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ORIGINAL ARTICLE

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Long-term survival and quality of life after extracorporeal life support: a 10-year report†

Daniele Camboni[a,*], Alois Philipp[a], Verena Rottenkolber[a], Matthaeus Zerdzitzki[a], Andreas Holzamer[a], Bernhard Floerchinger[a], Dirk Lunz[b], Thomas Mueller[c], Christof Schmid[a] and Claudius Diez[a]

[a] Department of Cardiothoracic Surgery, University Medical Center Regensburg, Regensburg, Germany
[b] Department of Anesthesiology, University Medical Center Regensburg, Regensburg, Germany
[c] Department of Internal Medicine II, University Medical Center Regensburg, Regensburg, Germany

* Corresponding author. Department of Cardiothoracic Surgery, University Medical Center Regensburg, Franz-Josef-Strauß-Allee 11, 93053 Regensburg, Germany. Tel: +49-941-9449801; fax: +49-941 9449802; e-mail: daniele.camboni@ukr.de (D. Camboni).

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Abstract

OBJECTIVES: Information is lacking about long-term survival and quality of life (QOL) after treating patients on extracorporeal life support.

METHODS: Outcome data were assessed by phone interviews, a QOL analysis using the EuroQol 5-dimensions questionnaire and a retrospective inquiry of the Regensburg ECMO Registry database for the decade 2006–2015. A statistical analysis was obtained by comparing patients with a cardiosurgical intervention (CS = 189 patients) with those without (w/oCS = 307 patients).

RESULTS: Survival to discharge in the w/oCS group was higher than that in the CS group (w/oCS: 41.7% vs CS: 29.5%; $P = 0.004$). A Kaplan–Meier analysis showed a significant difference between both groups in favour of patients w/oCS (log rank $P = 0.02$). This difference was no longer statistically significant after propensity score matching ($P = 0.07$). The 1- and 2-year survival rates of discharged patients were 67% and 50% in the w/oCS group vs 60% and 45% in the CS group (log rank $P = 0.29$). Eighty-two patients answered the QOL questionnaire after a mean follow-up time of 4.2 ± 2.9 years. A total of 75% could handle their daily life; 57% were not limited in their usual activities. Mobility impairment was noted in 50%; 25% returned to work or school. There were no differences in the EuroQol 5-dimension indices between the patient groups. However, compared to a normative age-matched population, significantly lower indices were calculated.

CONCLUSIONS: Long-term survival rates in patients requiring extracorporeal life support are acceptable with a probable advantage for patients without an operation and a narrowed QOL. The results are promising and encouraging, but there is also a need for improvement.

Keywords: Extracorporeal life support • Outcome • Quality-of-life

INTRODUCTION

Prompt initiation of circulatory assistance in patients with cardiogenic shock is an emerging field of interest in cardiac surgery and beyond. Several researchers clinicians have reported that extracorporeal life support (ECLS) may improve survival in patients who have cardiogenic shock or circulatory arrest, with survival to discharge rates ranging between 25% and 45% [1, 2]. The majority of studies of patients on ECLS focused on complication rates and short-term survival rates [3, 4]. Worldwide, the benchmark parameter is survival to discharge. Little information exists on the patient's fate after discharge with regard to long-term survival and quality of life (QOL). There are different ways to analyse QOL, which is considered to be the general well-being of an individual [5, 6]. The most frequently applied instruments to measure QOL in medicine are the Short-Form 36 Health Survey and the EuroQol 5-dimensions (EQ-5 D) questionnaire. The EQ-5 D test is a postal questionnaire for self-completion, easy to complete, applicable to everyone and not specific to a disease producing a single index value [7]. Thus, the EQ-5 D questionnaire was chosen as the appropriate measure for our purposes.

The aims of the study were as follows:

1. To measure short-term outcomes, including survival to discharge rates and causes of in-hospital deaths.
2. To measure long-term survival in patients on ECLS.
3. To measure QOL using the standardized EQ-5D instrument.
4. To explore possible differences in short- and long-term outcomes between patients undergoing cardiac procedures and patients not undergoing surgical procedures.

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Our hypothesis was that long-term survival would be impaired and QOL would be reduced in survivors of ECLS. To test our hypothesis, we evaluated all ECLS runs in our institution from 2006 to 2015.

METHODS

Indication for extracorporeal life support

A retrospective review of our prospective Regensburg ECMO database indicated that 496 patients required ECLS between January 2006 and December 2015. All patients requiring primarily venovenous extracorporeal membrane oxygenation were excluded.

No definite exclusion or inclusion criteria exist at our institution, because ECLS is initiated mainly on a case-by-case basis. ECLS is not implanted in patients who have had advanced basic life support (cardiopulmonary resuscitation) for less than 15 min known irreversible brain damage, known terminal malignancy, a traumatic injury with uncontrolled bleeding, unwitnessed circulatory arrest and an existing, credible declaration that the patient does not wish to receive life-prolonging measures such as mechanical circulatory assist devices. Age *per se* is not a contraindication at our institution.

The institutional ethical board approved this study (ethical board case number: 15-101-0051). The need for informed consent for the retrospective collection of anonymized demographic, physiological and hospital outcome data was waived. However, informed consent was obtained from survivors for the prospective long-term assessment of QOL.

ECLS management

ECLS was managed using a standardized protocol as previously described [8]. A more detailed description is provided as Supplementary Material. We made some modifications to our ECLS protocol during this 10-year period. The most important change was the routine implementation in 2011 of distal perfusion and close monitoring with near infrared spectroscopy to avoid limb ischaemia.

Outcome variables

The main outcome variables were survival to discharge, long-term survival and QOL parameters. To assess QOL, patients were contacted with an introductory letter. A trained assessor completed the modified EQ-5 D questionnaire by phone if needed. Complications included all types of ECLS-related complications (e.g. malperfusion, oxygenator failure, pump thrombosis, cannula displacement etc.).

The quality of life analysis

The questionnaire defines health in terms of 5 dimensions of life—mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension includes 3 levels from 'no', 'some' to 'severe problems', which result in 243 (3^5) combinations. Therefore, an evaluation model is required to describe the different states of health in a single QOL index value. The QOL of the best imaginable health state is represented as a constant factor (100). The instalments are deduced from a linear ordinary least squares regression. Because the independent variables are scaled as ordinal variables, dummy variables were used to code the responses 'no' and 'yes' as 0 and 1. The parameters are connected multiplicatively, and the dummy variable operates as an exponent. Last but not least, a regression equation is modified to connect the instalments for the second 'some problems' and third 'severe problems' answering levels. The questionnaire was modified by adding 5 more ECLS-related questions regarding the course after discharge. The questions were (i) return to work status; (ii) groin problems due to cannulation; (iii) hospitalizations due to cardiac or pulmonary problems; (iv) the occurrence of deep vein thrombosis and (v) the occurrence of a pulmonary embolism. Only patients who survived longer than 12 months after discharge were included into the analysis to reduce the impact of a long-term stay in the intensive care unit (ICU) (e.g. weakness, polyneuropathy).

Statistical analysis

Data were analysed with Stata 14.1 for Windows (StataCorp LP, College Station, TX, USA). Excel for Windows (Microsoft Corp. Redmond, WA, USA) was used for data collection and verification before import into Stata.

Continuous data were presented as mean plus standard deviation or 95% confidence interval (CI) of the mean if normally distributed, or as median and interquartile range (25th–75th percentile) for non-normally distributed data. Normality was formally tested with the Shapiro-Wilk test and graphically with quantile–quantile plots.

Categorical data were presented as frequencies and percentage.

Intergroup comparisons for normally distributed continuous data were done with the Student *t*-test and for non-normally distributed data with the rank sum test (Mann–Whitney). Categorical data in $n \times k$ contingency tables were analysed with the chi-square test (Pearson) and for 2×2 tables in addition with the Fisher's exact test. All tests were 2-sided. A P-value < 0.05 was considered statistically significant.

The average treatment effect in the population was estimated by propensity score matching using Stata's command *teffects psmatch* with 3 covariates (age, renal replacement therapy and cardiopulmonary resuscitation before initiation of ECLS) and overall mortality rate as outcome. The covariates body mass index, serum haemoglobin, serum Quick, epinephrine and norepinephrine before ECLS initiation could not be included in the propensity score estimation because of significant imbalance. Propensity scores were estimated by a logistic model. Propensity score matching (nearest neighbour with at least 1 match) was used to adjust for significant differences in baseline characteristics in patients who received ECLS with a cardiac surgical procedure (treatment group = CS) versus those who received ECLS without a cardiac surgical procedure (control group = w/oCS).

Balance after propensity score matching was checked using standardized differences, variance ratios and a box plot of raw data versus matched data with Stata's command *tebalance*.

A univariable logistic regression was used to identify independent risk factors for the binary outcome variable in-hospital-mortality.

Survival analysis was used to examine survival in patients with or without a cardiac surgical procedure. The Kaplan–Meier estimate was used to estimate the proportion of surviving patients, and survival curves were compared with the log rank test. Time to event was defined as the period between the start of extracorporeal support until the time of death or the follow-up interview. Only 1 patient was lost to follow-up due to a site of residence abroad. Since no information on the long-term outcome of this patient existed, he could only be included in the short-term outcome up to discharge.

For survival analysis after propensity score matching, all pairs with more than 1 match were eliminated from analysis. Only observations from the treatment group with 1 match in the control group were kept for subsequent survival estimation by Kaplan–Meier. In total, data from 69 pairs remained for analysis. Survival curves were compared by the log rank test.

RESULTS

Study population

During the study period from January 2006 until December 2015, a total of 496 patients in refractory cardiogenic shock received ECLS. The largest group of patients was placed on ECLS during cardiopulmonary resuscitation ($n = 176$ patients). The second largest group comprised patients who failed to come off bypass after a cardiac surgical procedure ($n = 97$ patients). The entire institutional ECLS population was divided in 2 large groups depending on their relationship to a cardiac surgical intervention during the same hospital admission. The division resulted in a group of 307 patients with no relationship to a cardiac surgical intervention (group w/oCS) and another group of 189 patients who were placed on ECLS in relation to a cardiac surgical intervention (group CS, type of surgery was provided as Supplementary Material, Table S1). There were significant differences between both groups. Patients who had CS were older (w/oCS = 56.2 ± 13.4 years; vs CS = 64.2 ± 11.4 years, $P < 0.001$), had a higher body mass index (w/oCS: 27.4 ± 5.4 kg/m^2, vs 28.5 ± 5.8 kg/m^2; $P = 0.03$) and lower doses of norepinephrine and epinephrine as well as lower haemoglobin levels in comparison to patients w/oCS prior to implantation (Table 1). Renal failure requiring renal replacement therapy was more frequent in the CS group; however, ECLS-assisted resuscitation was more frequent in the group w/oCS.

Short-term outcome

A total of 290 patients (58.5%) were successfully weaned from ECLS, of whom 107 (21.5%) died during the further hospital course, resulting in an overall survival to discharge of 36.9% (Fig. 1).

Patients w/oCS reached a survival to discharge of 41.7% compared to 29.5% in the CS group ($P = 0.004$). After propensity score matching, a statistically not significant survival benefit of patients w/oCS was demonstrated ($P = 0.21$). The incidence of ECLS-related complications was significantly higher in the w/oCS group (w/oCS 33.2% vs CS 19.6%; $P = 0.001$). In particular, bleeding that required more than 1 unit of red blood cells a day (6.1% vs 1.6%) and leg ischaemia (15.3% vs 8.5%; see also Supplementary Material, Table S2: *Location of Cannulation*) were more frequent in patients w/oCS (see also Supplementary Material, Table S3: *Distal Perfusion)*. The propensity score adjustment related to the preceding parameters (age, renal replacement therapy and ECLS-assisted cardiopulmonary resuscitation) resulted in significantly fewer complications in the CS group ($P = 0.006$). The causes of death were significantly different between both groups (Table 2). A subgroup of 32 patients was bridged by ECLS to other types of circulatory support like a left ventricular assist device or a biventricular assist device, reaching a survival to discharge of 50%.

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Regression analysis for in-hospital deaths

Most of the available parameters were analysed to determine the odds ratios (OR) for in-hospital deaths. CS was a significant risk factor for in-hospital death with an OR of 1.74 (95% CI: 1.182–2.566; $P = 0.005$). Age and renal failure requiring renal preplacement therapy were also significant risk factors for in-hospital death (OR 1.01; 95% CI: 1.001–1.029; $P = 0.03$, respectively; OR:

Table 1: Preimplantation data

	w/oCS (n = 307 patients)	95% CI	CS (n = 189 patients)	95% CI	P-value
Age (years)	56.2	54.7–57.7	64.7	63.0–66.3	**0.001**
BMI (kg/m^2)	27.4	26.8–28.0	28.5	27.4–29.4	**0.03**
SOFA score	11.9	11.4–12.2	12.4	11.8–13.0	0.13
Lactate (mg/dl)	89	82–96	82	73–90	0.20
Norepinephrine (µg/kg/min)	0.68	0.58–0.80	0.30	0.25–0.34	**0.001**
Epinephrine (µg/kg/min)	0.31	0.26–0.36	0.22	0.18–0.26	0.02
MAP (mmHg)	54	52–56	56	53–58	0.39
Haemoglobin (g/dl)	10.9	10.6–11.2	9.3	9.0–9.6	**0.001**
Prothrombin time (Quick %)	56.4	53.4–59.3	62.5	58.9–66.0	**0.01**
LDH (U/l)	1037	806–1267	950	625–1274	0.65
GOT/ASAT (U/l)	762	514–1010	693	373–1014	0.75
CRP (mg/l)	63	53–73	78	64–93	0.08
Thrombocytes (/nl)	190	179–201	198	181–215	0.39
ECPR	129	42%	47	24%	**0.001**
Dialysis prior to ECLS	57	19%	51	27%	**0.02**
Ventilation time prior to ECLS (h)	45	20-63	28	22–55	0.34

Statistically significant P-values are reported in bold.
w/oCS: without cardiac surgery; CI: confidence interval; CS: with cardiac surgery; BMI: body mass index; SOFA: sepsis-related organ failure assessment; MAP: mean arterial pressure; LDH: lactate dehydrogenase; GOT/ASAT: aspartate transaminase; CRP: C-reactive protein; ECLS: extracorporeal life support; ECPR: ECLS-assisted cardiopulmonary resuscitation.

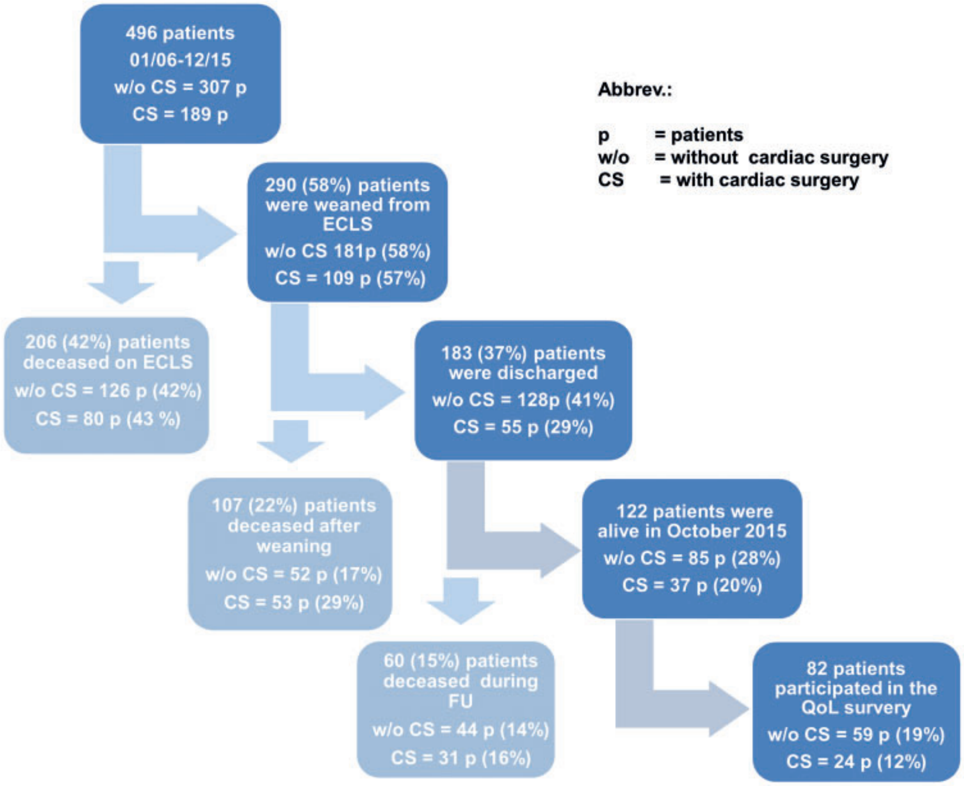

Figure 1: Patient flow.

Table 2: Causes of death

(Index admission)	w/oCS (*n* = 307 patients)		CS (*n* = 189 patients)		*P*-value
	%[a]	*n*	%	*n*	
Cerebral	21.8	67	8.9	17	**<0.001**
Bleeding	5.2	16	2.1	4	**0.066**
Persisting LOC	8.8	27	28.5	54	**<0.001**
MOF	12.7	39	22.2	42	**0.008**
Sepsis	4.9	15	5.8	11	0.403
No prognosis	3.6	11	2.6	5	0.381
Intestinal ischaemia	1.3	4	0.5	1	0.367
Respiratory insufficiency	0.7	2	1.1	2	0.494

Statistically significant *P*-values are reported in bold.
w/oCS: without cardiac surgery; CS: with cardiac surgery LOC: low cardiac output; MOF: multiorgan failure.
[a]Percentage from group w/oCS or CS.

1.93; 95% CI: 1.192–3.140; *P* = 007). All other factors are listed in Table 3.

Long-term outcome

The Kaplan–Meier analysis yielded a significant difference between both groups in favour of patients w/oCS (log rank *P* = 0.02; Fig. 2). After propensity score matching, a statistically not significant survival difference between both groups in favour of those w/oCS was calculated (*P* = 0.07). One-to-one propensity score matching resulted in 69 matched pairs, demonstrating a trend

Table 3: Regression analysis for in-hospital deaths

	Odds ratio	Standard error	*P*-value	95% CI
Group CS	1.74	0.344	**0.005**	1.182–2.556
Complication[a]	1.31	0.278	0.194	0.869–1.991
Pre-ECLS lactate	1.01	0.002	**0.001**	1.006–1.014
Pre-ECLS haemoglobin	0.91	0.038	**0.022**	0.839–0.998
Female gender	0.90	0.189	0.628	0.599–1.362
Age	1.01	0.007	**0.030**	1.001–1.029
BMI	1.05	0.205	**0.003**	1.019–1.099
SOFA Score	1.14	0.43	**0.001**	1.058–1.229
Renal failure[b] prior to ECLS	1.93	0.47	**0.007**	1.192–3.140
Reanimation prior to ECLS/ECPR	1.12	0.23	0.574	0.746–1.169
FiO_2 prior to ECLS	2.16	0.94	0.077	0.920–5.079

Statistically significant *P*-values are reported in bold.
Group CS: group who had cardiac surgery; BMI: body mass index; SOFA: sequential organ failure; FiO_2: fraction of inspired oxygen; CI: confidence interval.
[a]Complication is any kind of ECLS-related complication during the ECLS run.
[b]Renal failure prior ECLS is any kind of renal failure requiring renal replacement therapy.

towards better survival in the group w/oCS (*P* = 0.10; Fig. 3). The Kaplan–Meier calculation including only patients who survived until discharge found no differences between the 2 groups (log rank *P* = 0.29). The mean follow-up time was 983 ± 682 days (interquartile range 252–1478 days). One patient was lost to follow-up; thus the follow-up was 99% complete. Patients who died during follow-up (mean age, 59.7 ± 12.1 years) were slightly

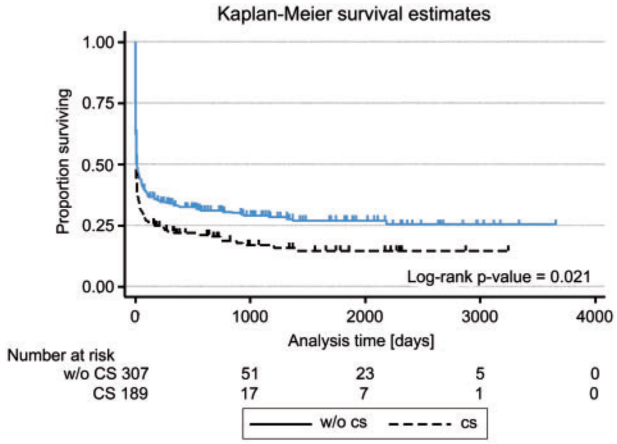

Figure 2: Kaplan–Meier estimation of survival over the entire observation time.

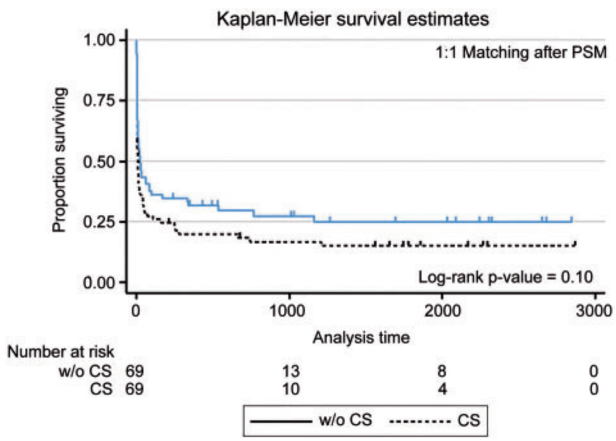

Figure 3: Corrected Kaplan–Meier estimation after one-to-one propensity score matching.

but not significantly older at the time of implantation compared to survivors (mean age 56.8 ± 14.1 years, $P = 0.29$). The 1- and 2-year survival rates of discharged patients were 67% and 50% in the group w/oCS vs 60% and 45% in the group with CS.

Quality of life analysis

On October 15 2015, 122 patients were alive after discharge. A group of 15 patients had a survival shorter than 12 months. Hence, this group of patients was not eligible for the QOL analysis. The 107 patients who were eligible for a QOL analysis were contacted by mail and phone. Twenty-five patients were excluded because they did not give their consent to participate in this study. Four of them were in a nursing home due to neurological impairments, leaving 82 patients who participated in the QOL analysis. The demographic data of this population are displayed in Table 4. The detailed results are shown in Fig. 4. Briefly, nearly 50% of the patient cohort had no mobility impairments; 75% could handle self-care by themselves; and 57% had no problems with usual activities such as household chores or buying groceries. Sixty percent of the interviewed cohort said they did not have signs of anxiety, depression or pain. One quarter of the population returned to work or school; 50% were older than 60 years and retired. Groin problems were present in 21% of the population. Interestingly, 70% of the population with a groin

Table 4: Demographics of the survey population

Total survey population (patients)	108
Denied participation (patients)	25
Returned surveys (patients)	82
Patients w/oCS	59
Patients with CS	24
Mean age @ survey (years)	59 ± 17
Gender male (%)	54 (65)
Mean age @ implant (years)	56 ± 17
Mean support time (days)	4 ± 4
Mean follow-up (days)	1598 ± 1393
Min–max follow-up (days)	449–3897

CS: with cardiac surgery; w/o: without; min–max: minimum–maximum.

problem after discharge had a surgical cannula placement or replacement. The EQ-5 D indices of patients w/oCS and with CS during the index admission were similar (w/oCS = 69; 95% CI 62–77; vs CS = 63; 95% CI 49–77; $P = 0.64$). The mean EQ-5 D index was significantly lower compared to that of a non-ECLS age-matched control population (EQ-5-D index of the study population 67; 95% CI 61–74 vs 88; $P < 0.001$) [9].

DISCUSSION

To our knowledge, this study is the first large-scale analysis of long-term outcomes in patients requiring ECLS due to a cardiogenic shock that includes a QOL analysis. We describe a 10-year, single-institution experience that includes all types of cardiogenic shock (also called an all-comers study). This factor is important, because most long-term studies thus far have analysed just one type of cardiogenic shock and comprised smaller cohorts [10–12]. However, in daily practice, all patients, regardless of the type of cardiogenic shock, are considered possible candidates for ECLS. This policy is reflected by this study. The overall survival to discharge was 37%. This value is comparable to those in the literature on outcomes with ECLS. The most important all-comers registry is the international ELSO registry, with more than 20 000 registered cases of adults on ECLS. The registry contains the entire ECLS population including all indications reaching a survival to discharge of 41%, and adult patients requiring ECLS supported resuscitation with a survival to discharge of 29% [13].

The entire study population was divided into 2 groups according to whether the patient had a cardiac surgical intervention during the same hospital admission or not. This division was made because patients with a cardiac surgical intervention during the same hospital admission have to cope with possible negative effects of the surgical intervention (e.g. increased inflammatory status) and may have a persistent low cardiac output despite surgical correction, which reduces the chances for recovery [14, 15]. Thus, it is not surprising that the survival to discharge was different between patients who had a surgical intervention and patients who did not. Possible reasons underlying these differences in survival may be the older age of the surgical intervention group, paired with the negative impact of the intervention. Interestingly, the propensity score analysis adjusting for age, resuscitation and renal failure demonstrated only a trend towards a survival benefit with regards to hospital survival in patients without surgical intervention.

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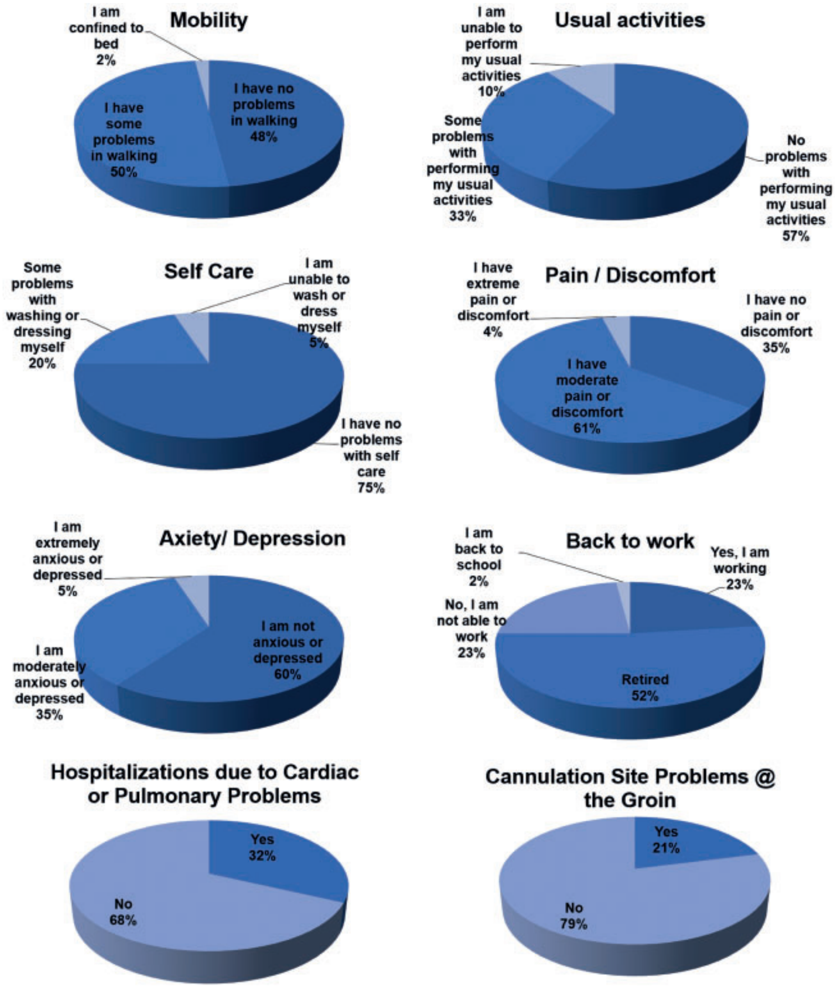

Figure 4: Quality-of-life diagrams.

On the other hand, it is surprising that the differences in hospital survival were not persistent in the long-term analysis. After propensity score matching, the statistically significant survival benefit was lost; however, a trend towards better survival rates in patients without CS was observed. The long-term survival analysis was confirmed by a one-to-one propensity score matched analysis with similar survival results between both groups. Last but not least, a Kaplan–Meier analysis of patients who survived to discharge displayed similar survival estimations between both groups.

According to the World Health Organization, QOL refers to an individual's own perceptions of his or her life in the context of the culture and of the value systems to which they are exposed [16]. In the past, medical treatment such as ECLS emphasized prognosis and survival of the patient or complications of a certain therapy. However, it is also necessary to determine whether patients can return to their previous lifestyle [17].

The literature contains only a few studies on QOL after ECLS. Of the patients surviving to discharge, 25% were able to return to work or school. However, it has to be taken into account that 50% were already retired and older than 60 years. A comparison of the EQ-5 D indices with those of a healthy normative age-matched German population revealed significantly lower EQ-5 D indices [9]. Lower QOL indices in comparison to a matched normative population were also seen in a smaller population by Muller *et al.* from Paris [4]. The study followed 81 patients in cardiogenic shock who were treated with ECLS. QOL was measured using the Short Form 36 Questionnaire in 34 survivors. Studies on QOL of patients with critical illnesses also describe scores for survivors that are lower than the norm [18, 19]. Other research has shown that some factors are predictive for QOL following discharge from the ICU, such as severity of illness, restrictions to mobility and depression [20]. Thus, evaluating the health status of ECLS survivors is a difficult, complex process. Different factors impact QOL, including the underlying disease, ECLS and associated complications as well as a prolonged stay in the ICU.

Due to the scarcity of QOL studies with regard to ECLS, it is also feasible to look at patients surviving a severe lung failure who require extracorporeal support. Reduced QOL indices in this population were also found to be similar to those of ECLS patients [21, 22]. The similarities between ECLS and respiratory ECMO survivors underline the multifactorial causes of the impaired QOL. One important factor seems to be the critical illness itself [23].

The study strengths include the large population and its longitudinal design covering a 10-year period. However, the study also has some limitations. First, QOL was not evaluated before the onset of the critical disease. The survivors' impaired QOL could reflect pre-existing health status and not be linked to ECLS. However, it is impossible to survey the QOL before ECLS. Second, QOL was only evaluated once after ECLS. The results can be misleading because some parts of the QOL evaluation (e.g. pain perception) change daily.

Third, as mentioned previously, the survivors' persistently poor physical health and vitality might be the consequence of a prolonged stay in the ICU (e.g. critical illness, muscle wasting and weakness) or of ongoing chronic morbidity. Additional tests to discriminate between ECLS and length of stay in the ICU were not applied due to the lack of adequate tests.

Fourth, death after discharge altered the evaluation of QOL. A significant number of patients refused to or could not participate. Delay between discharge and QOL assessment varied from one patient to another.

SUMMARY

Patients in cardiogenic shock or cardiac arrest requiring ECLS have a 30–40% rate of survival to discharge depending on the underlying cause. A cardiac surgical intervention seems to attenuate the short-time survival. Long-term survival on the other hand seems to be affected to a lesser degree. QOL seems to be reasonable but narrowed with a return to work rate of 25% in patients reaching survival to discharge.

CONCLUSION

Long-term survival rates in patients requiring ECLS are acceptable with a probable advantage for patients w/oCS and a narrowed QOL. Underlying factors remain unclear and are multifactorial. The results are promising and encouraging but there is also a need for improvement.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

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Conflict of interest: Claudius Diez works full time for MAQUET, Germany.

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