Individual and mean maximal oxygen uptake at baseline and one, three, six, and twelve months after randomization.

Figure 4: NYHA class at baseline and one, three, six, and twelve months after randomization.

Figure 5: Individual and average quality of life (assessed by the Minnesota Living with Heart Failure questionnaire, MLHFQ) at baseline and one, three, six, and twelve months after randomization. Reduction of MLHFQ values indicates improved quality of life.

Tables

Table 1: Patient characteristics

	OMT	**CAVI**
n	14	14
males, n (%)	7 (50%)	2 (14%)
age, years (IQR)	77 (72.2-79.5)	77 (68.2-82.0)
NYHA class, n (%)		
1	0 (0%)	0 (0%)
2	3 (21%)	2 (14%)
3	10 (71%)	12 (86%)
4	1 (7%)	0 (0%)
log. EuroScore, % ± SD	14.2 ± 7.9	14.6 ± 11.6
$\dot{V}O_{2max}$, $ml \cdot kg^{-1} \cdot min^{-1}$ ± SD	11.2 ± 3.6	11.7 ± 2.8
BMI, kg/m^2 ± SD	25.0 ± 4.1	25.5 ± 4.6
LVEF, % ± SD	58.1 ± 7.1	56.4 ± 6.4
EROA, cm^2 ± SD	1.35 ± 1.1	1.23 ± 0.6
regurgitation volume, ml ± SD	74.4 ± 17.3	68.7 ± 24.6
TAPSE, mm ± SD	14.8 ± 5.1	16.1 ± 5.2
RV diameter, mm ± SD	54.6 ± 7.4	49.0 ± 6.6
RA area, cm^2 ± SD	35.8 ± 9.7	33.5 ± 15.3
systolic pulmonary artery pressure, mmHg (IQR)	40.0 (32.8-46.8)	39.0 (33.5-55.5)
NT-proBNP, ng/l ± SD	3294 ± 2447	2242 ± 979
Creatinine, mg/dl ± SD	1.4 ± 0.4	1.5 ± 0.5
MLHFQ ± SD	41.8 ± 14.0	41.9 ± 15.1
six minute walk test, m ± SD	286 ± 114	294 ± 115
History of heart surgery, n (%)	6 (43%)	3 (21%)

Table 2: Heart failure classification and medication at baseline.

	OMT	**CAVI**
heart failure with preserved ejection fraction (≥50%)		
n	13	12
diuretics, %	100%	100%
beta blocker, %	77%	83%
ACE inhibitor, %	46%	83%
mineralocorticoid receptor antagonist, %	62%	67%
heart failure with mid-range ejection fraction (40-49%)		
n	1	2
diuretics, %	100%	100%
beta blocker, %	100%	100%
ACE inhibitor, %	0%	50%
mineralocorticoid receptor antagonist, %	100%	100%
heart failure with reduced ejection fraction (<40%)		
n	0	0

Table 3: Changes from baseline of the primary and secondary endpoints three months after randomization in patients with complete follow-up.

	OMT	**CAVI**	***p* value**
n	10	8	
$\dot{V}O_{2max}$, $ml \cdot kg^{-1} \cdot min^{-1}$ ± SD	-0.1 ± 1.8	-1.0 ± 1.6	0.299
NT-proBNP, ng/l ± SD	547 ± 1801	427 ± 758	0.862
Creatinine, mg/dl ± SD	0.2 ± 0.4	-0.1 ± 0.5	0.226
NYHA class, ± SD	-0.3 ± 0.9	-0.6 ± 0.5[*]	0.401
improved by 2 classes	0	0	
improved by 1 class	5 (46%)	5 (63%)	
unchanged	5 (46%)	3 (38%)	
worsened by 1 class	0	0	
worsened by 2 classes	1 (9%)	0	
MLHFQ, ± SD	-7.6 ± 16.3	-19.9 ± 13.1[#]	0.098
six minute walk test, m ± SD	-2.8 ± 71.3	18.9 ± 47.0	0.494
dyspnea, Likert scale ± SD	-0.2 ± 1.3	1.5 ± 1.1	0.008
RV diameter, mm (IRQ)	2.5 (0.2-4.5)	-0.5 (-4-2.5)	0.229
RA area, cm^2 ± SD	1.6 ± 4.3	0.6 ± 9.8	0.787
EROA, cm^2 ± SD	0.16 ± 0.36	0.14 ± 0.56	0.930
regurgitation volume, ml ± SD	7.8 ± 19.4	8.0 ± 22.6	0.989
TAPSE, mm ± SD	2.1 ± 5.3	-1.1 ± 4.5	0.188

[*]) $p = 0.025$ vs. baseline, [#]) $p = 0.004$ vs. baseline

Table 4: Major adverse events.

	OMT	**CAVI**	***p*-value**
all-cause mortality, n (%)	4 (29%)	8 (57%)	0.159
right heart failure, n (%) sepsis, n (%) hemorrhage, n (%)	3 (21%) 1 (7%)	4 (29%) 3 (21%) 1 (7%)	
heart failure hospitalizations, n (%)	4 (29%)	4 (29%)	1.000

Treatment of Severe TRIcuspid Regurgitation in Patients with Advanced Heart Failure with CAval Vein Implantation of the Edwards Sapien XT VALve (TRICAVAL): a controlled prospective randomized trial

Henryk Dreger, MD; Isabel Mattig, MD; Bernd Hewing, MD; Fabian Knebel, MD[1]; Alexander Lauten, MD; Alexander Lembcke, MD; Martin Thoenes, MD; Robert Roehle, MSc; Verena Stangl, MD; Ulf Landmesser, MD; Herko Grubitzsch, MD; Karl Stangl, MD; Michael Laule, MD

Supplementary Data

Exclusion criteria

- VCI diameter at site of implantation > 32 mm
- severe left ventricular dysfunction with left ventricular ejection fraction (LVEF) < 30%
- severe mitral regurgitation
- estimated life expectancy < 12 months due to carcinoma, chronic liver disease, chronic renal disease or chronic end stage pulmonary disease
- evidence of an acute myocardial infarction ≤ one month before the intended treatment
- evidence of stroke / transient ischemic attack during the last 180 days
- leukopenia (white blood cell count < 3000 cell/mL),
- anemia (hemoglobin < 9 g/dL)
- thrombocytopenia (platelet count < 50,000 cells/mL) or any known blood clotting disorder
- evidence of an intracardiac mass, thrombus or vegetation in the right heart
- active upper gastrointestinal bleeding within one month prior to procedure
- patients with an acute emergency

- contraindication or hypersensitivity to all anticoagulation regimens, or inability to be anticoagulated for the study procedure
- allergy against the use of implanted stent / prosthesis
- patient undergoing regular dialysis or a serum creatinine above 3.0 mg/dl
- patients unsuitable for implantation because of thrombosis of the lower venous system or vena cava filter
- active bacterial endocarditis within six months of procedure.
- women of childbearing potential without highly effective contraception (PEARL-Index < 1%)
- inability to comply with all of the study procedures and follow-up visits
- subjects who are legally detained in an official institute

Figure 1

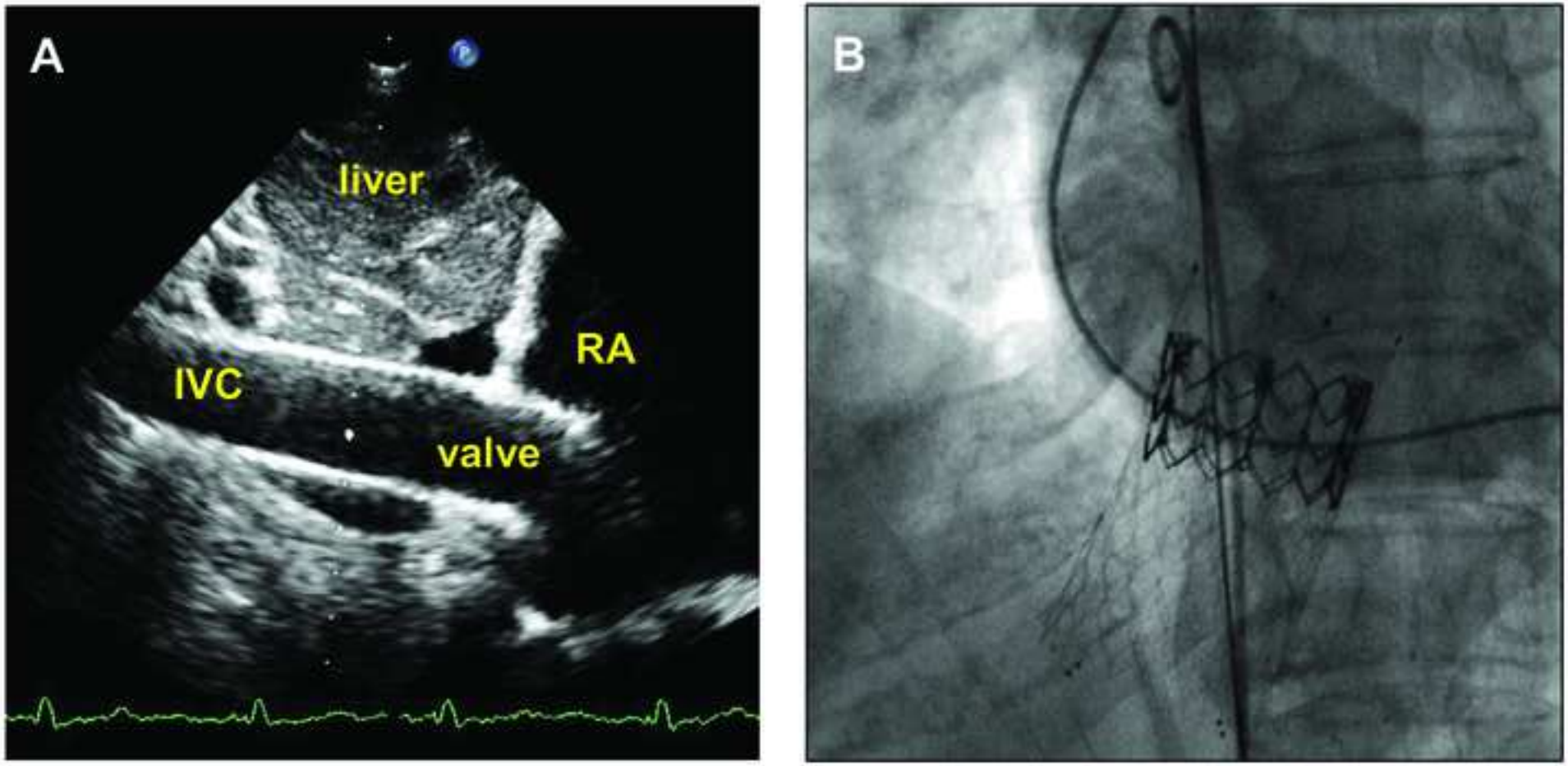


Figure 2

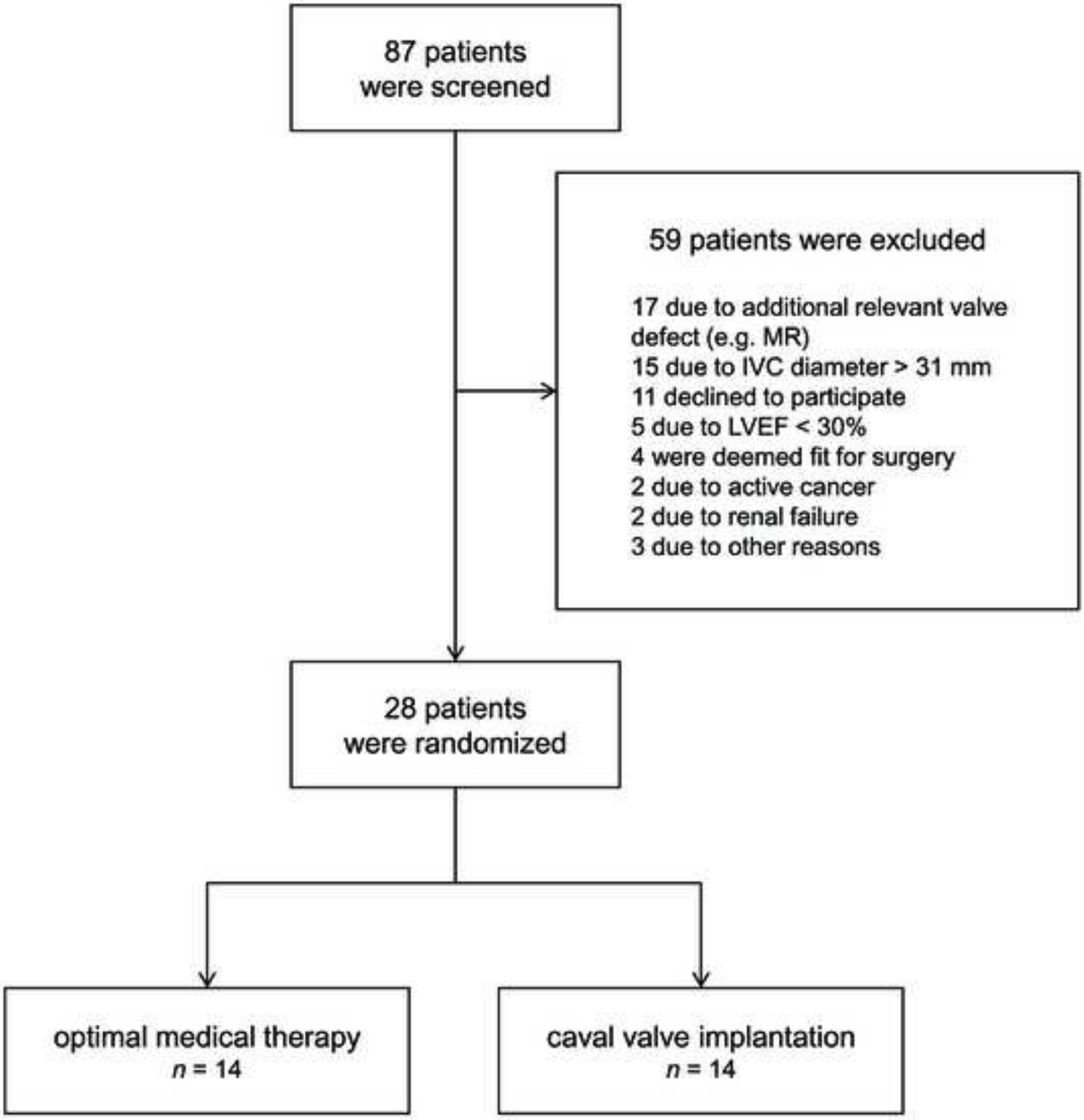

87 patients were screened
59 patients were excluded
17 due to additional relevant valve defect (e.g. MR)
15 due to IVC diameter > 31 mm
11 declined to participate
5 due to LVEF < 30%
4 were deemed fit for surgery
2 due to active cancer
2 due to renal failure
3 due to other reasons
28 patients were randomized
optimal medical therapy
n = 14
caval valve implantation
n = 14

Figure 3

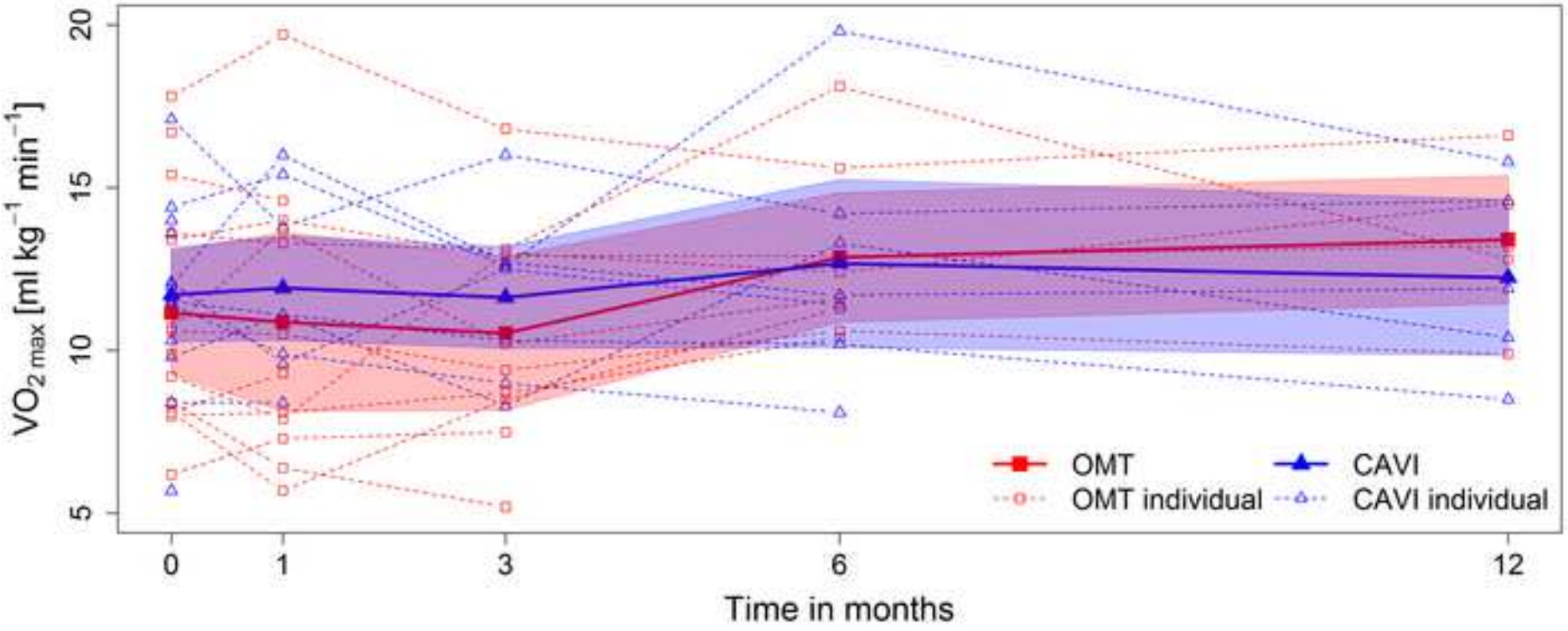

$VO_{2\,max}$ [ml kg^{-1} min^{-1}]
5
10
15
20
0
1
3
6
12
Time in months
OMT
OMT individual
CAVI
CAVI individual

Figure 4

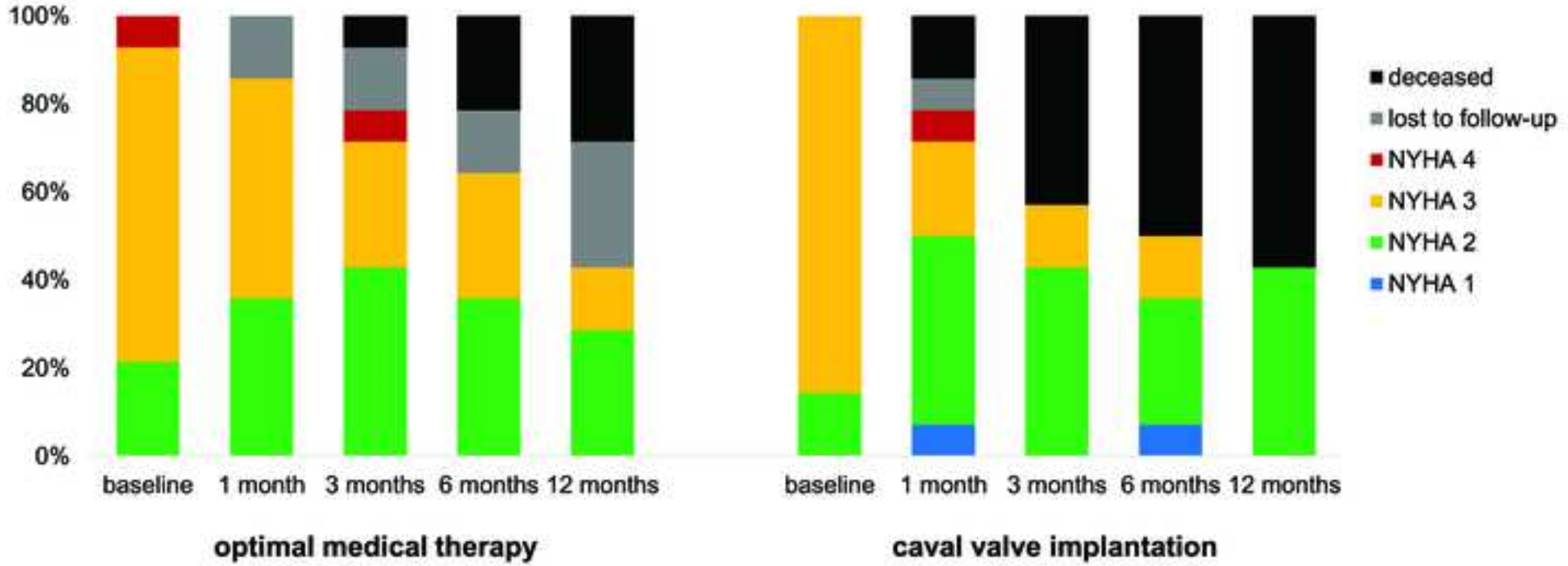
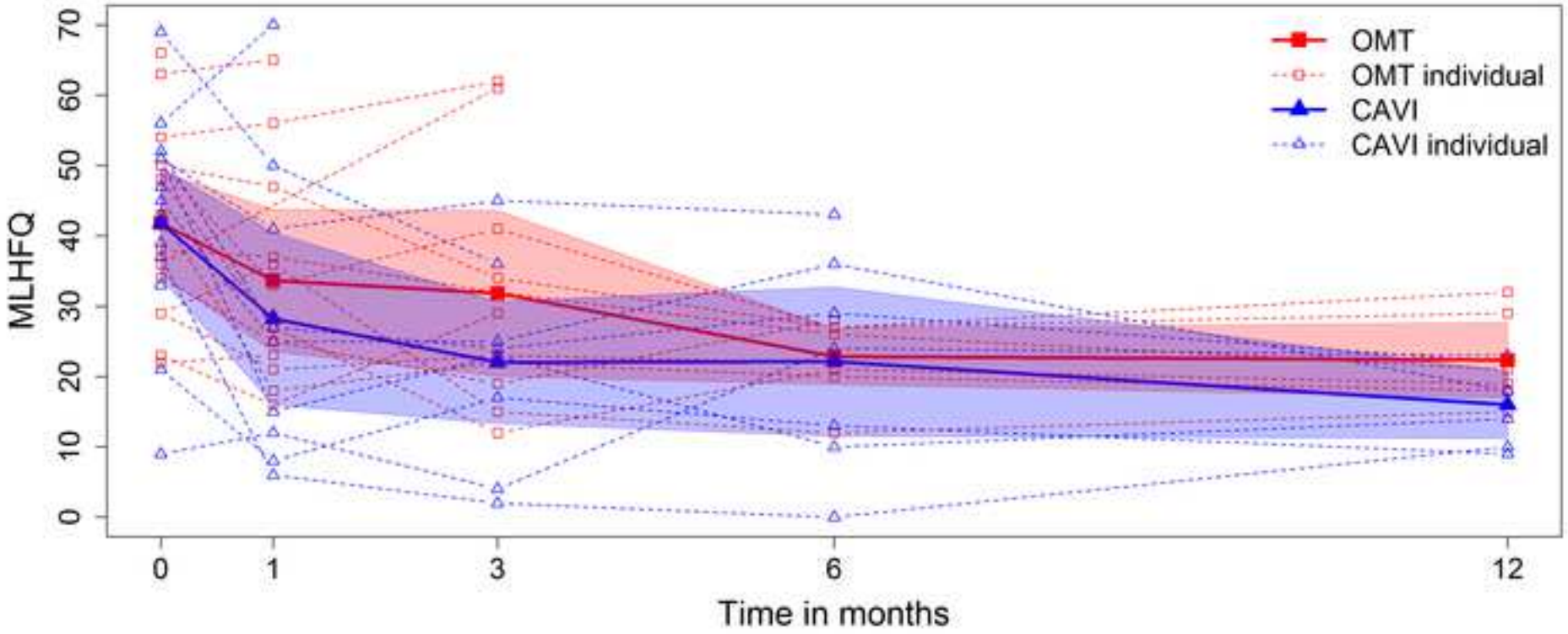

100%
80%
60%
40%
20%
0%
baseline
1 month
3 months
6 months
12 months
optimal medical therapy
baseline
1 month
3 months
6 months
12 months
caval valve implantation
deceased
lost to follow-up
NYHA 4
NYHA 3
NYHA 2
NYHA 1

Figure 5


MLHFQ
0
10
20
30
40
50
60
70
0
1
3
6
12
Time in months
OMT
OMT individual
CAVI
CAVI individual

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Corresponding Author's Name: Karl Stangl

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Treatment of Severe TRIcuspid Regurgitation in Patients with Advanced Heart Failure with CAval Vein Implantation of the Edwards Sapien XT VALve (TRICAVAL): a controlled prospective randomized trial

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Berlin Institute of Health	☑	☐	☐	☐	BIH fellowship

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Non-Financial Support: Examples include drugs/equipment supplied by the entity, travel paid by the entity, writing assistance, administrative support, etc.
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Issued: The patent has been issued by the agency
Licensed: The patent has been licensed to an entity, whether earning royalties or not
Royalties: Funds are coming in to you or your institution due to your patent

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Verena
2. Surname (Last Name): Stangl
3. Date: 12-December-2019

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Karl Stangl

5. Manuscript Title: Treatment of Severe TRIcuspid Regurgitation in Patients with Advanced Heart Failure with CAval Vein Implantation of the Edwards Sapien XT VALve (TRICAVAL): a controlled prospective randomized trial

6. Manuscript Identifying Number (if you know it):

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Are there any relevant conflicts of interest? ☑ Yes ☐ No

If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Edwards Life Sciences, Inc.	☑	☐	☐	☐	

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? ☐ Yes ☑ No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☑ No

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

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Dr. Stangl reports grants from Edwards Life Sciences, Inc., during the conduct of the study; .

Evaluation and Feedback

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Alexander
2. Surname (Last Name): Lauten
3. Date: 12-December-2019

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Karl Stangl

5. Manuscript Title: Treatment of Severe TRIcuspid Regurgitation in Patients with Advanced Heart Failure with CAval Vein Implantation of the Edwards Sapien XT VALve (TRICAVAL): a controlled prospective randomized trial

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Are there any relevant conflicts of interest? ☐ Yes ☑ No

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Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Abbott	☐	☑	☐	☐	
Edwards LifeSciences	☐	☑	☐	☐	
P&F TricValve	☐	☑	☐	☐	

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Dr. Lauten reports personal fees from Abbott, personal fees from Edwards LifeSciences, personal fees from P&F TricValve, outside the submitted work; .

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Alexander
2. Surname (Last Name): Lembcke
3. Date: 12-December-2019

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Karl Stangl

5. Manuscript Title
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Are there any relevant conflicts of interest? ☐ Yes ☑ No

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Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☑ No

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Dr. Lembcke has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Bernd
2. Surname (Last Name): Hewing
3. Date: 12-December-2019

4. Are you the corresponding author? ☐ Yes ☑ No
Corresponding Author's Name: Karl Stangl

5. Manuscript Title
Treatment of Severe TRIcuspid Regurgitation in Patients with Advanced Heart Failure with CAval Vein Implantation of the Edwards Sapien XT VALve (TRICAVAL): a controlled prospective randomized trial

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Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Edwards Life Sciences, Inc.	☑	☐	☐	☐	
Charité and Berlin Institute of Health	☑	☐	☐	☐	clinician scientist program

Section 3. Relevant financial activities outside the submitted work.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Fabian
2. Surname (Last Name): Knebel
3. Date: 12-December-2019

4. Are you the corresponding author? ☐ Yes ☑ No
Corresponding Author's Name: Karl Stangl

5. Manuscript Title
Treatment of Severe TRIcuspid Regurgitation in Patients with Advanced Heart Failure with CAval Vein Implantation of the Edwards Sapien XT VALve (TRICAVAL): a controlled prospective randomized trial

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Berlin Institute of Health	☑	☐	☐	☐	BIH fellowship

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Royalties: Funds are coming in to you or your institution due to your patent

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Henryk
2. Surname (Last Name): Dreger
3. Date: 12-December-2019

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Karl Stangl

5. Manuscript Title: Treatment of Severe TRIcuspid Regurgitation in Patients with Advanced Heart Failure with CAval Vein Implantation of the Edwards Sapien XT VALve (TRICAVAL): a controlled prospective randomized trial

6. Manuscript Identifying Number (if you know it):

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Are there any relevant conflicts of interest? ☑ Yes ☐ No

If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Edwards Life Sciences, Inc.	☑	☐	☐	☐	

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? ☐ Yes ☑ No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☑ No

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 5. Relationships not covered above

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Dr. Dreger reports grants from Edwards Life Sciences, Inc., during the conduct of the study; .

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Herko
2. Surname (Last Name): Grubitzsch
3. Date: 12-December-2019

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Karl Stangl

5. Manuscript Title
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Are there any relevant conflicts of interest? ☐ Yes ☑ No

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Dr. Grubitzsch has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Isabel
2. Surname (Last Name): Mattig
3. Date: 12-December-2019

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Karl Stangl

5. Manuscript Title: Treatment of Severe TRIcuspid Regurgitation in Patients with Advanced Heart Failure with CAval Vein Implantation of the Edwards Sapien XT VALve (TRICAVAL): a controlled prospective randomized trial

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Edwards Life Sciences, Inc.	☑	☐	☐	☐	
Deutsche Herzstiftung	☑	☐	☐	☐	Kaltenbach scholarship

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? ☐ Yes ☑ No

Section 4. Intellectual Property -- Patents & Copyrights

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Karl
2. Surname (Last Name): Stangl
3. Date: 12-December-2019

4. Are you the corresponding author? ☑ Yes ☐ No

5. Manuscript Title
Treatment of Severe TRIcuspid Regurgitation in Patients with Advanced Heart Failure with CAval Vein Implantation of the Edwards Sapien XT VALve (TRICAVAL): a controlled prospective randomized trial

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Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Edwards Life Sciences, Inc.	☑	☐	☐	☐	

Section 3. Relevant financial activities outside the submitted work.

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Abbott	☐	☑	☐	☐	speaker and proctoring fees
Edwards LifeSciences	☐	☑	☐	☐	speaker and proctoring fees
Medtronic	☐	☑	☐	☐	speaker and proctoring fees

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Martin
2. Surname (Last Name): Thoenes
3. Date: 12-December-2019

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Karl Stangl

5. Manuscript Title
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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Robert
2. Surname (Last Name): Roehle
3. Date: 12-December-2019

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Karl Stangl

5. Manuscript Title: Treatment of Severe TRIcuspid Regurgitation in Patients with Advanced Heart Failure with CAval Vein Implantation of the Edwards Sapien XT VALve (TRICAVAL): a controlled prospective randomized trial

6. Manuscript Identifying Number (if you know it)

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Are there any relevant conflicts of interest? ☑ Yes ☐ No

If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Edwards Life Sciences, Inc.	☑	☐	☐	☐	

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? ☐ Yes ☑ No

Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Roehle reports grants from Edwards Life Sciences, Inc., during the conduct of the study; .

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1. Identifying information.

2. The work under consideration for publication.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

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1. Given Name (First Name): Gert
2. Surname (Last Name): Baumann
3. Date: 12-December-2019

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Karl Stangl

5. Manuscript Title
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Section 1. Identifying Information

1. Given Name (First Name): Christoph
2. Surname (Last Name): Schöbel
3. Date: 12-December-2019

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Karl Stangl

5. Manuscript Title: Treatment of Severe TRIcuspid Regurgitation in Patients with Advanced Heart Failure with CAval Vein Implantation of the Edwards Sapien XT VALve (TRICAVAL): a controlled prospective randomized trial

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Dr. Schöbel has nothing to disclose.

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