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Awake ECMO for COVID-19 Induced Acute Respiratory Distress Syndrome

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The outcome of COVID-19 patients treated on intensive care units (ICU) is unsatisfying (1). Veno-venous extracorporeal membrane oxygenation (vv-ECMO) can serve as a rescue strategy when patients deteriorate during invasive ventilation (2, 3). Utilizing extracorporeal membrane oxygenation (ECMO) in awake patients without endotracheal intubation (awake-ECMO) has shown satisfying results in immunocompromised patients or as a bridge-to-transplant strategy (4-6), but bears ECMO-specific risks such as bleeding and – specifically in awake patients - self-inflicted lung injury (p-SILI)(7). Reports on awake-ECMO for COVID-19 are currently limited to case reports (8, 9).

We report eighteen adult patients with real-time RT-PCR-confirmed SARS-CoV-2 infection and hypoxemic COVID-19-ARDS (CARDS) supported awake on vvECMO on four German tertiary care ICUs from 1st February to 30th April 2021. During the study period, a total of 248 COVID-19 patients were hospitalized on these wards. Seventy-nine of these (31.9%) were supported with non-invasive oxygenation strategies (non-invasive ventilation (NIV) or high-flow nasal oxygen therapy (HFNO). Eighty-six (34.7%) received invasive mechanical ventilation without vvECMO. In total, 83 of 248 patients (33.5%) eventually received vvECMO. Patients suitable for vvECMO were fulfilling ECMO eligibility criteria of the EOLIA trial (10), while patients with serious comorbidities (e.g. advanced cardiac, respiratory, or liver failure, metastatic cancer and hematological malignancies) or patients older than 65 years (exemptions were made according to biological age) were excluded. All ECMO patients were part of the prospective DIVI COVID ECMO registry. The Ethics Committee at Würzburg University Hospital (Ethik-Kommission der Universität Würzburg 131-20) in addition to local ethics committees in centers approved the study protocol. Informed consent was waived for the anonymous data analysis.

Eighteen of these patients qualified for awake-ECMO in the study period, since they were admitted awake, fully oriented and able to provide informed consent to the procedure during the study period (**Figure 1A**). Awake-ECMO patients were 55 ± 13 years, with a body mass index (BMI) of 30.1 ± 6.3 kg/m². Immediately prior to ECMO initiation, P_{aO_2}/F_{iO_2} ratio at a PEEP of ≥ 5 cmH₂O was 64.0 ± 7.3 mmHg. Awake patients had a high respiratory rate (median 28.3 ± 6.3 min⁻¹) and low recruitability prior to cannulation. All awake-ECMO patients continued non-invasive oxygen delivery via HFNO or NIV during ECMO treatment. Average demand on HFNO was 50 ± 9 L/min, average inspiratory oxygen fraction $75\pm 18\%$). Mean PEEP on mask or helmet non-invasive ventilation was 8.4 ± 1.9 cmH₂O, average pressure support 11.1 ± 5.0 cmH₂O and average inspiratory oxygen fraction on NIV 0.74 ± 0.17 . ECMO and ventilator support were adjusted at least every three hours according to blood gas analysis and patients' current respiratory effort. The following complications occurred in awake-ECMO patients: pulmonary superinfections (11/18, 61%), septic shock in 11/18 (61%), tension pneumothorax (3/18, 17%) and intracranial bleeding (1/18, 6%). Initially, all patients were devoid of sedatives and hence remained awake on participating wards. Patients were able to communicate with ICU personnel and able to express symptoms. Except for two patients who were able to stand and walk in the ICU, mobilization was limited within the bed or to the side of the bed in all other cases.

Importantly, 14 of 18 patients (78%) were intubated during intensive care therapy. Main reasons for switching from awake- to IMV-ECMO were delirium, patients' explicit wish to be sedated, tension pneumothorax with compromised airway, major bleeding or failure to oxygenate despite high ECMO blood flows. Awake-ECMO patients requiring delayed intubation had worse survival rates

compared to the overall cohort (9/14, 64% vs. 50% in the overall cohort), as intubation was performed mainly due to complications. Subgroup analysis revealed that patients in the awake-ECMO group who managed to avoid intubation had lower BMI (25.2 ± 2.4 vs 32.0 ± 6.4 kg/m², $p=0.005$) and were cannulated sooner following admission to ICU for respiratory failure (mean time from admission to cannulation 81 ± 21 hours vs. 192 ± 167 hours, $p=0.036$). Average time on awake-ECMO was 320 ± 252 hours.

Awake-ECMO patients were compared to a 1:1 propensity-score-matched control group receiving conventional management with vvECMO and IMV. Patients were matched according to ARDS severity (P_aO_2/F_iO_2 ratio at a PEEP of ≥ 5 cmH₂O), age, BMI and left ventricular ejection fraction on admission (**Table I**). We did not detect significant differences in the occurrence of complications between groups. Overall time on vv-ECMO (independent of awake or sedated) was very well comparable between the two groups (583 ± 478 hours for awake ECMO vs. 518 ± 392 hours for control, $p=0.66$). ICU mortality for both the awake ECMO group and the matched control group (9 of 18, $p=0.99$; **Figure 1B**) was 50% while the overall mortality of COVID-19 patients treated non-awake with vvECMO in the study period was 53.8%.

The main findings of this study are: i) a high rate of patients receiving awake-ECMO in COVID-19 was finally intubated, ii) those subsequently intubated seem to have a higher mortality compared to COVID patients managed conventionally with IMV and vvECMO.

Despite theoretical advantages of awake-ECMO with regard to gas exchange, respiratory effort and mobilization, endotracheal intubation could not be prevented in

most patients. Apart from acute complications (e.g. relevant bleeding or pneumothorax), bacterial superinfections, sepsis and disease progression finally led to respiratory exhaustion despite combined treatment with vvECMO and NIV.

Our study has limitations that need to be addressed: first, cohort size is relatively small, hence any conclusions on safety and complication rates of awake-ECMO for CARDS are uncertain. Second, we chose to compare the efficacy of awake-ECMO for COVID-19 to a cohort of patients being supported by both IMV and ECMO. Patients endotracheally intubated and managed without ECMO after failing noninvasive respiratory support might be in fact more suitable as a control group for awake-ECMO patients. However, a well-matched group might be difficult to define, as COVID-19 is a complex disease with variable clinical courses. Intubated and mechanically ventilated patients with COVID-19 that did not qualify for ECMO had a very high mortality rate (11).

In conclusion, the results so far don't favor an awake-ECMO approach for CARDS over conventional ECMO management, as most patients intubated after failing awake-ECMO appeared to have worse clinical outcome compared to the control group.

Thus, we cannot recommend an awake-ECMO approach for severe COVID-19 outside of clinical trials unless it were the explicit wish of the patient not to be intubated (9). Trials on the utilization and potential benefit of awake-ECMO will need to carefully identify patients suitable for an awake-ECMO approach and distinguish those patients with high chances to avoid IMV. Novel and additional strategies might be necessary to improve the success rate of awake-ECMO in CARDS patients.

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Table I – Basic characteristics, clinical course and outcome of study populations

Sex	Age [years]	BMI [kg/m ²]	P/F-Ratio [mmHg]	Time admission to cannulation / intubation [h]	Serum creatinine [mg/dl]	Leftventricular ejection fraction on admission	Comorbidities	Type of cannulation	Time on mechanical ventilation [h]	Time on vv-ECMO (h)	Secondary intubation?	Reason for intubation	Outcome/ Mortality	Cause of death	
Control cohort															
1	m	55	28	65	96	3.7	>60%	AHT; deep venous thrombosis	fem-jug	192	162		alive		
2	m	46	26	64	12	2.2	>60%	AHT; COPD; liver insufficiency; immunosuppression	fem-jug	148	120		alive		
3	m	61	27	74	12	0.5	>60%	AHT; S.P. sigma resection	DLC 31F	2040	1704		alive		
4	m	63	32	80	96	1.4	>60%	AHT; hyperuricemia	DLC 31F	1488	696		alive		
5	m	48	34	81	96	0.8	>60%	AHT	fem-fem / fem-fem-jug	1344	1200		dead	Septic shock	
6	m	53	42	76	72	1.0	>60%	AHT	fem-jug	432	264		alive		
7	m	39	23	69	12	1.0	>60%	AHT; DM Type II; S.P. astrocytoma	fem-jug	1032	408		dead	ICB	
8	m	69	35	80	120	1.1	>60%	Rheumatoid arthritis; AHT; DM Type II	fem-jug	816	576		dead	Ischemic colitis; DIC	
9	m	54	26	62	12	0.7	>60%		fem-jug	360	336		dead	MOF	
10	f	69	29	62	48	0.8	>60%	AHT; CKD	fem-jug	720	528		alive		
11	m	54	28	55	192	2.5	>60%		fem-jug	864	600		alive		
12	m	30	29	60	12	1.1	>60%		fem-jug	216	96		alive		
13	m	67	28	50	72	2.9	>60%	AHT; Atrial fibrillation; CKD	fem-jug	912	288		dead	MOF	
14	m	68	35	70	24	2.4	>60%	AHT; DM Type II	fem-jug	432	408		dead	MOF	
15	m	57	25	78	216	0.6	>60%	AHT	fem-jug	600	480		dead	MOF	
16	m	65	26	85	192	1.3	>60%	AHT; DM Type II	Fem-jug	648	336		alive		
17	m	56	31	63	336	0.9	>60%		fem-jug	672	660		dead	Septic shock	

18	m	61	33	55	12	4.0	>60%	COPD;	fem-jug	480	456		dead	MOF	
Σ	m	56.4 \pm 10.7	29.8 \pm 4.7	68.3 \pm 10.3	91 \pm 90	1.8 \pm 1.2	>60%		fem-jug (15) / DLC (2) / fem-fem (1)	744 \pm 492	518 \pm 392		50% (9/18)		
Awake cohort															
1	m	54	29	65	88	0.9	>60%	COPD;	fem-jug	144	240	yes	Hypox- emia	alive	
2	m	41	27	68	429	1.1	>60%	COPD; Rheumatoid arthritis; CKD;	fem-jug	192	600	yes	Hypox- emia	alive	
3	m	56	25	61	24	1.0	>60%		fem-jug	408	744	yes	Airway protect- ion	alive	
4	m	34	40	58	12	1.1	>60%	CKD; Epilepsy; Borderline personality disorder	fem-jug	768	816	yes	Patient's wish	dead	ICB / septic shock
5	m	62	44	71	48	0.9	>60%	AHT; DM Type II;	fem-jug	1176	1872	yes	Septic shock	Alive	
6	m	72	26	80	96	0.7	>60%	Coronary artery disease; Atrial fibrillation; AHT	DLC 31F	144	408	yes	Septic shock	alive	Septic shock
7	m	62	36	74	120	0.6	>60%	DM Type II	fem-jug	288	1008	yes	Septic shock	dead	Septic shock, bleeding
8	m	61	27	63	72	1.6	>60%		DLC 31F	0	96	no		alive	
9	f	18	32	65	264	0.7	>60%	AHT; DM Type II	fem-jug	576	840	yes	Patient's wish	dead	MOF
10	f	72	28	58	96	1.0	>60%	AHT	fem-jug	288	360	yes	Airway protection	dead	MOF
11	m	67	25	52	96	0.8	>60%	AHT; Rheumatoid arthritis	DLC 27F	0	216	no		alive	
12	m	60	26	54	408	1.5	>60%	COPD; DM Type II; CKD; AHT; VTE	DLC 27F	288	552	yes	Patient's wish	dead	MOF
13	m	67	35	61	456	1.3	>60%		fem-jug	984	1416	Yes	Airway protection	dead	Septic shock
14	m	51	28	61	24	0.7	>60%		Fem-jug	48	504	yes	Septic shock	dead	Septic shock
15	m	52	22	74	96	0.6	>60%	AHT	Fem-fem	0	120	no		alive	
16	m	54	40	63	336	0.8	>60%	AHT	fem-jug	120	144	yes	Septic shock	dead	MOF
17	m	52	24	65	48	1.0	>60%		fem-jug	0	144	no		alive	
18	m	55	28	57	192	0.8	>60%	Coronary artery disease; AHT; DM Type II	fem-jug	36	408	yes	Hypox- emia	dead	MOF

Σ	m	55.0 ± 13.4	30.1 ± 6.3	64.0 ± 7.3	161 ± 149	0.9 ± 0.3	>60%	Fem-jug (13) / DLC (4) / fem-fem (1)	390 ± 357	583 ± 478	yes (13/18) /no (5/18)	50% (9/18)
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Abbreviations: **AHT** = arterial hypertension / **BMI** = body mass index / **CKD** = chronic kidney disease / **COPD** = chronic obstructive pulmonary disease / **DIC** = Diffuse intravascular coagulation / **DLC** Double lumen cannula **DM** = diabetes mellitus / **f** = female / **F** = French / **fem-jug** = femoral-jugular / **fem-fem** = femoro-femoral / **ICB** = Intracerebral hemorrhage / **ICU** = intensive care Unit // **m** = male / **MOF** = Multiorgan failure / **P/F-Ratio** = arterial oxygen partial pressure to inspiratory oxygen fraction ratio / **S.P.** = status post / **vv-ECMO** = veno-venous ECMO

Figure Legend

Figure 1A: Consort Diagram of Patients included in the final analysis.

Figure 1B: Kaplan-Meier estimate of survival for patients with CARDS managed awake on ECMO or conventionally (including intubation and mechanical ventilation). Kaplan-Meier-functions were plotted with SPSS version 26.0.0.0 and survival between both groups was compared using log-rank test.

Declarations

Ethics approval and consent to participate

Informed consent for the initiation of ECMO or awake-ECMO as part of intensive care measures for severe COVID-19 was obtained by the patient or legal representative.

ECMO patients were included in a prospective registry study (that has been approved by the ethics committee of the University of Würzburg (Ethik-Kommission der Universität Würzburg 131-20), the institutional review board of the board of physicians of the Federal State of Hessen (Ethik-Kommission bei der Landesärztekammer Hessen 2020-2135-AF and 2020-1653-zvBO, for the sites Kassel and Offenbach, respectively), the institutional review board of the board of physicians of the Federal State of Saarland (Ethikkommission der Ärztekammer des Saarlandes 208/20) and the Ethical committee of Hannover Medical School (Ethikkommission der Medizinischen Hochschule Hannover 9411_BO_K_2020). Informed consent for the analysis of data was waived by the institutional review board due to the anonymous and retrospective analysis of data.

Consent for Publication

Not applicable

Availability of data and materials

Data can be provided on request addressed to the corresponding author. All data sharing statements are subject to conformity with German data protection legislation and rules (Datenschutzgrundverordnung - DGSVO).

Competing interests

R.B. received funding from AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Grifols, Novartis, CSL Behring, German Federal Ministry of Education and Research (BMBF) Competence Network, Sander Stiftung, Dr Rolf M. Schwiete Foundation, German Cancer

help (Krebshilfe) and Mukoviszidose e.V. All other authors have no conflicts of interest to declare.

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Author's Contribution

P.M.L., R.M.M., C.R. and S.M. drafted the study. C.R., H.M., P.M.L. and S.M. oversaw collection, review, and/or analysis of the data; C.R., P.M.L. and S.M. drafted the manuscript, H.M., R.N., C.L., D.G.-S., R.B., G.D., P.M., A.C., C.K., P.M.L. and R.M.M. revised the manuscript for important intellectual content. P.M.L. takes responsibility for the integrity of the work as a whole, from inception to published article. All authors have seen and approved the final version of the manuscript.

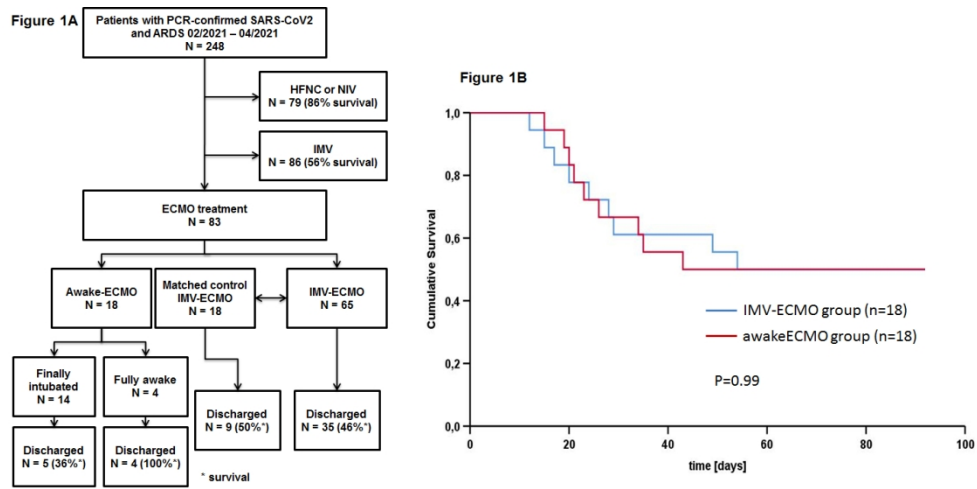


Figure 1A: Consort Diagram of Patients included in the final analysis.
 Figure 1B: Kaplan-Meier estimate of survival for patients with CARDS managed awake on ECMO or conventionally (including intubation and mechanical ventilation). Kaplan-Meier-functions were plotted with SPSS version 26.0.0.0 and survival between both groups was compared using log-rank test.

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