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First results of the COVID-19 patients treated with the Seraph® 100 Microbind® Affinity filter (COSA) registry

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Background: The COVID-19 pandemic has serious impact on health and economics worldwide. Despite the recent advent of SARS-Cov-2 vaccines, treatment options are needed, yet pharmacologic interventions remain limited. Several extracorporeal treatments are currently explored concerning their potential to improve the clinical course and outcome of critically ill patients with COVID-19. The Seraph® 100 Microbind® Affinity adsorber (Exthera Medical, CA, USA) has recently been introduced for the elimination of several pathogens from the blood and an emergency authorization in patients with COVID-19 was granted by the FDA. Bacteria, viruses (including the SARS-CoV-2 spike glycoprotein), fungi and toxins have been shown to bind to the immobilized heparin on the ultra-high molecular weight polyethylene beads of the device in a similar way to the interaction with heparan sulfate on the cell-surface and are thereby removed from the bloodstream. Here we report the interim analysis of the COVID-19 patients treated with the Seraph® 100 Microbind® Affinity filter (COSA) registry. The goal of the registry is to gather data regarding the safety and efficacy of the Seraph® 100 in the treatment of COVID-19 patients.

Patients and Methods: Participating sites were advised to insert patient data of COVID-19 patients, treated with the Seraph® 100, during their hospital stay into the COSA registry (ClinicalTrials.gov Identifier: NCT04361500). A total of 66 items were asked in a web-based platform.

Results: Until January 2021, 33 critically ill COVID-19 patients with 39 treatment sessions form six different hospitals were documented in the registry (seven female, median age 61 years, Table 1). The median time from the onset of symptoms to the Seraph® 100 treatment was 9 days, without any difference between survivors and

non-survivors. Overall, an in-hospital mortality of 27% was reported. Serious comorbidities (as preadmission immunosuppressive therapy, lung fibrosis or CKD5D) were reported in all of the non-survivors. Invasive mechanically ventilation was performed in 67% patients at the time Seraph® 100 treatment was initiated. A non-significant trend towards higher median ferritin levels in non-survivors (2000 (1963 – 8326) vs. 989 (644 - 2000), p=0.09) was found. All treatments were well tolerated. Three clotting events despite anticoagulation led to premature end of the treatment.

Discussion: Viral SARS-CoV-2 RNA is frequently (up to 78 %) seen in the blood of critically ill COVID-19 patients and correlates with the severity of the disease. The Seraph® 100 can bind to viral spike protein, proinflammatory cytokines may be reduced by the device and hemodynamic stabilization has been reported during the Seraph®100 treatment of COVID-19 patients. Platelets can be hyperactivated in association with SARS-CoV-2 proteins and thus presumably trigger the hypercoagulation and thrombosis. In this context several properties of the Seraph 100® seem to offer a pathophysiological benefit in the complex course of COVID-19. Overall the observed mortality in our cohort was lower than the predicted one. Moreover, respiratory deterioration and the need to intensify support from non-invasive ventilation to mechanical ventilation or ECMI therapy was decreased. All reported deaths were associated with serious preexisting comorbidities like immunosuppression, underlying chronic lung conditions, dialysis dependent renal failure, or a combination of these factors. Hence, Seraph® 100 treatment may be most beneficial in COVID-19 courses of patients without multi organ failure. More clinical data are needed to evaluate the possible benefits of the Seraph®100 and select the appropriate patient population and time point for this treatment in COVID-19 patients.

Table 1: Main characteristics of the treated patients. Results are given in No (%) or median (IQR).

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		Survivor N = 24 (73%)	Non-Survivor N = 9 (27%)	Total N = 33
DEMOGRAPHICS				
Median age	years	57 (51 - 68)	67 (54 – 70)	61 (54 – 68)
Female sex	No	4 (17%)	3 (33%)	7 (21%)
Caucasian race	No	18 (75%)	7 (78%)	25 (76%)
Height	cm	175 (174 – 179)	172 (170 – 180)	175 (172 – 179)
Weight	kg	91 (80 – 119.3)	88.5 (85.5 – 96)	90 (80 - 107)
Symptom onset - Seraph	days	9 (6 – 12)	10 (5 – 17)	9 (6 – 13)
Ferritin	ng/mL	989 (644 - 2000)	2000 (1963 – 8326)	1203 (830 – 2000)
Leucocyte count	1000/µL	10 (4.6 – 16)	12.7 (10.4 – 13.9)	11.3 (5.5 – 14.2)
d-dimer	mg/L	1.78 (1 – 3.3)	3.5 (1 – 11.7)	2.1 (1 – 3.9)
Dialysis dependency	No	7 (29%)	4 (44%)	11 (33%)
Bacterial superinfection	No	6 (25%)	6 (66%)	12 (36%)
SERAPH TREATMENT				
Blood flow	ml/min	200 (150 – 250)	225 (195 – 250)	200 (172 – 250)
Duration	hours	4 (4 – 5)	4.2 (3.9 – 10.5)	4.1 (4 – 5)
Citrate anticoagulation	No	3 (13%)	4 (44%)	7 (21%)
Stand-alone treatment	No	15 (63%)	1 (11%)	2 (6%)
Clotting events	No	3 (13%)	0 (0%)	3 (9%)