Received: 5 February 2020 | Revised: 13 June 2020 | Accepted: 17 June 2020

DOI: 10.1111/aor.13760

MAIN TEXT ARTICLE

Artificial Organs WILEY

Extracorporeal life support system during cardiovascular procedures: Insights from the German Lifebridge registry

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Abstract

The frequency of mechanical circulatory support (MCS) device application has increased in recent years. Besides implantation in the emergency setting, such as circulatory arrest, MCS is also increasingly used electively to ensure hemodynamic stability in high-risk patients, for example, during percutaneous coronary interventions (PCI), valve interventions or off-pump coronary bypass surgery. Lifebridge (Zoll Medical GmbH, Germany) is a compact percutaneous MCS device widely used in daily clinical routine. The present study aimed to investigate the indications, feasibility, and outcomes after use of Lifebridge in cardiac interventions, evaluating a large-scale multicenter database. A total of 60 tertiary cardiovascular centers were questioned regarding application and short-term outcomes after the use of the Lifebridge system (n = 160 patients). Out of these 60 centers, eight consented to participate in the study (n = 39 patients), where detailed data were collected using standardized questionnaires. Demographic and clinical characteristics of the patient population, procedural as well as follow-up data were recorded and analyzed. In 60 interrogated centers, Lifebridge was used in 74% of emergency cases and 26% in the setting of planned interventions. The subcohort interrogated in detail displayed the same distribution of application scenarios, while the main cardiovascular procedure was high-risk PCI (82%). All patients were successfully weaned from the device and 92% (n = 36) of the patients studied in detail survived after 30 days. As assessed 30 days after insertion of the device, bleeding requiring red blood cell (RBC) transfusion constituted the main complication, occurring in 49% of cases. In our analysis of clinical data, the use of Lifebridge in cardiac intervention was shown to be feasible. Further prospective studies are warranted to identify patients who benefit from hemodynamic MCS support despite the increased rate of RBC transfusion due to challenges in access sites during cardiovascular procedures.

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Funding information
Maryna Masyuk received funding for hotel and travel by Zoll Medical GmbH to present the data at the annual Congress of the European Society of Cardiology in 2017. All other authors have not received any funding by Zoll Medical GmbH in the last three years or any funding related to the present study. Zoll Medical GmbH had no role in the design, data collection, interpretation of results, and the manuscript preparation of the study.

KEYWORDS
extracorporeal life support, high-risk, mechanical circulatory support, percutaneous coronary intervention

1 | INTRODUCTION

In recent years, the use of mechanical circulatory support (MCS) devices has continuously increased.[1] Although the main application field of percutaneous extracorporeal life support (ECLS) devices remains support in emergency settings, such as circulatory arrest, they can also be applied electively as hemodynamic support during procedures. Percutaneous coronary intervention (PCI) is an alternative to coronary artery bypass grafting (CABG) in patients with high perioperative risk due to multiple comorbidities or complex coronary artery anatomy and lesion patterns in combination with low left ventricular ejection fraction (LVEF). During those high-risk PCIs, ECLS devices are used as temporary support to ensure hemodynamic stability and therefore reduce peri-procedural complications.[2-4] Moreover, as off-pump CABG surgery has progressed in the last decades, the use of ECLS to overcome hemodynamic instabilities and reduce organ hypoperfusion during cardiac surgery has also increased.[5,6] Another application field is percutaneous valve interventions in patients at high risk of peri-interventional circulatory failure. Thus, patients with aortic stenosis undergoing transcatheter aortic valve implantation (TAVI) or balloon aortic valvuloplasty (BAV), who are at high risk of circulatory failure, for example, due to concomitant severe left ventricular dysfunction, have been shown to benefit from ECLS support in some single-center reports.[7-9] Also, combined procedures with ECLS support, such as high-risk PCI followed by BAV, have been described.[10]

Lifebridge (Zoll Medical GmbH, Germany) is a compact portable percutaneous ECLS device with a simple application technique due to its automated design.[3,11] The aim of the present study was to evaluate the indications, feasibility, safety, and outcome after elective use of ECLS Lifebridge in a retrospective multicenter all-comer cohort.

2 | PATIENTS AND METHODS

2.1 | Study population and data collection

Sixty tertiary cardiovascular centers using Lifebridge system between June 2006 and June 2014 with altogether 604 patients were questioned concerning application and short-term outcome. Out of 604 patients, 444 received hemodynamic support by Lifebridge in acute and 160 in elective setting. In the present work, 160 patients in elective setting have been further studied. The acute patients (n = 444) of the entire cohort were analyzed in another context before.[11] The median number of patients receiving Lifebridge support per year in all the centers was 4.9 [IQR 2.7; 8.1]. Per individual center, the median number of patients per year was 0.6 [IQR 0.25; 1.5], with a maximum of 9.6 and a minimum of 0.125 patients per year. All patients at age over 18 years receiving hemodynamic

support by Lifebridge device were included in the study. Subsequently, detailed data were collected by means of standardized questionnaires (case report forms, CRF; see Supporting Information) in all centers which consented to participation in the study. Eight tertiary cardiovascular centers from Germany with altogether 39 patients receiving Lifebridge support in elective settings participated in the detailed query. Demographic and clinical baseline characteristics of the patient population, procedural data concerning Lifebridge use as well as complications were recorded and analyzed retrospectively. Vascular injury was defined as bleeding requiring transfusion or percutaneous intervention or surgery. Acute renal failure was defined as an increase in serum creatinine by ≥0.3 mg/dL within 48 hours, or an increase in serum creatinine to ≥1.5 times baseline within 7 days, or a urine volume <0.5 mL/kg/h for 6 hours.[12] The study has been approved by the local ethics committee of the Düsseldorf University Hospital and, if required by specific local regulations, confirmed at the single study sites. The present study cohort included patients at high periprocedural risk with Lifebridge support, but without cardiogenic shock at the time of device insertion. The decision for the necessity of ECLS support to prevent circulatory deterioration was made at the discretion of the treating physician. The study flow is presented in Figure 1.

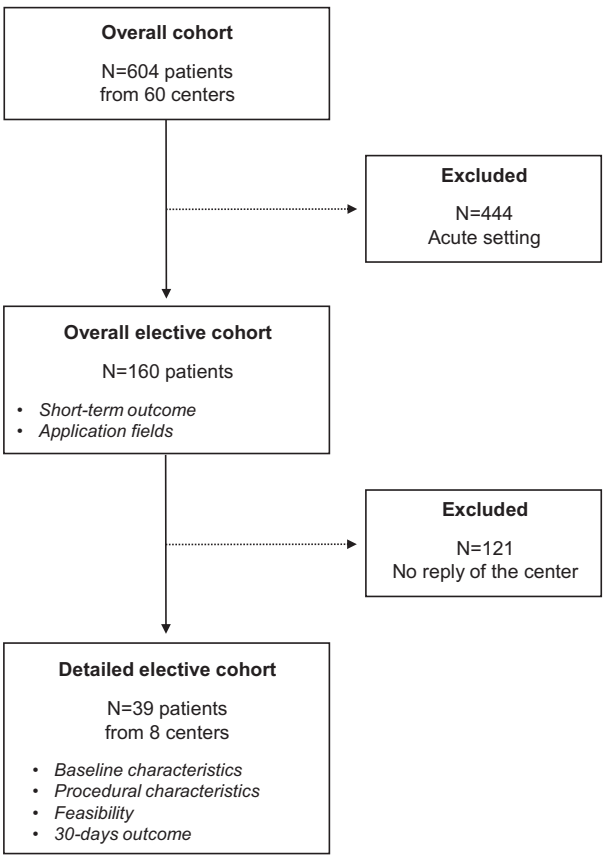

FIGURE 1 Flowchart of patient selection of patients supported with the Lifebridge device

2.2 | Device and procedure

Lifebridge is a compact and portable percutaneous MCS system with a relatively low weight of about 20 kg (Figure S1 in Supporting Information). It consists of different modules including a disposable patient module with cardiopulmonary bypass circuit, control module, base module with power supply, embedded computer, and a user interface. Another advantage is the automated design created for intuitive and easy application even for non-perfusionists. The implantation was performed via femoral access using a 15-17 Fr arterial cannula and a 17-21 Fr venous cannula.

2.3 | Feasibility score

Feasibility was assessed by CRF and graded as "easy," "suitable," or "difficult" by the survey participants.

2.4 | Statistical analysis

Categorical variables are expressed by numbers and percentages. For continuous variables, normally distributed data are expressed as mean ± standard deviation. Non-normally distributed data are presented as median with interquartile range. All variables were tested for normal distribution using Shapiro–Wilk test.

SPSS statistic software, version 22.0 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows. Armonk, NY, USA) was used for statistical analyses.

3 | RESULTS

Out of 604 patients in 60 tertiary cardiovascular centers, 74% (n = 444) were treated in emergency and 26% (n = 160) in the setting of planned interventions. The same distribution was present in detailed analyzed subcohort, including 151 patients from eight centers, with 112 patients (74%) treated in emergency setting and 39 patients (26%) with Lifebridge use during planned interventions. Thus, data of 39 patients were available for our detailed study of elective Lifebridge use. In both, overall and subcohort studied in detail, the main indication for planned Lifebridge use was high-risk PCI (81% in the overall and 82% in the detailed cohort), other indications were CABG or percutaneous valve interventions (Figure 2). Analogous to the indications, 82% (n = 32) of the implantations have been performed by interventional cardiologists

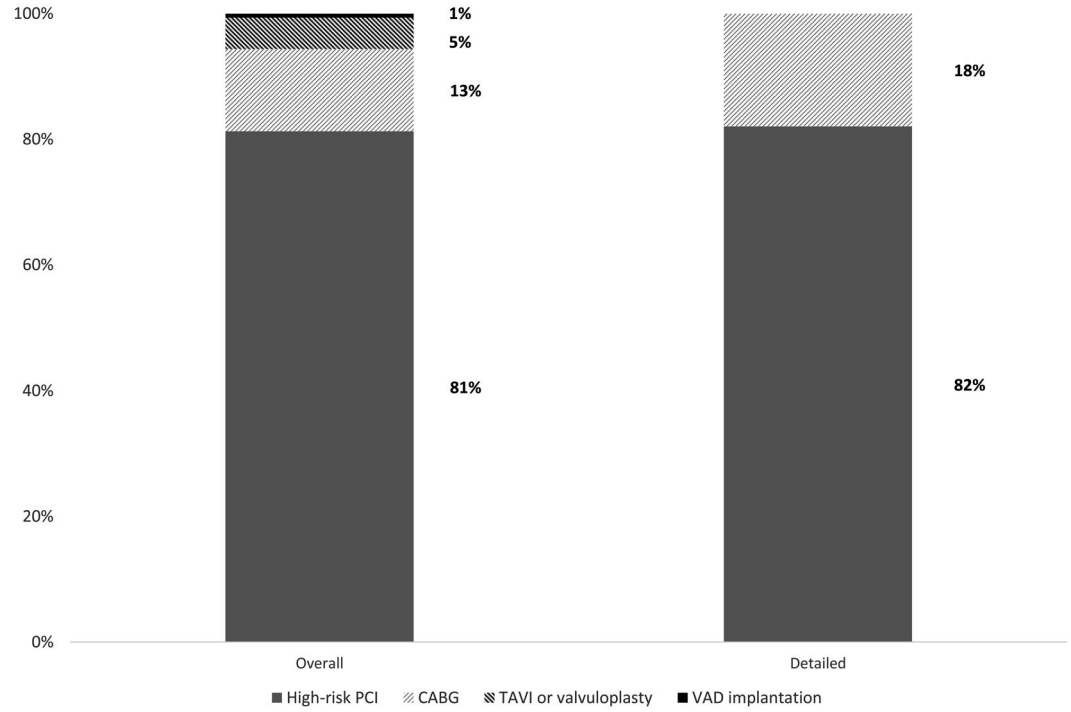

FIGURE 2 Indications for supportive Lifebridge use in the overall (n = 160) and detailed study cohort (n = 39). The main indication for planned Lifebridge use was high-risk percutaneous coronary interventions (PCI). Other indications were coronary artery bypass grafting (CABG), transcatheter aortic valve implantations (TAVI), and valvuloplasty or ventricular assist device (VAD) implantations

TABLE 1 Baseline characteristics of the patients receiving Lifebridge support during planned interventions in the detailed study cohort (n = 39)

	Detailed study cohort (n = 39)
Age (years)	70 [62-78]
Male	30 (77%)
Weight (kg)	80 [72-94]
Cardiovascular risk factors	
BMI (kg/m^2)	28 [25-31]
Hypertension	37 (95%)
Diabetes mellitus	18 (46%)
Hypercholesterolemia	21 (54%)
Current smoking status	10 (27%)
Preexisting comorbidities	
COPD	3 (8%)
Chronic renal insufficiency	10 (26%)
Atrial fibrillation	10 (26%)
Peripheral vascular disease	5 (13%)
Previous stroke/TIA	0 (0%)
Previous AMI	6 (16%)
AMI within previous 90 days	9 (25%)
Previous CABG	4 (10%)

Abbreviations: AMI, acute myocardial infarction; BMI, body mass index; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; TIA, transient ischemic attack.

TABLE 2 Functional parameters prior to Lifebridge initiation, procedural characteristics. Patients receiving mechanical circulatory support by Lifebridge during planned interventions initially displayed normal hemodynamic parameters, normal serum lactate levels, and only a mild reduction in left ventricular function. The feasibility of device implantation was graded by operators as easy or suitable in most cases

	Detailed study cohort (n = 39)
RR sys (mm Hg)	124 ± 26
RR diast (mm Hg)	64 ± 14
Heart rate (1/min)	67 [60-80]
EF (%)	46 [27-55]
Lactate initial (mmol/L)	1.0 [0.7-1.7]
Duration of support (h)	1.6 [1.2-2.1]
Feasibility easy/suitable	23 (96%)

Abbreviations: EF, ejection fraction; RR sys, systolic blood pressure; RR diast, diastolic blood pressure.

in the catheterization laboratory under angiographic control and 18% (n = 7) by cardiac surgeons in the operation theater. Baseline characteristics of the study population are presented in Table 1. The median age of the patients was 70 [IQR 62; 78] years and the majority of the patients were male (77%) and overweight with a median body mass index (BMI) of 28 [IQR 25; 31]. Furthermore, cardiovascular risk factors such

TABLE 3 Endpoints at 30-day follow-up. The requirement of red blood cell transfusion was the main complication after Lifebridge application, whereas hemolysis was absent in our study cohort

	Detailed study cohort (n = 39)
Transfusion required	19 (49%)
Renal failure	4 (12%)
Multi-organ failure	1 (3%)
Hemolysis	0 (0%)
Vascular injury	2 (6%)
Myocardial infarction	3 (8%)
Stroke	0 (0%)

as hypertension (95%), hypercholesterolemia (54%), or diabetes (46%) were found in most patients. Analysis of initial hemodynamic status revealed normal systolic blood pressure (mean 124 ± 26 mm Hg), heart rate (median 67 [IQR 60; 80]/min), and mild reduction in left ventricular function as assessed by ejection fraction (46 [IQR 27; 55] %). The median duration of hemodynamic support by Lifebridge was 1.6 [IQR 1.2; 2.1] hours and operators evaluated the feasibility of device implantation as easy or suitable in most cases (Table 2).

In the next step, we analyzed the outcome of the patients. Immediate survival after discontinuation of Lifebridge support was achieved in all patients in the large cohort (n = 160). After 30 days, the analysis of the subpopulation studied in detail revealed a survival rate of 92% (n = 36).

As shown in Table 3, the requirement of red blood cell (RBC) transfusion was the main complication (49%). Renal failure occurred in 12% of patients, vascular injury, as defined above, in 6%, and myocardial infarction in 8%. Hemolysis as a complication of ECLS device application was absent in our study cohort. All complications were assessed at 30 days after the intervention.

4 | DISCUSSION

The growing use of MCS devices in clinical practice has aroused interest in the research community. The main application field of these devices still remains the hemodynamic support during cardiogenic shock.[13-15] Further, advances in interventional therapies led to the establishment of PCI as an alternative revascularization approach to CABG in patients displaying high perioperative risk due to severe comorbidities, complex coronary artery disease and highly reduced LVEF.[16,17] In these and other high-risk interventions, ECLS devices are used electively to ensure hemodynamic stability.[8,18-21] The present multicenter study gives insight into clinical experience with a percutaneous ECLS system in unstable patients with still compensated circulatory situation to prevent further deterioration during planned cardiovascular procedures. The patient population in the present study did not display cardiogenic shock prior to initiation of hemodynamic support with Lifebridge device, in contrast to the main application field of MCS.

Considering the application fields in elective use of Lifebridge, our study cohort displayed the same application fields as described in the literature, protected high-risk PCI being the most frequent procedure, followed by CABG or valvular interventions.[2,6,8] The largest prospective randomized-controlled trial dealing with interventional ECLS use so far, is the PROTECT II trial published in 2012 by O'Neill and colleagues and analyzing Impella 2.5 versus intra-aortic balloon pump (IABP) in protected high-risk PCI. When comparing the study cohort in this trial, including 226 patients in the Impella 2.5 group, to our study population, it is notable that this trial has a severely reduced LVEF (23.4 ± 6.3% in the Impella and 24.1 ± 6.3% in the IABP group) as inclusion criterion, while in our study cohort the median LVEF was 46%.[19] However, a different registry study published by Baumann et al in 2018, with a total of 154 patients under Impella protection during high-risk PCI, reported a moderately/mildly reduced or even normal LVEF in the majority of patients, which is comparable to the LVEF in our study collective.[2] Two important retrospective registry studies, investigating interventional use of another ECLS device, Impella 2.5 (Abiomed, Danvers, MA, USA), are Europella and USpella, including 144 and 175 consecutive patients respectively.[22,23] After 30 days, the mortality rate was 5.5% in the Europella and 6.9% in the USpella collective, which is similar to the mortality rate of 8% in our study cohort. Another endpoint investigated in all three registries was myocardial infarction. Interestingly, in the Europella registry no infarctions occurred, while USpella investigators report a rate of 13.4% which is slightly higher than our results (8%).[22,23] Very recently, Flaherty et al could show in a prospective multi-center study that ECLS use during high-risk PCI protected the patients from acute kidney injury (AKI) after observing it in a retrospective single-center cohort two years earlier.[24,25] Here, the authors report a significantly reduced rate of AKI of only 4.9% as compared to the predicted rate of AKI according to Mehran score of 21.9%.[25] In our cohort protected by ECLS, the rate of renal failure, 12%, was slightly higher than in Flaherty's study, but still lower than the described unprotected rate. The main complication in our study cohort was bleeding requiring RBC transfusion, occurring in 49% of cases, which is considerably more frequent than in other prospective and retrospective cohorts described elsewhere.[26] Although anemia has been shown to be associated with adverse outcome in patients with acute coronary syndrome or patients undergoing PCI, numerous studies have demonstrated that RBC transfusion is independently associated with increased mortality and increased rate of major

adverse cardiac events (MACE) in these patients.[27-32] A meta-analysis by Kwok et al including more than two million patients from 19 studies has demonstrated blood transfusion as being independently associated with a threefold risk of mortality and MACE in patients undergoing PCI.[33] Interestingly, the mean prevalence of blood transfusions in this meta-analysis of a heterogeneous PCI collective was only 2.3%, whereas our cohort of MCS-protected interventions displayed a very high rate of 49%. Also, the results from the Europella cohort with a transfusion rate of 5.5% strongly deviate from the high rate in our study cohort.[22] However, the overall outcome when considering the 30-day survival was good with a survival rate of 92%. A systematic review published in 2017 and analyzing different works regarding Impella support in high-risk PCI has described 30-day mortality rates ranging from 3.7% to 10% in uncontrolled studies, which is comparable with the rate in our group. However, the authors point out that the heterogeneity of the outcome is a result of the heterogeneity of the patient collectives and inclusion criteria in different studies.[26]

The present study is mainly limited by its retrospective character resulting in a lack of information, for example, on the experience of the interventionalists. In addition, the decision to perform a protected procedure was completely on behalf of the treating physician without standardized criteria for definition of a high-risk procedure. Regarding the procedure itself, we cannot provide any specific information on the cannulae used in the different procedures, making statements to the flow produced by ECLS impossible. We thus cannot analyze whether the contribution of the ECLS to the cardiac output was sufficient for every single patient and cannot compare it to the outcomes. Another critical limitation, especially regarding the high transfusion rate in our study collective, is the lack of information on the threshold for RBC transfusion and absent predefined thresholds for the different centers. Here, the need for transfusion was set upon the treating physician's decision and is unfortunately not transparent in our retrospective study setting. Furthermore, we do not have any information on clinical signs or sites of bleeding requiring transfusion, hemoglobin levels prior to and after the procedure, or the priming technique of ECLS (crystalloid fluids vs. whole blood). Therefore, we cannot differentiate if transfusion was a reaction to decreased hemoglobin levels only due to a bleeding or additional effect caused by dilution. Similarly, we have only binary information on acute renal failure as complication, not on the exact creatinine levels or predicted rate of AKI according to the Mehran score. Moreover, the outcome and complications after Lifebridge use can only be considered and analyzed in comparison to other studies, as the retrospective design with a temporal distance between the event and data querying did not allow us to provide a matched control group without ECLS support during high-risk cardiovascular procedures. Another crucial limitation is the relatively low number of patients in the detailed study cohort (n = 39 patients). This is due to the low rate of centers consenting to participate in the detailed retrospective query. Although all the centers have been repeatedly approached, the participation in the present study was only driven by research interest of the single centers, resulting in eight centers providing detailed information. Thus, the baseline characteristics, hemodynamic status of the patients prior to Lifebridge use, feasibility of device implantation, and, most importantly, the outcome at 30-day follow-up were only available for 39 patients but not for the overall cohort of 160 patients. Therefore, we can only assume the transferability of these results to the entire elective cohort.

5 | CONCLUSIONS

In conclusion, the present study provides data from clinical experiences with a transportable automated ECLS system. Here we show that MCS using Lifebridge in cardiac interventions in unstable but compensated patients is feasible. However, the potential gain in hemodynamic support during interventional procedures has to be balanced against an increased rate of subsequent RBC transfusion due to challenges in access sites. Thus, further randomized studies are warranted to identify optimal candidates for MCS application during cardiac interventions.

AUTHOR CONTRIBUTIONS

Maryna Masyuk collected, analyzed, and interpreted the data, wrote the manuscript, and approved the final version to be published.

Peter Abel, Martin Hug, Assad Haneya, Stefan Sack, Konstantinos Sideris, Nicolas Langwieser, Tobias Graf, Georg Fuernau, Marcus Franz, and Stephan B. Felix substantially contributed to acquisition of data, revised the manuscript critically for important intellectual content, and approved the final version to be published.

Bernhard Wernly, Ralf Westenfeld, and Malte Kelm substantially contributed to the interpretation of data, revised the manuscript critically for important intellectual content, and approved the final version to be published.

Christian Jung substantially contributed to conception and design and the interpretation of data, revised the manuscript critically for important intellectual content, and approved the final version to be published.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the Supporting Information section.

How to cite this article: Masyuk M, Abel P, Hug M, et al. Extracorporeal life support system during cardiovascular procedures: Insights from the German Lifebridge registry. *Artif Organs*. 2020;00:1–8. https://doi.org/10.1111/aor.13760