Conflict of interest

1) Research support: Fresenius Medical Care, ExThera Medical

2) Honoraria: Fresenius Medical Care, Menarini

3) Stock: Chemocentryx

Extracorporeal therapies in acute COVID-19

Jan T Kielstein

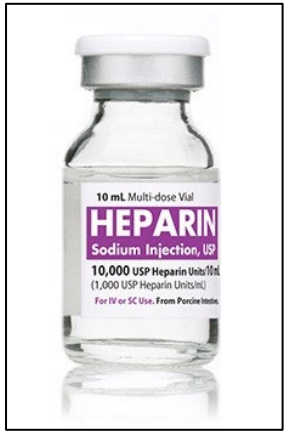
Nephrology | Rheumatology | Blood Purification

Academic Teaching Hospital Braunschweig

Hannover Medical School GERMANY

@JTKidney

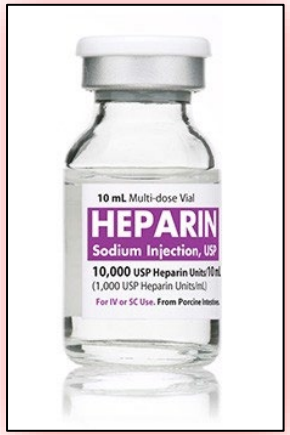
The magic bullet to treat SARS-CoV-2



https://de.wikipedia.org/wiki/Desmond_Llewelyn

Klinikum Braunschweig

The magic bullet to treat SARS-CoV-2



https://de.wikipedia.org/wiki/Desmond_Llewelyn

Klinikum Braunschweig

Extracorporeal treatments to:

1) Remove SARS-CoV-2

2) Replenish ADAMTS-13 / deliver antibodies

3) Fight the cytokine storm

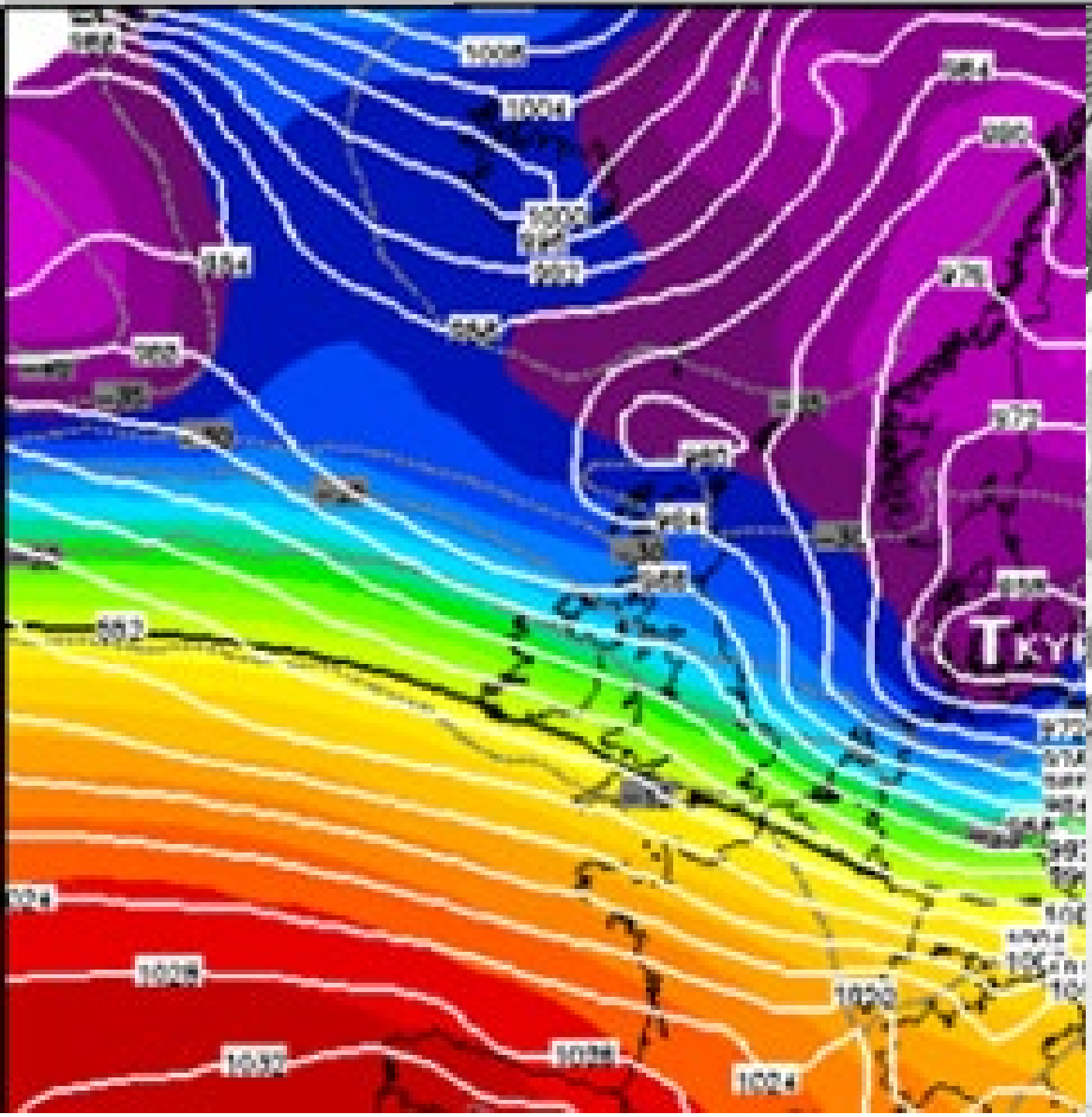
Klinikum Braunschweig

Extracorporeal therapies in acute COVID-19

1) **CytoSorb® - Hemoperfusion**

2) **Therapeutic Plasma Exchange**

3) **Seraph® 100 Microbind Affinity Blood Filter**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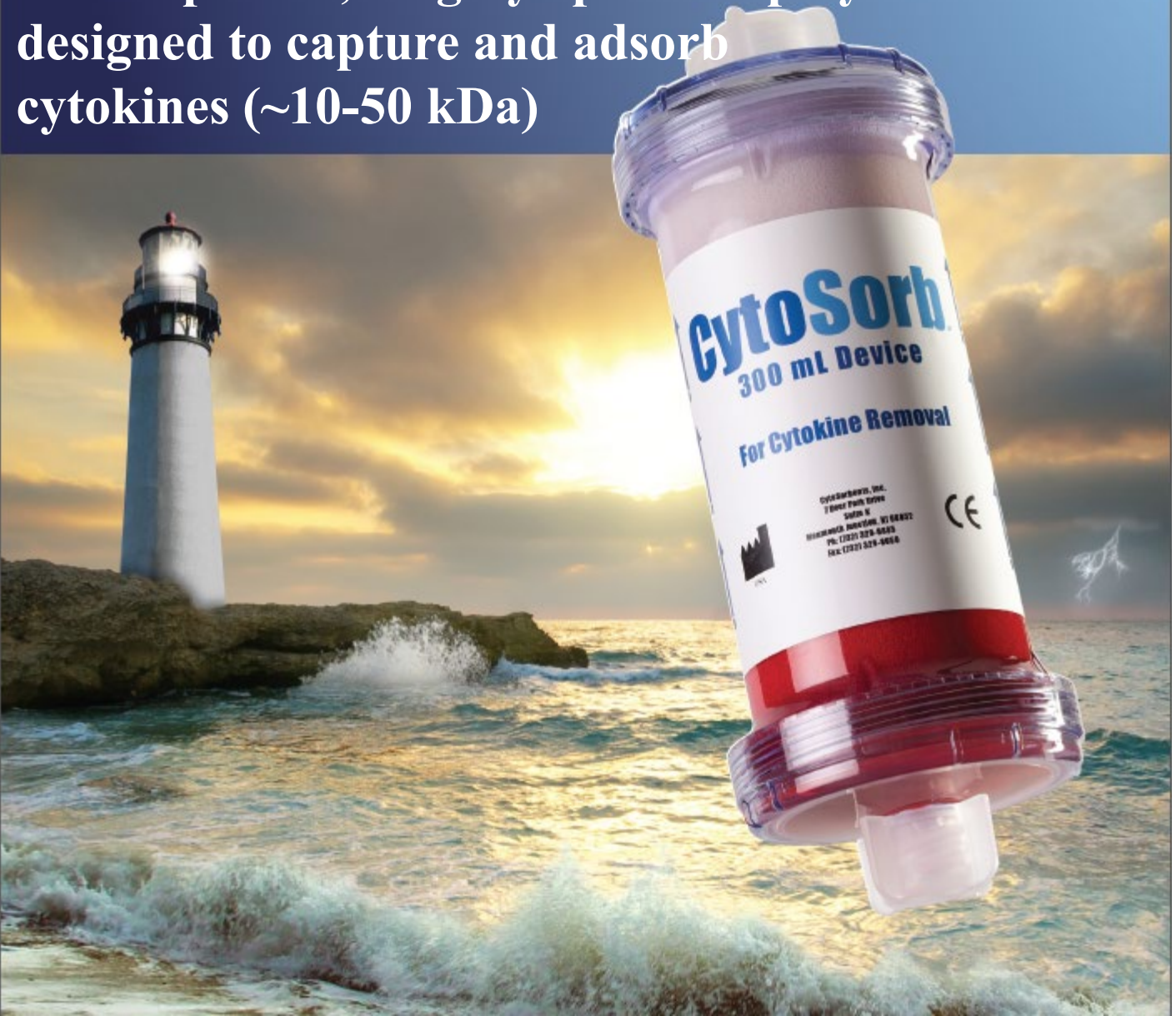
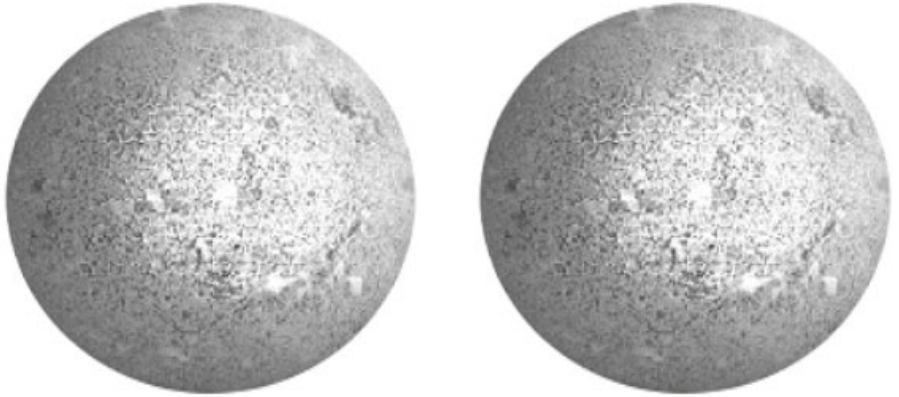
A powerful new weapon in the fight against Cytokine Storm

biocompatible, highly porous polymer bead designed to capture and adsorb cytokines (~10-50 kDa)





Cytokine	Molecular weight	% removal
IL-8	8 kDa	100%
IL-1ra	17 kDa	100%
IL-1α	17 kDa	100%
IL-10	18 kDa	85%
IL-6	26 kDa	87%
HMGB1	30 kDa	80%
TNF-α trimer	51 kDa	55%

Hemoperfusion with CytoSorb® in Critically Ill COVID-19 Patients (n=10)

	Patient									
	1	2	3	4	5	6	7	8	9	10
Sex	Male	Male	Male	Female	Female	Male	Male	Male	Male	Male
Age, years	59	77	50	58	85	76	68	73	66	65
Height, cm	154	170	170	158	155	170	170	172	175	172
Weight, kg	48	60	85	50	50	70	70	70	72	72
APACHE II pre-cytosorb, D0	21	22	14	24	23	17	28	27	35	24
SOFA pre-cytosorb, D0	11	11	3	12	6	15	14	15	16	11
CytoSorb columns, *n*	4	3	4	3	3	6	3	1	1	2
Treatment duration, h	78.5	42.5	75	44.5	53.5	92	36	12	12	24
Hours on ECMO	0	0	0	0	0	0	624	696	0	0
Days on IMV	23	15	0	6	0	25	27	31	8	7
Days on CRRT	2	1	4	1	0	6	27	31	8	6
ICU stay, days	30	33	5	6	15	15	35	32	5	16
Hospital stay, days	56	49	21	8	15	25	46	36	5	39
Coexisting chronic diseases										
Hypertension	N	N	N	N	Y	N	Y	Y	Y	Y
COPD	N	N	N	N	N	N	N	N	N	N
Diabetes	Y	N	N	N	N	N	N	Y	N	N
Myocardial infarction	N	N	N	Y	Y	Y	N	N	N	N
Cerebral infarction	Y	Y	Y	N	Y	N	N	Y	Y	N
Chronic renal dysfunction	N	N	Y	N	Y	N	N	N	N	Y
Steroid use	N	Y	N	Y	Y	N	N	N	N	Y
Outcome (ICU survival)	N	N	Y	Y	N	Y	Y	N	N	Y

ECMO, extracorporeal membrane oxygenator; IMV, invasive mechanic ventilation; N, no; Y, yes.

PENG et al.
Blood Purif 2021 Aug 18;1-7.

Klinikum Braunschweig

Hemoperfusion with CytoSorb® in Critically Ill COVID-19 Patients (n=10)

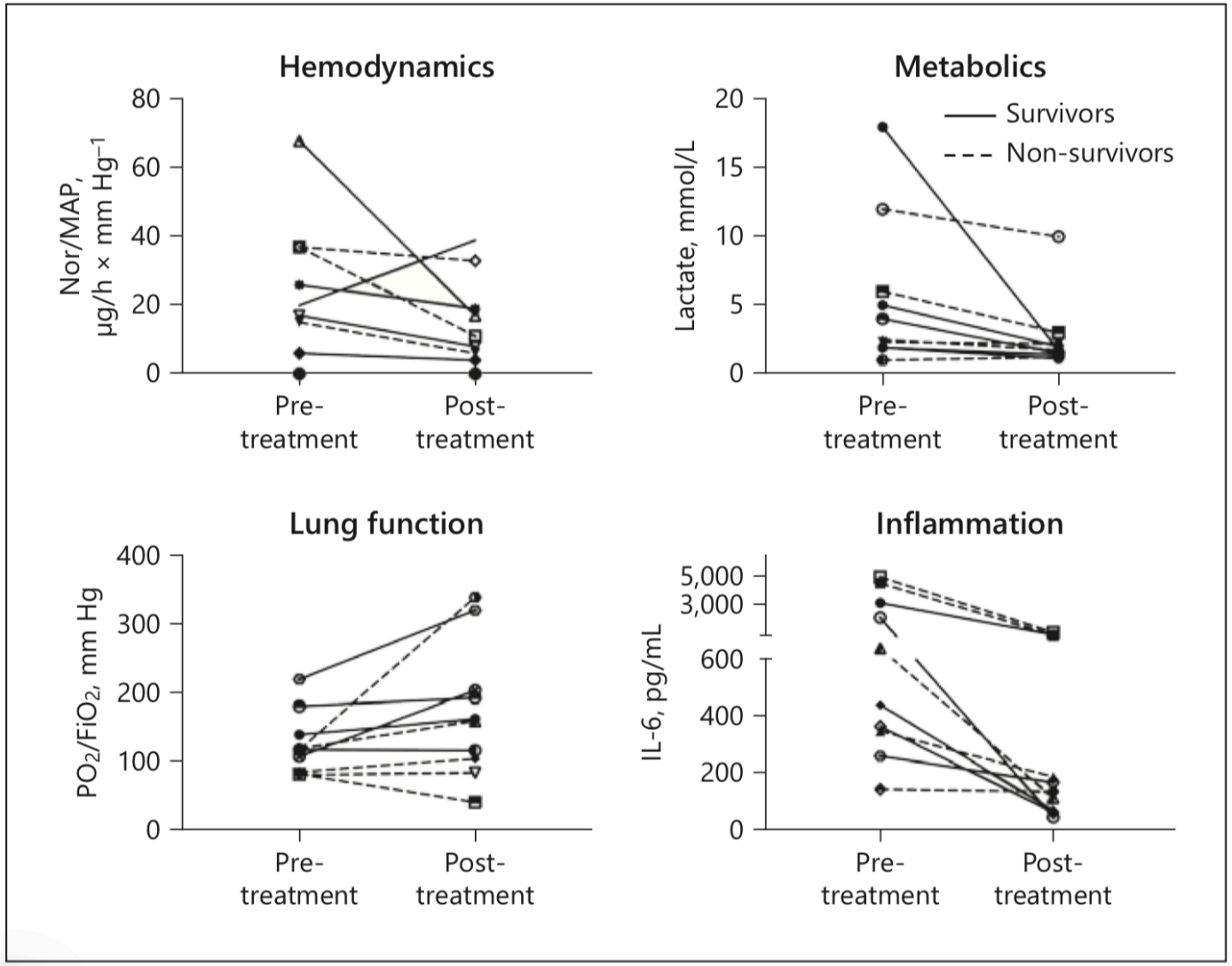
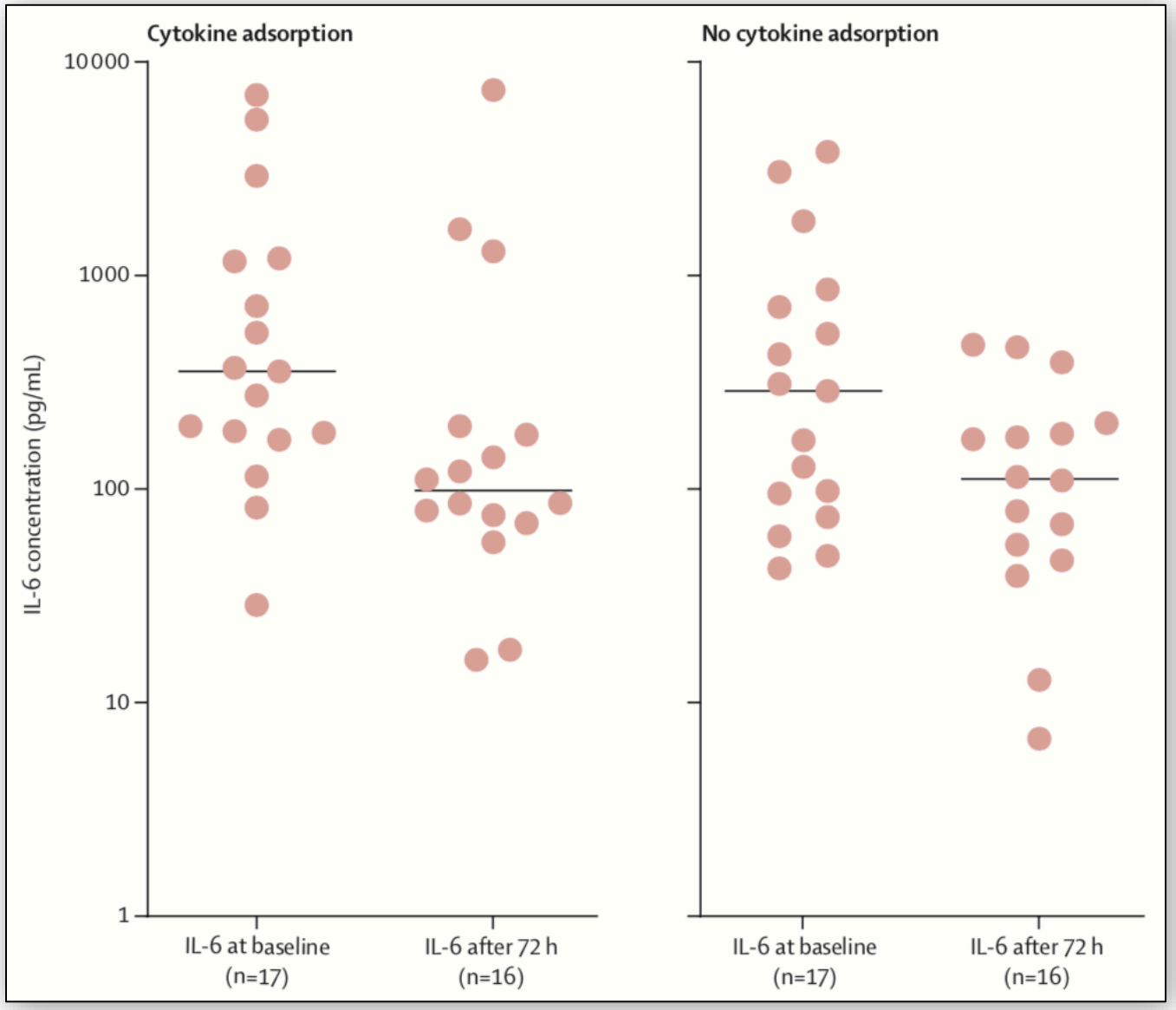


Fig. 1. The comparison of IL-6 and organ functions between pre- and post-treatments by CytoSorb. Nor, norepinephrine, Nor/MAP reflecting the hemodynamics; P/F, PaO_2/FiO_2, reflecting the severity of ARDS. $p = 0.09$ for Nor/MAP; $p = 0.005$ for IL-6; $p = 0.04$ for P/F, $p = 0.009$ for lactate.

PENG et al. *Blood Purif 2021 Aug 18;1-7.*

Klinikum Braunschweig

Cytokine adsorption in patients with severe COVID-19 pneumonia requiring ECMO (CYCOV): a single center, open-label, randomised, controlled trial (n=34)



SUPADY et al.
Lancet Respir Med 2021 May 14, 2021

Klinikum Braunschweig

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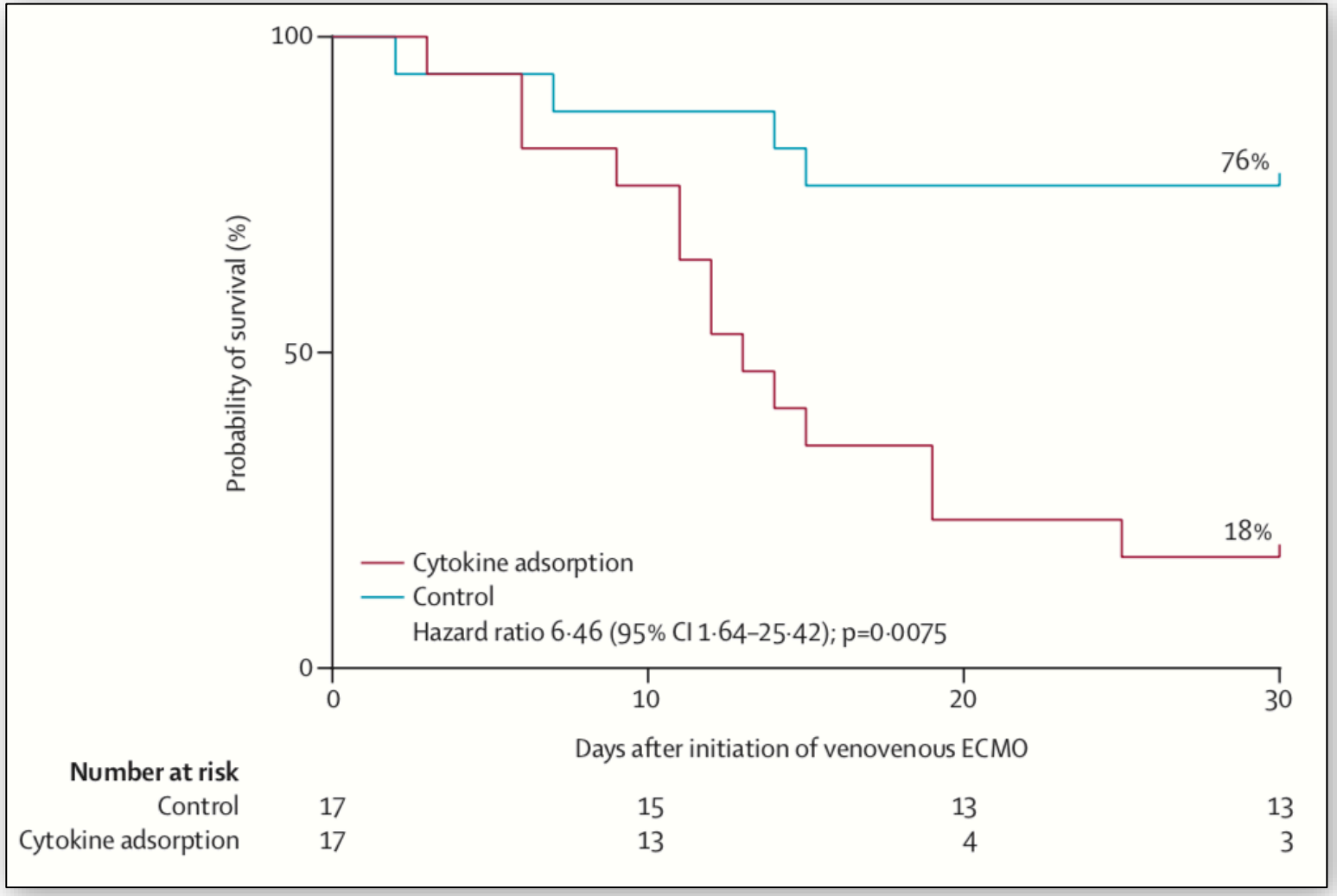
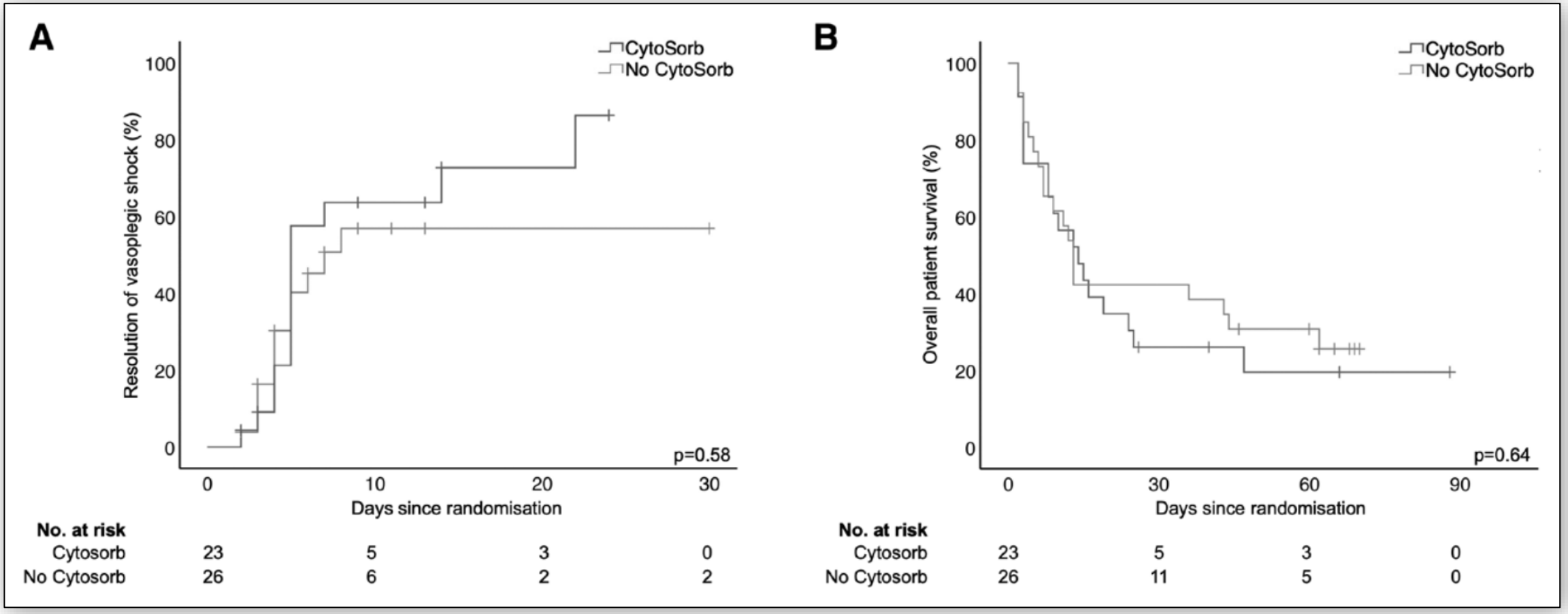


6.5 x more likely to die !

SUPADY et al.
Lancet Respir Med 2021 May 14, 2021

Klinikum Braunschweig

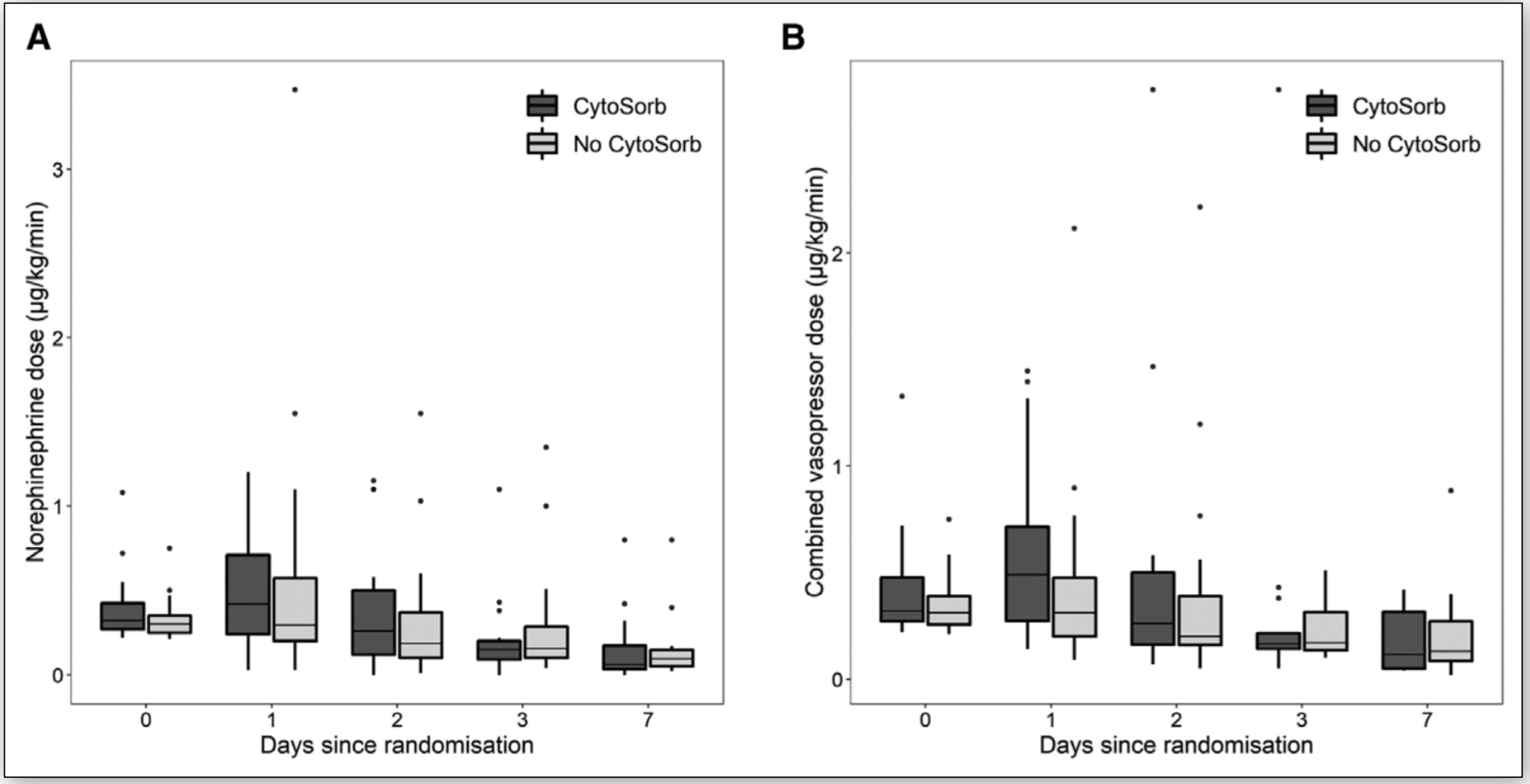
CytoSorb Rescue for COVID-19 Patients With Vasoplegic Shock and Multiple Organ Failure: A Prospective, Open-Label, Randomized Controlled Pilot Study



STOCKMANN et al.
Crit Care Med 2022 Feb 9.

Klinikum Braunschweig

CytoSorb Rescue for COVID-19 Patients With Vasoplegic Shock and Multiple Organ Failure: A Prospective, Open-Label, Randomized Controlled Pilot Study



STOCKMANN et al.
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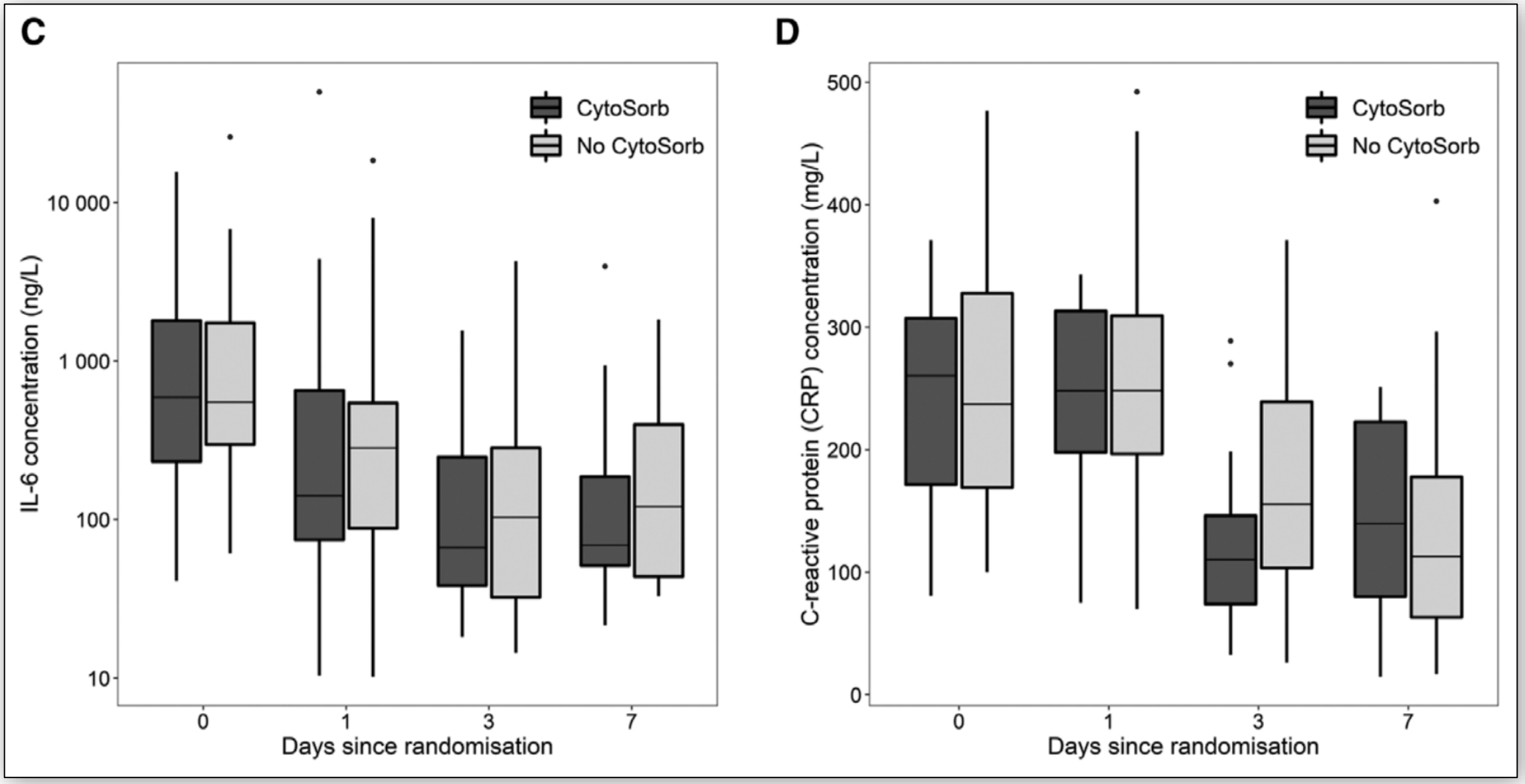
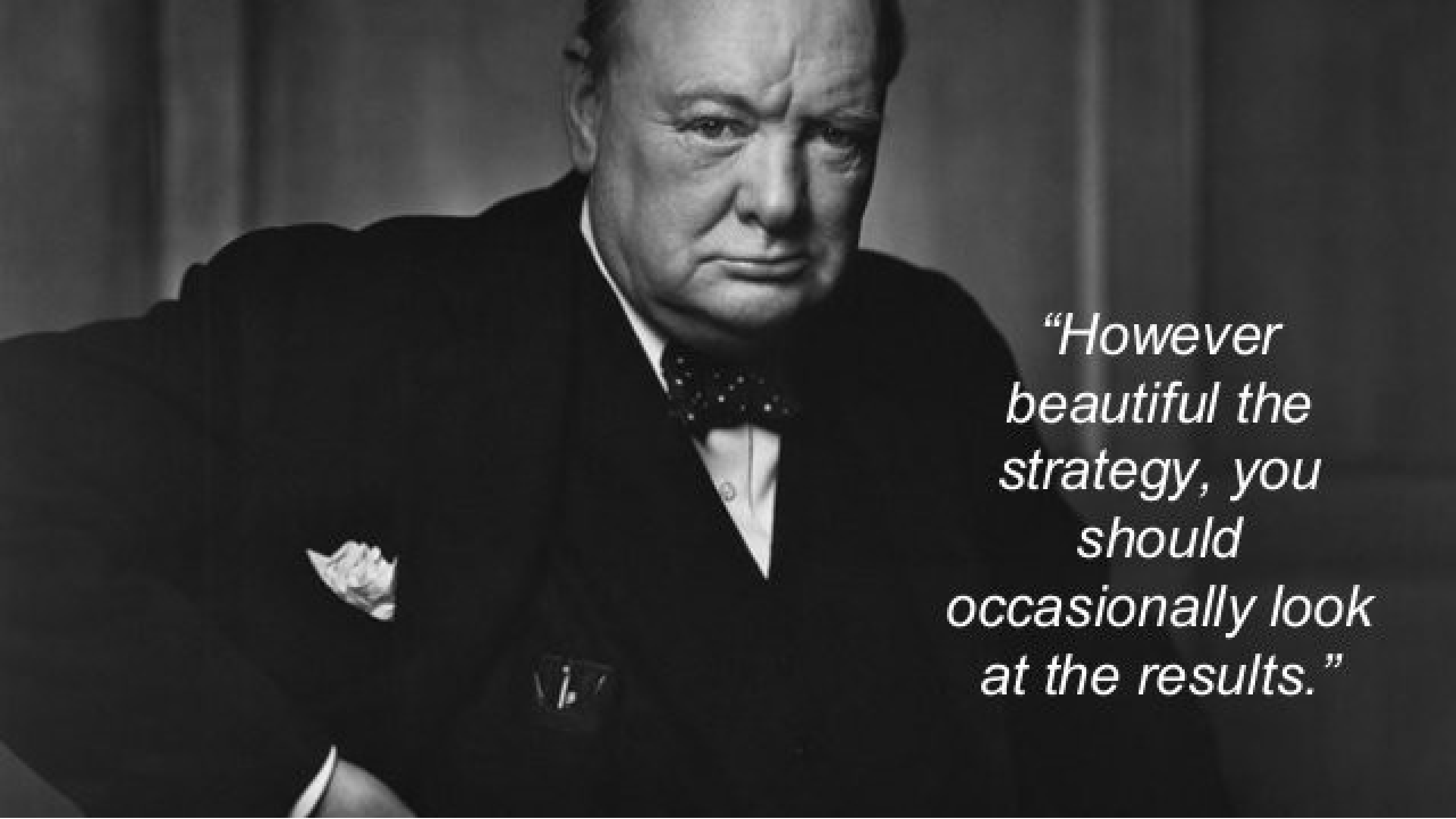


STOCKMANN et al.
Crit Care Med 2022 Feb 9.

Klinikum Braunschweig


"However beautiful the strategy, you should occasionally look at the results."

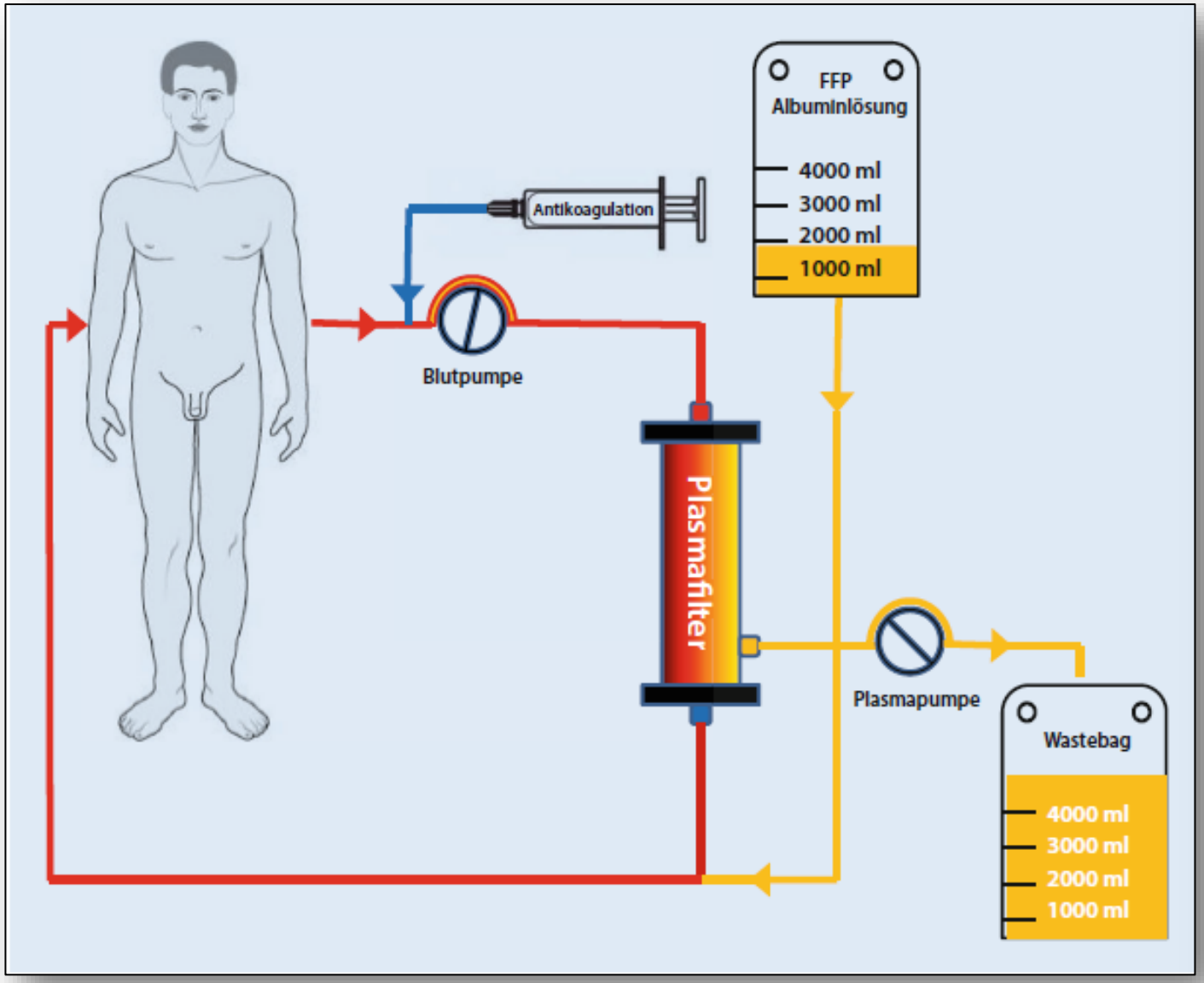
Extracorporeal therapies in acute COVID-19

1) CytoSorb® - Hemoperfusion

2) **Therapeutic Plasma Exchange**

3) Seraph® 100 Microbind Affinity Blood Filter

Therapeutic Plasma Exchange



Z Rheumatol 75: 964-972, 2016

BOSER & KIELSTEIN

Klinikum Braunschweig

What Is the Role of Therapeutic Plasma Exchange as an Adjunctive Treatment in Severe COVID-19: A Systematic Review

Table 2. Summary of the included studies.

Author	Study Type	Population	Intervention	Median Time from First Symptoms to TPE Initiation	Replacement Fluid	Adverse Effects of TPE	Outcome
Zhang et al. [21]	Case-series	3 severely ill patients	1 TPE session	15 days	FFP	N/A	Mortality (day 14): 0%
Morath et al. [22]	Case-series	5 patients with COVID-19-induced multi-organ failure and ARDS	All patients received 1–2 TPE sessions	12 days	FFP	N/A	Mortality: 20%
Faqihi et al. [23]	Case-series	10 patients with ARDS, APACHE II score >20, septic shock or cytokine release syndrome	All patients received 5–7 TPE	6.5 days	5% albumin or FFP	None	Mortality (day 28): 10%
Gucyemetz et al. [17]	Case-control	73 patients with COVID-19-related pneumonia	18 patients received 3 TPE sessions	N/A	N/A	N/A	Mortality (non-TPE vs. TPE): 58.3% vs. 8.3% *
Khamis et al. [35]	Case-control	31 critically ill patients with COVID-19-related ARDS, severe pneumonia, septic shock or multiple organ dysfunction syndrome	11 patients underwent 5 TPE sessions	N/A	FFP	One hypotension episode treated with fluid bolus and hydrocortisone	Mortality (non-TPE vs. TPE, day 28): 35% vs. 0% *
Jaiswal et al. [24]	Case-series	14 patients with severe COVID-19 infection according to WHO classification	All patients received 1 TPE session	9 days	Convalescent Plasma	3 cases of hypotension treated with fluid bolus	Mortality (day 28): 28.6%
Gluck et al. [25]	Case-series	10 patients with COVID-19 and Penn class 3 and 4 cytokine release syndrome	All patients received 5 TPE sessions	N/A	5% albumin or FFP	None	Mortality (day 14): 0%
Karman et al. [36]	PSM	90 patients with severe COVID-19 infection and cytokine release syndrome	45 patients received one TPE until resolution of the disease	N/A	FFP and normal saline in 2:1 ratio	1 femoral artery puncture and thrombophlebitis treated accordingly	Mortality (non-TPE vs. TPE, day 28): 38.5% vs. 8.9% *
Fernandez et al. [26]	Case-series	4 critically ill patients with COVID-19	2–6 plasma exchange sessions	20 days	5% albumin + FFP	1 episode of hypotension and tachycardia	Mortality (day 28): 0%
Dogan et al. [27]	Case-series	6 patients with COVID-19–related autoimmune meningoencephalitis	1–9 plasma exchange sessions	N/A	5% albumin	N/A	Mortality (day 14): 16.7%

KRZYCH et al.
Viruses 2021, 13(8),1484

Klinikum Braunschweig

What Is the Role of Therapeutic Plasma Exchange as an Adjunctive Treatment in Severe COVID-19: A Systematic Review

Table 2. *Cont.*

Author	Study Type	Population	Intervention	Median Time from First Symptoms to TPE Initiation	Replacement Fluid	Adverse Effects of TPE	Outcome
Adeli et al. [28]	Case-series	8 patients	3–5 plasma exchange sessions	N/A	FFP + albumin solution + calcium gluconate	None	Mortality (no specified day): 12.5%
De Prost et al. [29]	Case-series	4 critically-ill patients with high blood concentrations of neutralizing autoantibodies against type I interferons	3–4 plasma exchange sessions	18 days	5% albumin solution	None	Mortality (no specified day): 50%
Faqihi et al. [37]	RCT	87 intubated patients with either ARDS, APACHE II score >20 pts, septic shock or cytokine release syndrome	43 patients received 1–5 (median 3) plasma exchange sessions	8 days	FFP	None	Mortality (TPE vs non-TPE, day 35): 20.9% vs. 34.1 % ($p = 0.09$)
Hashemian et al. [30]	Case-series	15 patients	1–3 TPE sessions	N/A	5% albumin solution + 0.9% NaCl/convalescent plasma	N/A	Mortality (no specified day): 40%
Keith et al. [31]	Case-series	8 patients	1–7 plasma exchange sessions	N/A	FFP	N/A	Mortality (no specified day): 25%
Matsushita et al. [32]	Case-series	5 patients with PaO_2/FiO_2 ratio of less than 200 mmHg and/or labored respiration and/or tracheal intubation	3–7 plasma exchange sessions	14 days	FFP	N/A	Mortality (no specified day): 60%
Roshandel et al. [33]	Case-series	5 COVID-19 patients with respiratory failure	2 standard plasma exchange sessions	39 days	FFP + 5% albumin, then 0.9% NaCl/convalescent plasma	N/A	Mortality (no specified day): 20%
Truong et al. [34]	Case-series	6 critically ill patients with plasma hyperviscosity	2–3 plasma exchange sessions	N/A	FFP	None	Mortality (no specified day): 50%

Results presented in the "outcome" column are median. * results that were statistically significant. Absence of "*" means that the result was either not significant or the significance was not calculated; PaO_2: partial pressure of oxygen; FiO_2: fraction of inspired oxygen; ARDS: Acute Respiratory Distress Syndrome; SOFA—Sequential Organ Failure Assessment; APACHE II—Acute Physiology and Chronic Health Evaluation II; TPE—therapeutic plasma exchange; RCT–randomized controlled trial; PSM: propensity score matching; N/A: information not available.

KRZYCH et al.
Viruses 2021, 13(8),1484

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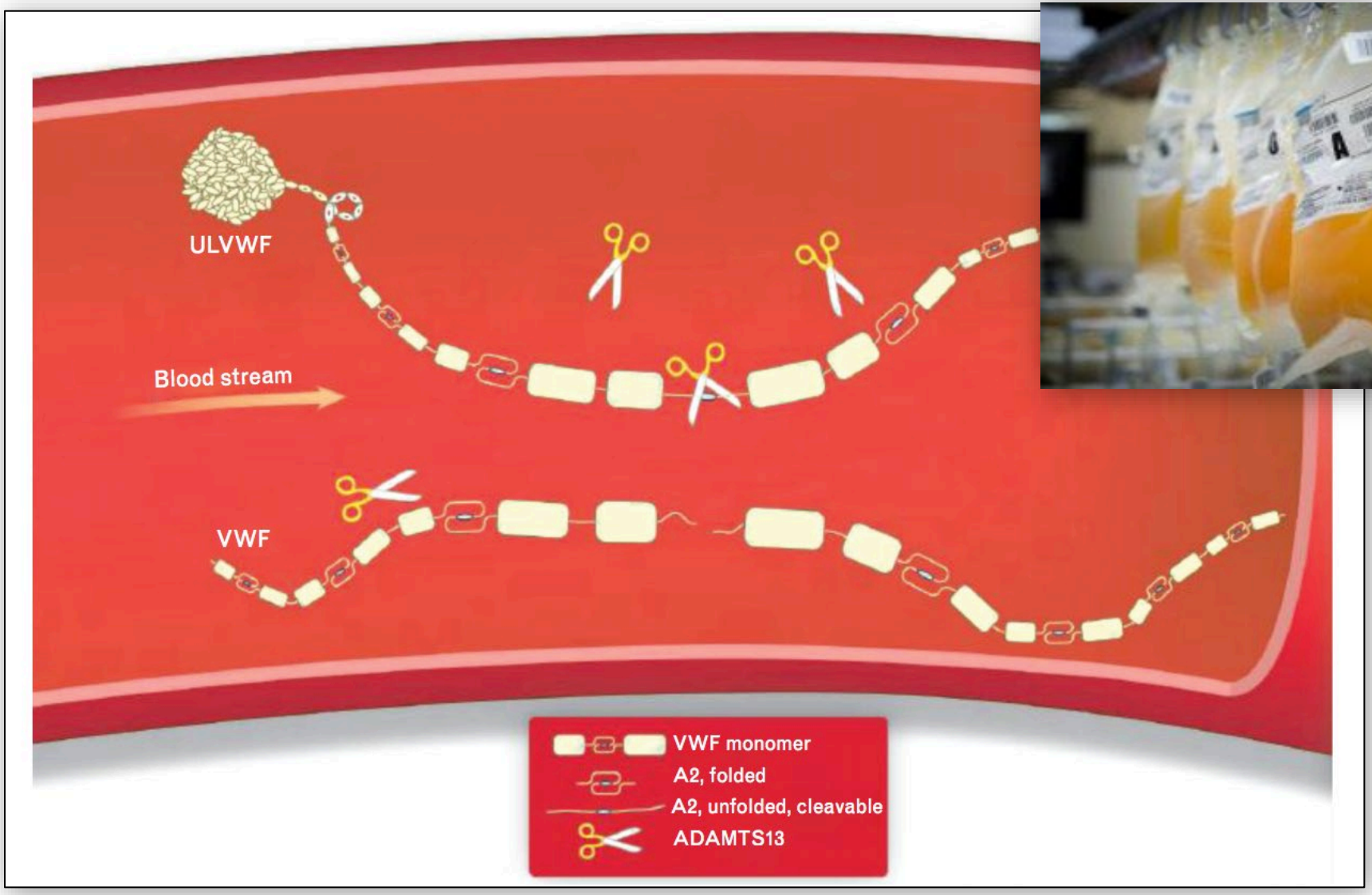
Update on von Willebrand factor multimers: focus on high-molecular-weight multimers and their role in hemostasis



TSTOCKSCHLAEGER et al .Blood Coagulation + Fibrinolysis 2014, 25:206–216

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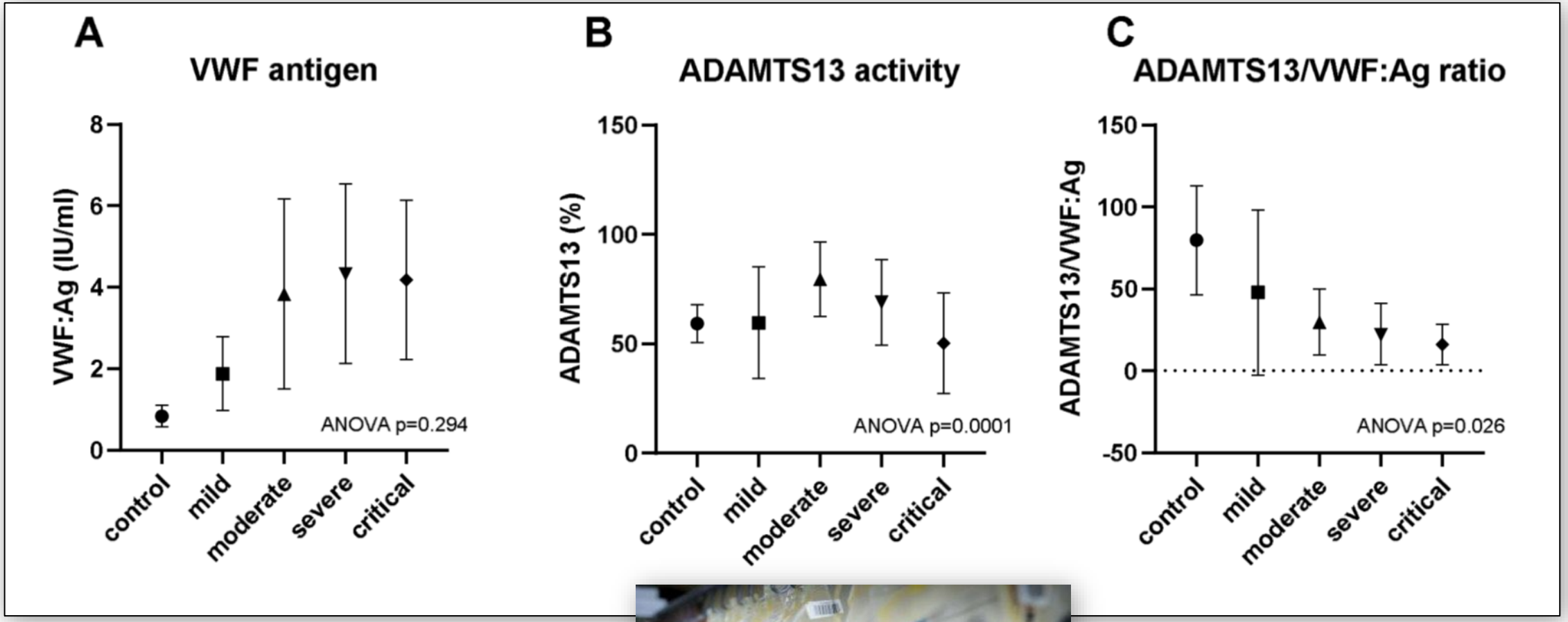
COVID-19 is associated with relative ADAMTS13 deficiency and VWF multimer formation resembling TTP



https://doi.org/10.1101/2020.08.23.20177824

DOEVELAAR et al.

Klinikum Braunschweig

Therapeutic plasma exchange in patients with life-threatening COVID-19: a randomised controlled clinical trial (n=87)

Highlights

- Open-label randomised clinical trial of ICU patients with life-threatening COVID-19.
- Standard treatment plus therapeutic plasma exchange (TPE) ($n = 43$) versus standard treatment ($n = 44$).
- Days on mechanical ventilation ($P = 0.007$) and ICU length of stay ($P = 0.02$) were lower in the TPE group versus controls.
- 35-day mortality was lower in the TPE group (20.9% vs. 34.1% in controls), but this did not reach statistical significance.
- Plasma exchange pilot studies showed promise in the treatment of multifaceted life-threatening COVID-19.

FAQUIHI et al. *Int J Antimicrob Agents* 2021 May;57(5):106334.

Klinikum Braunschweig

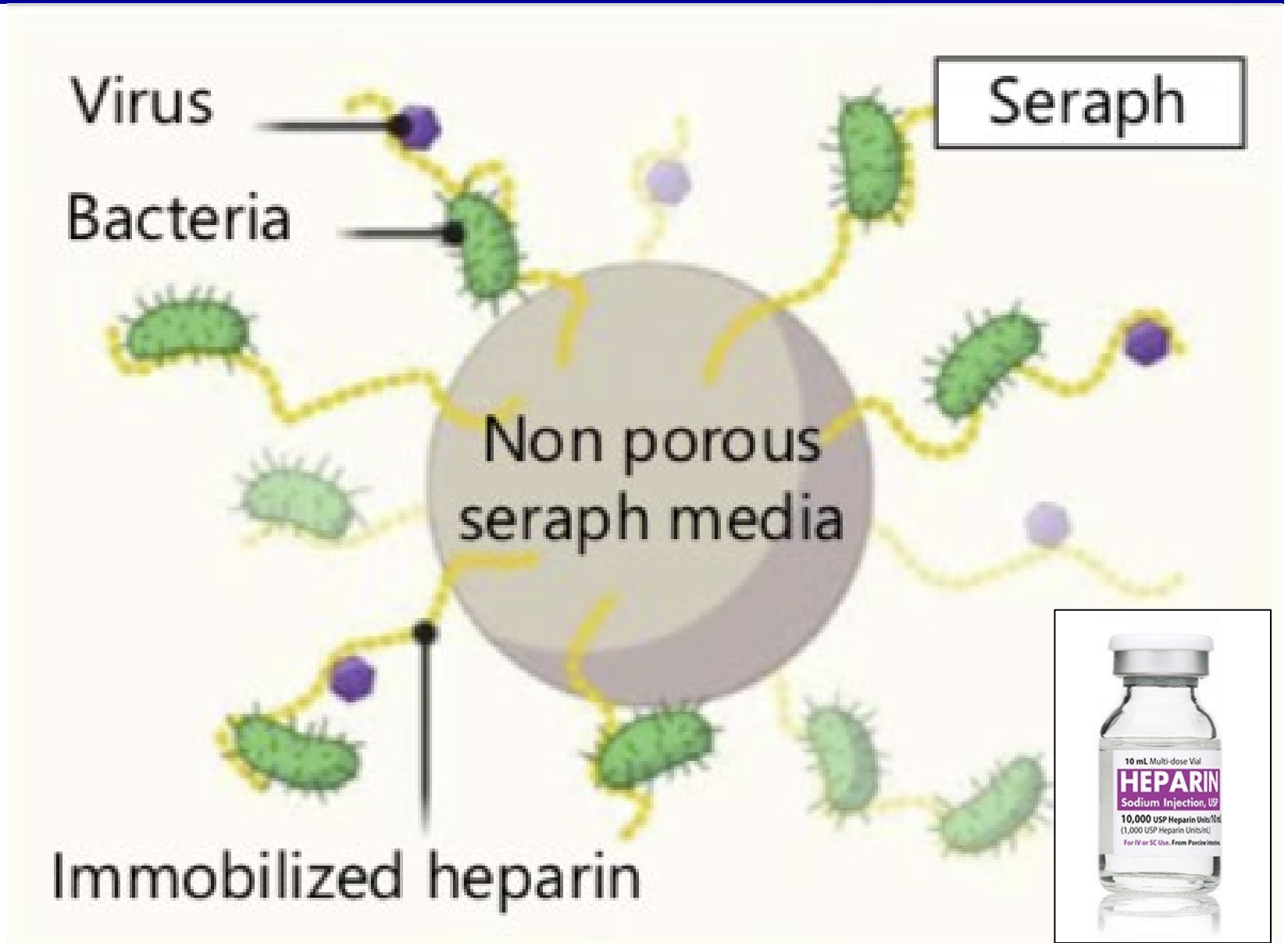
Extracorporeal therapies in acute COVID-19

1) CytoSorb® - Hemoperfusion

2) Therapeutic Plasma Exchange

3) **Seraph® 100 Microbind Affinity Blood Filter**

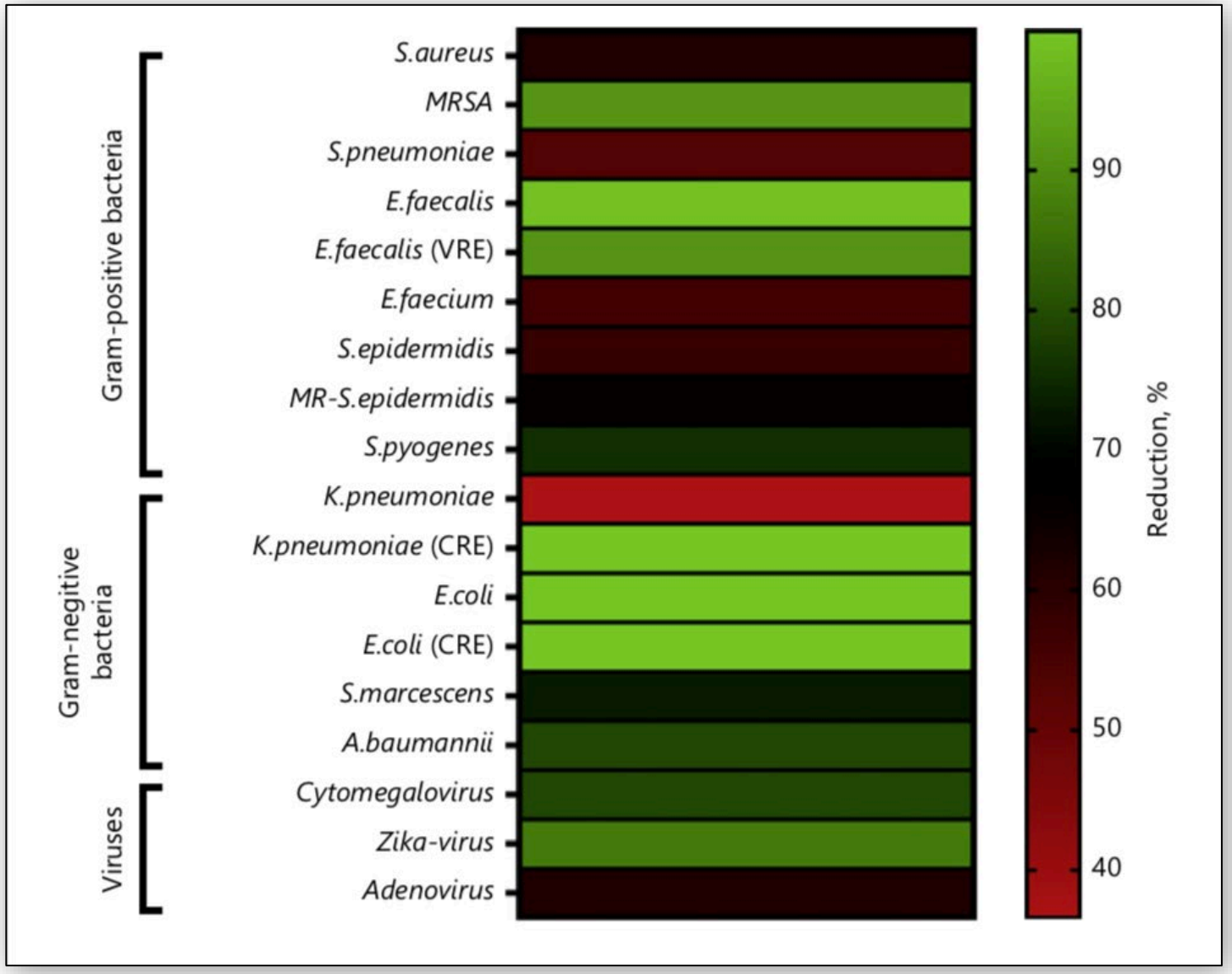
Heparin 2.0 – A New Approach To The Infection Crisis



SEFFER et al.
Blood Purif Jul 2:1-7, 2020

Klinikum Braunschweig

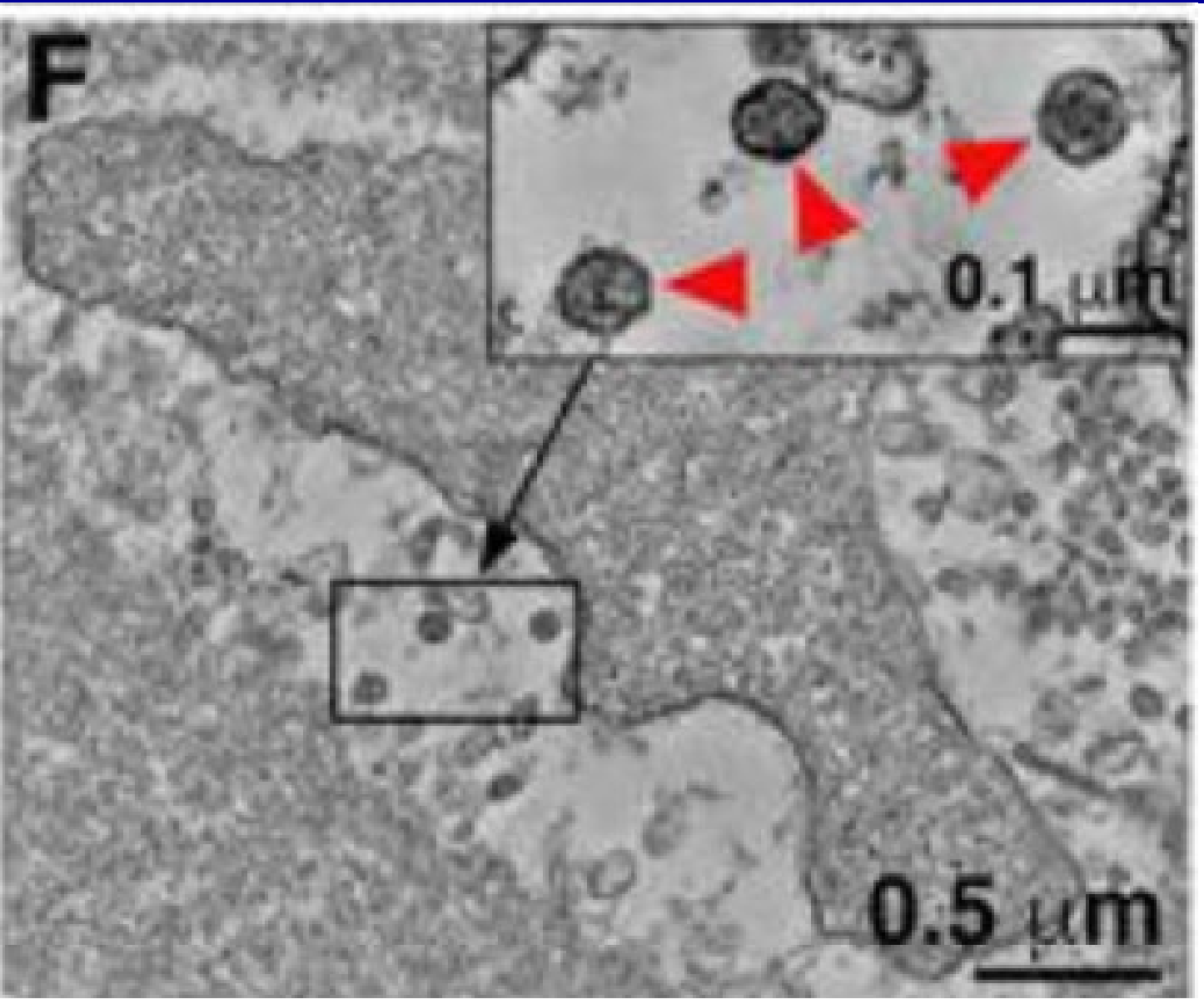
In vitro Reduction of pathogens by the Seraph®



SEFFER et al.
Blood Purif Jul 2:1-7, 2020

Klinikum Braunschweig

SARS-CoV-2 Viremia is Associated with COVID-19 Severity and Predicts Clinical Outcomes

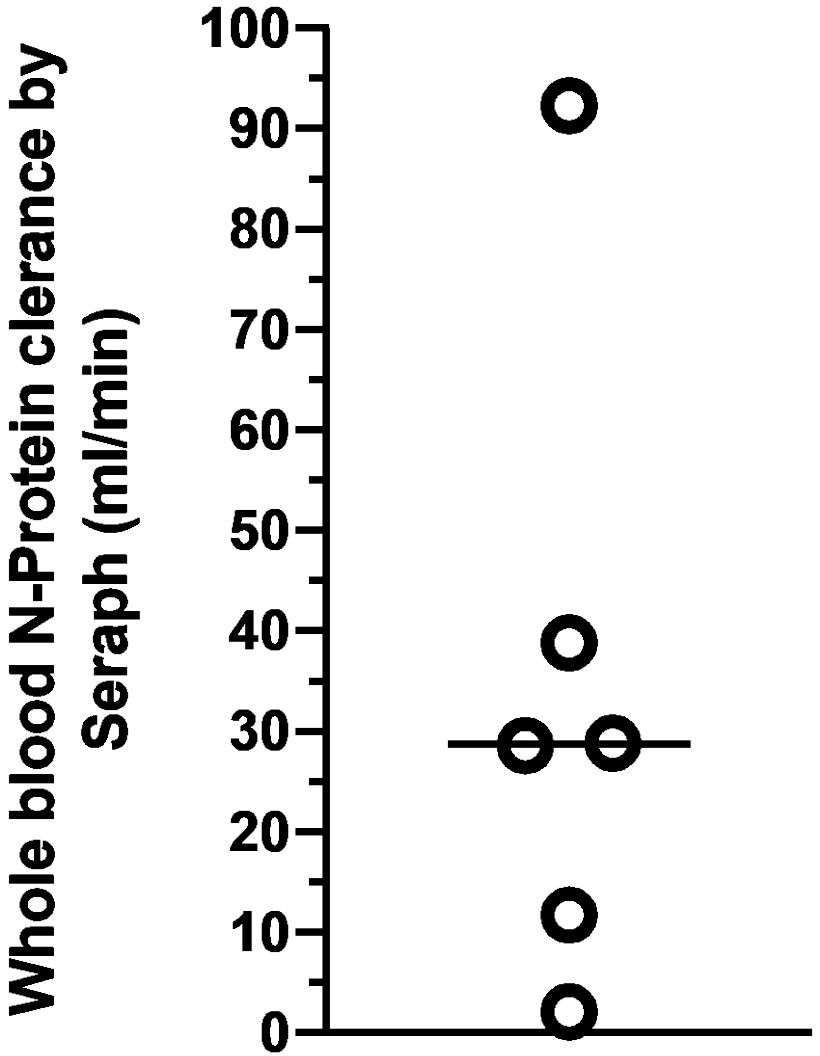


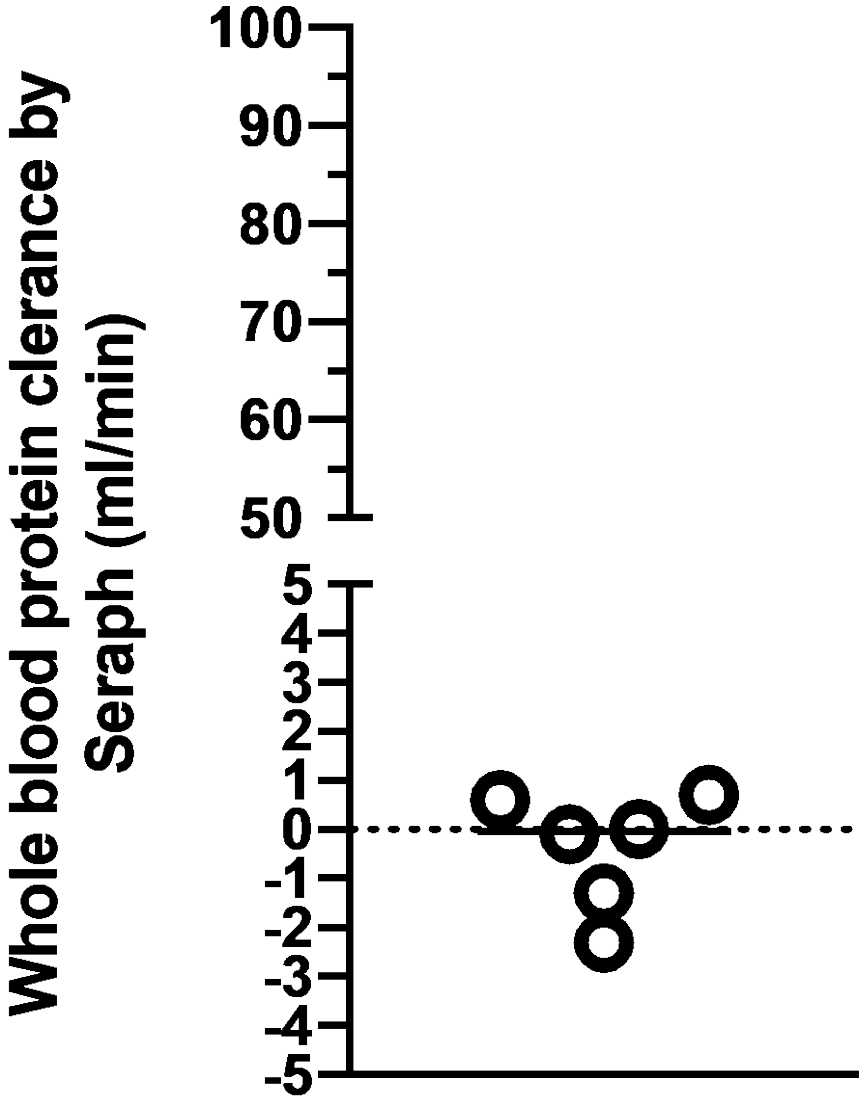
3 presumptive virions adjacent to platlet

JACOBS et al.
Clin Infect Dis 2021 Aug 10;ciab686.

Klinikum Braunschweig

Hemofiltration with the Seraph® 100 Microbind® Affinity filter decreases SARS-CoV-2 nucleocapsid protein in critically ill COVID-19 patients





KIELSTEIN et al. *Crit Care*, accepted

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

COSA Case Report Edit
New COSA Case Report

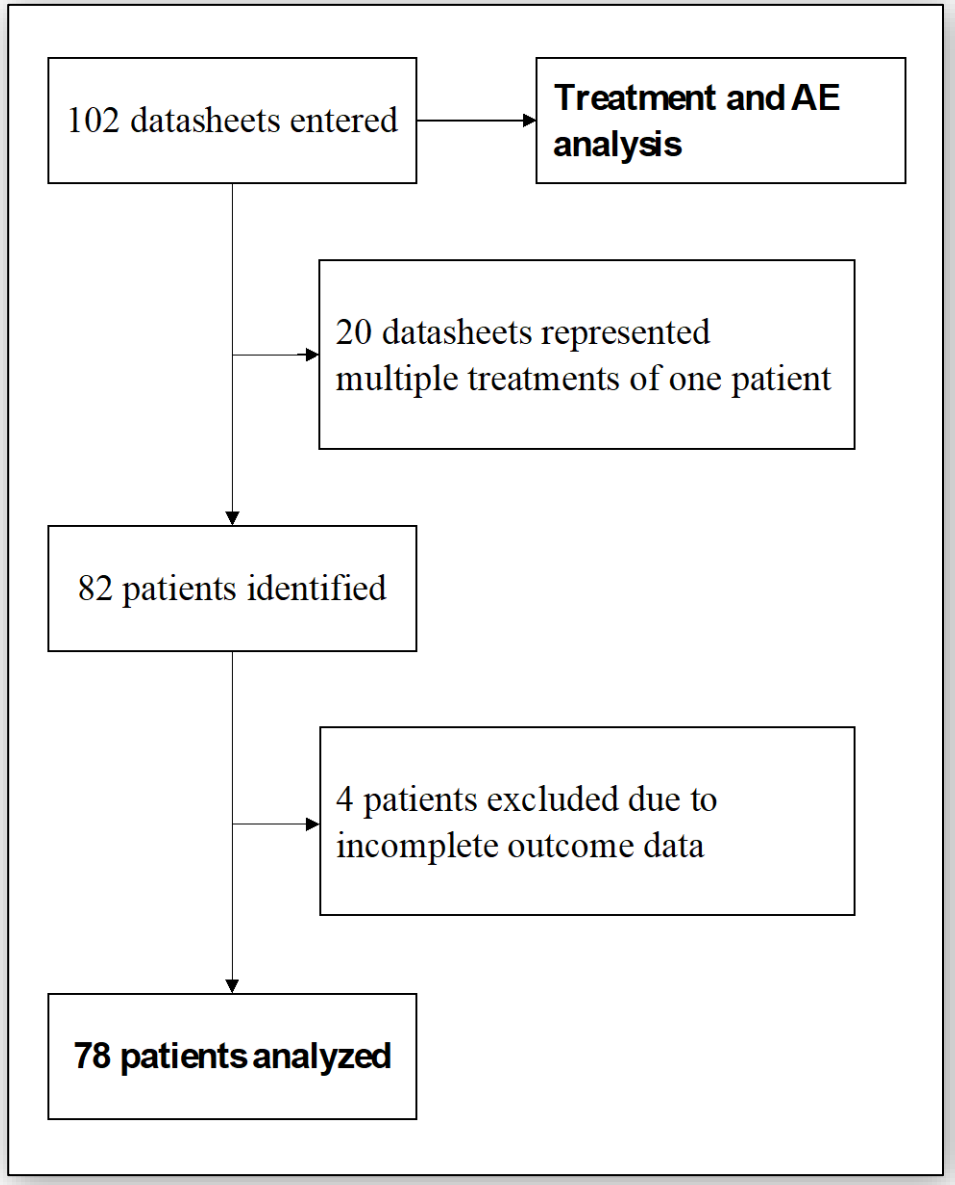
COSA Case Report Edit Save | Save & New | Cancel

Information

Hospital Reference	
Gender	--None--
Age (yr)	
Ethnicity	--None--
Admission date to the hospital	[06/06/2020]
Weight (kg)	
Estimated Weight	☐
Height (cm)	
Estimated Height	☐
Prior Immunosuppression ? (Yes/No)	--None--
Currently in ICU (Yes/No)	--None--
Admission to ICU	[06/06/2020]

Key Dates

Seraph treatment start date	[06/06/2020]
Seraph treatment start time	HH:MM
Seraph treatment end date	[06/06/2020]
Seraph treatment end time	HH:MM
1st day Ventil.independent/Extubation	[06/06/2020]
Last day ICU	[06/06/2020]
Last day in hospital	[06/06/2020]
Date of death	[06/06/2020]



SCHMIDT et al.
Nephrol Dial Transplant. 2021 Dec 7;gfab347

Klinikum Braunschweig

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

	Overall ($n = 78$)	Survivor ($n = 42$)	Non-survivor ($n = 36$)	P-value
Sex				
Female (%)	22 (28.2)	12 (28.6)	10 (27.8)	1
Male (%)	56 (71.8)	30 (71.4)	26 (72.2)	
Age (years)				
n	78	42	36	0.741
Median (Q1, Q3)	59.0 (50.3, 68.8)	57.0 (50.3, 68.0)	61.5 (49.8, 71.3)	
Ethnicity				
Black/African/Caribbean (%)	13 (16.7)	7 (16.7)	6 (16.7)	0.445
Mixed/multiple ethnic groups (%)	8 (10.3)	4 (9.5)	4 (11.1)	
White (%)	51 (65.4)	29 (69.0)	22 (61.1)	
Asian (%)	1 (1.3)	0 (0)	1 (2.8)	
Other ethnic group (%)	2 (2.6)	0 (0)	2 (5.6)	
Missing (%)	3 (3.8)	2 (4.8)	1 (2.8)	
Weight (kg)				
n	75	42	33	0.847
Median (Q1, Q3)	90.0 (79.0, 100)	90.0 (79.0, 109)	90.0 (80.0, 96.0)	
Missing (%)	3 (3.8)	0 (0)	3 (8.3)	
Height (cm)				
n	72	39	33	0.995
Median (Q1, Q3)	173 (168, 178)	174 (168, 178)	173 (168, 177)	
Missing (%)	6 (7.7)	3 (7.1)	3 (8.3)	
ICU admission				
No (%)	9 (11.5)	8 (19.0)	1 (2.8)	0.0592
Yes (%)	69 (88.5)	34 (81.0)	35 (97.2)	
SOFA score				
n	71	39	32	0.194
Median (Q1, Q3)	9.00 (7.00, 12.5)	9.00 (7.00, 12.0)	11.0 (8.00, 13.3)	
Missing (%)	7 (9.0)	3 (7.1)	4 (11.1)	
4C score				
n	47	29	18	0.0157
Median (Q1, Q3)	12.0 (9.50, 14.0)	11.0 (8.00, 12.0)	12.5 (11.3, 14.0)	
Missing (%)	31 (39.7)	13 (31.0)	18 (50.0)	

SCHMIDT et al.
Nephrol Dial Transplant. 2021 Dec 7;gfab347

Klinikum Braunschweig

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

	Overall ($n = 78$)	Survivor ($n = 42$)	Non-survivor ($n = 36$)	P-value
CRP (mg/L)				
n	73	40	33	0.907
Median (Q1, Q3)	155 (97.0, 279)	149 (110, 24)	162 (83.0, 386)	
Missing (%)	5 (6.4)	2 (4.8)	3 (8.3)	
PCT (µg/L)				
n	72	37	35	0.0884
Median (Q1, Q3)	1.50 (0.400, 10.9)	0.600 (0.400, 6.00)	4.40 (0.650, 13.8)	
Missing (%)	6 (7.7)	5 (11.9)	1 (2.8)	
Leucocytes				
n	76	41	35	0.26
Median (Q1, Q3)	11.0 (8.43, 14.8)	10.3 (7.30, 14.8)	11.9 (9.45, 14.9)	
Missing (%)	2 (2.6)	1 (2.4)	1 (2.8)	
Ferritin (ng/mL)				
n	48	30	18	0.0418
Median (Q1, Q3)	1260 (894, 2880)	1010 (777, 2000)	1980 (1040, 8140)	
Missing (%)	30 (38.5)	12 (28.6)	18 (50.0)	
D-Dimer (mg/L)				
n	66	38	28	0.364
Median (Q1, Q3)	3.53 (1.07, 25.1)	2.41 (0.848, 24.7)	4.18 (1.51, 23.3)	
Missing (%)	12 (15.4)	4 (9.5)	8 (22.2)	
Length of ICU stay (days)				
n	69	34	35	0.299
Median (Q1, Q3)	17.0 (10.0, 27.0)	15.0 (7.50, 26.3)	19.0 (14.0, 25.5)	
Missing (%)	9 (11.5)	8 (19.0)	1 (2.8)	
Length of hospital stay (days)				
n	78	42	36	0.173
Median (Q1, Q3)	22.0 (15.0, 33.3)	23.5 (16.3, 37.0)	20.0 (13.0, 30.3)	
Time from symptoms to Seraph treatment (days)				
n	74	39	35	0.0211
Median (Q1, Q3)	12.3 (7.43, 15.5)	9.56 (6.60, 14.6)	13.0 (11.0, 19.5)	
Missing (%)	4 (5.1)	3 (7.1)	1 (2.8)	
Time from ICU admission to Seraph treatment (days)				
n	69	34	35	0.0023
Median (Q1, Q3)	2.55 (1.53, 6.00)	1.73 (1.50, 3.24)	4.58 (2.05, 11.4)	
Missing (%)	9[a] (11.5)	8 (19.0)	1 (2.8)	

SCHMIDT et al.
Nephrol Dial Transplant. 2021 Dec 7;gfab347

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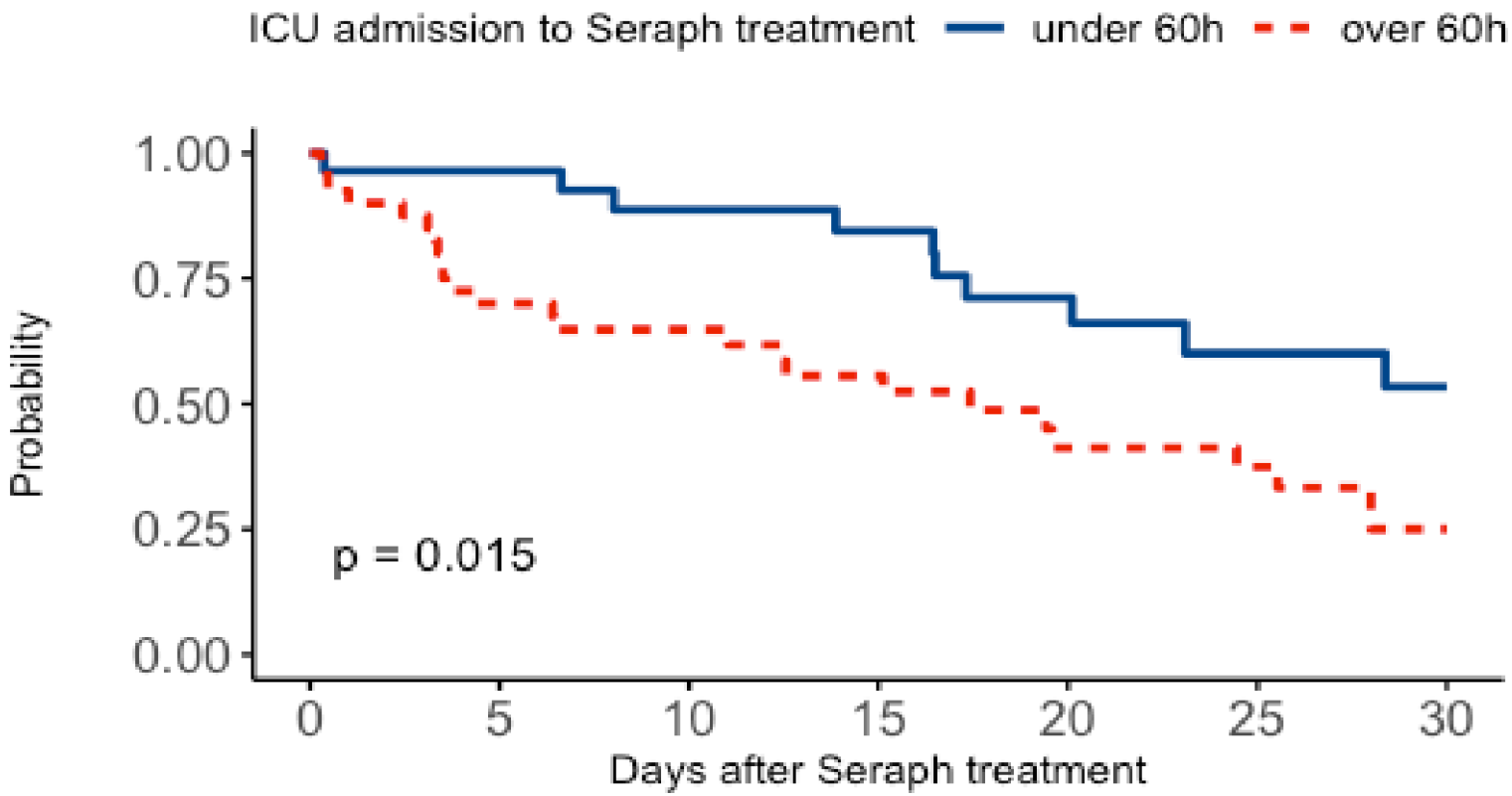
Interim-analysis of the COSA registry
(COVID-19 patients treated with the Seraph® 100 Microbind® Affinity filter)



No. at risk

under 60h	29	26	22	20	14	10	8
over 60h	40	28	22	18	11	10	5

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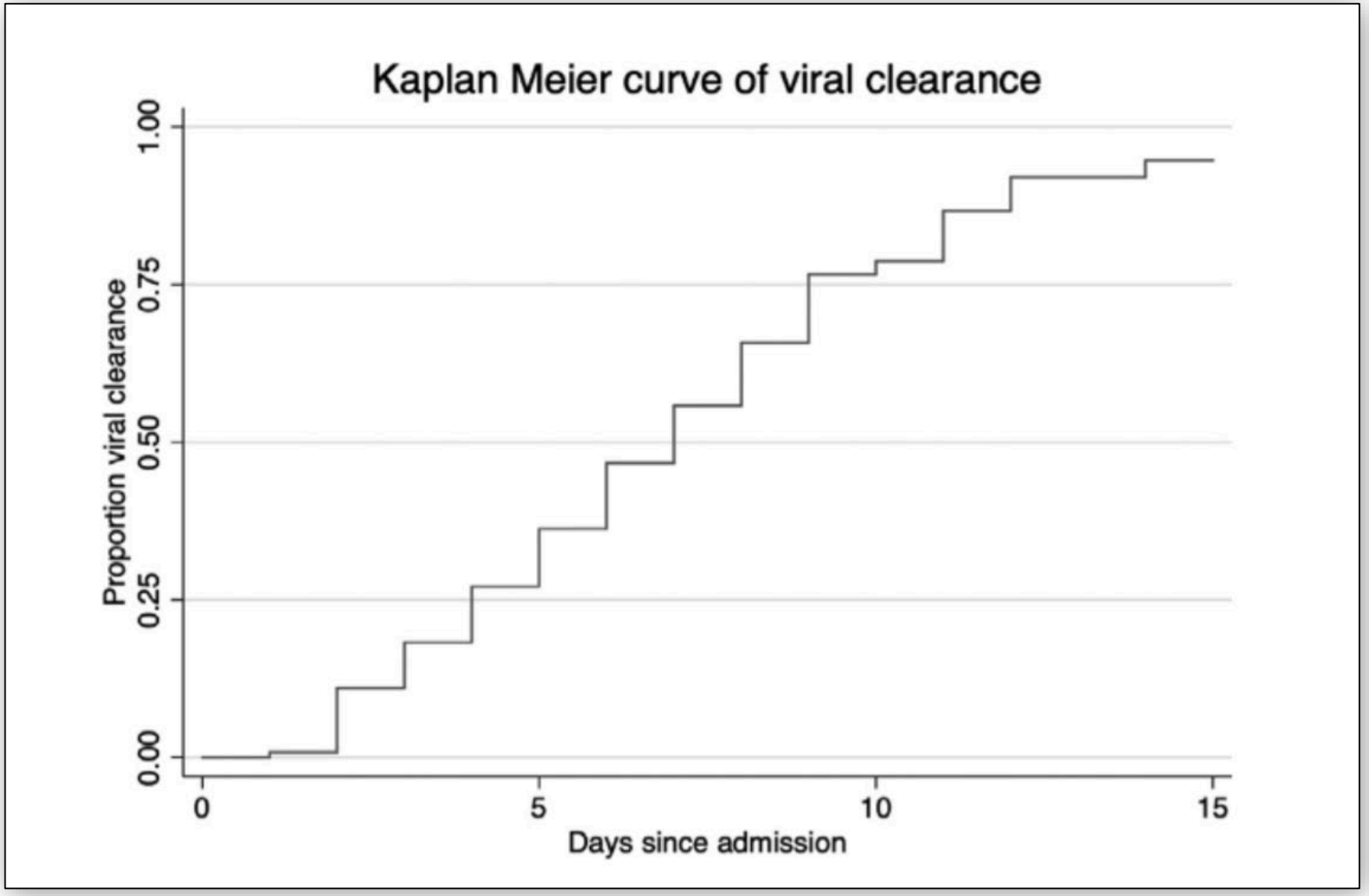
Duration of SARS-CoV-2 viremia and its correlation to mortality and inflammatory parameters in patients hospitalized for COVID-19: a cohort study



HAGMAN et al.
https://doi.org/10.1016/j.diagmicrobio.2021.115595

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

Methods

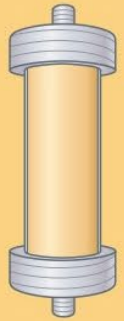
12 hospitals,
6 countries
and 2 continents

59 years

72%

n=82
SARS-CoV-2

Seraph® treatment



102 treatments
Standalone: 43.1%
Time: 5.0 [4.0–3.4] h
Days after 1st symptoms: 12.3

Deceased patients

↑ bacterial infection

Seraph® > 60 hours after ICU admission

Results

Mortality: calculated / observed

56.7% / 50.7%

n=78 with 30 d follow up

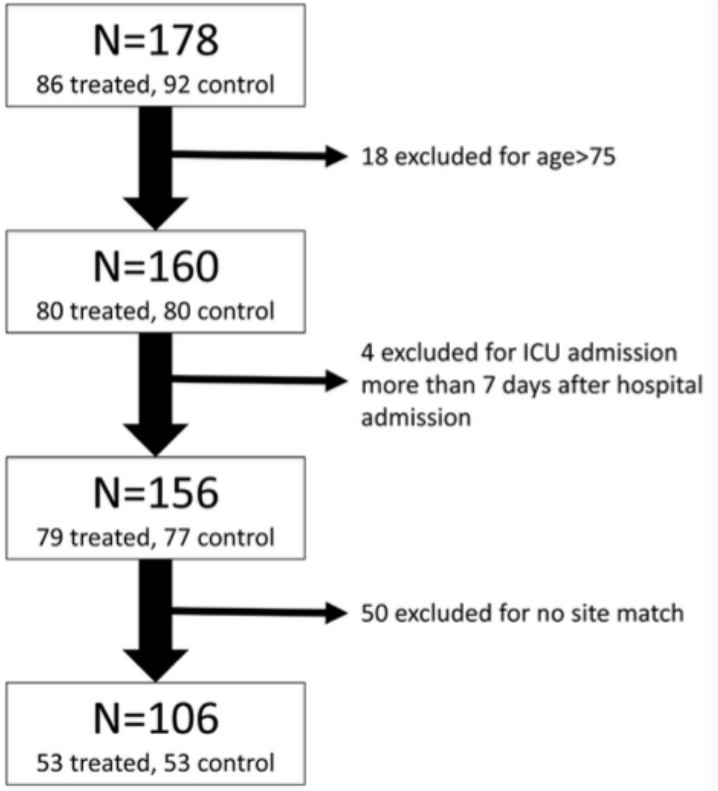
38.0% / 11.1%

8.8% circuit failure

Conclusion

Seraph® 100 treamtent was well tolerated and circuit failure rate was less than reported for kidney replacement therapy in COVID-19 patients. Multivariate Cox regression revealed that late Seraph®100 treatment after ICU admission (> 60 hours) as well as bacterial superinfection during the course of the disease were associated with mortality. Compared to established scores the mortality was lower.

A Multicenter Evaluation of the Seraph 100 Microbind Affinity Blood Filter for the Treatment of Severe COVID-19



Characteristics	Treatment ($n = 53$)	Control ($n = 53$)	p
Age, median (IQR)	56 (41–65)	64 (56–69)	0.009
Sex (%)			
Male	81.1	69.8	0.176
Female	18.9	30.2	
Race/ethnicity (%)			
NH White	45.3	50.9	0.773
NH Black	24.5	17.0	
Hispanic	13.2	11.3	
Other	17.0	20.8	
Body mass index, median (IQR)[a]	33.1 (28.6–40.7)	33.2 (28.8–40.1)	0.803
Acute Physiology and Chronic Health Evaluation II, median (IQR)	12 (9–17)	16 (12–21)	0.011
Charlson Comorbidity Index, median (IQR)	2 (0–3)	3 (2–4)	0.006
Diabetes (%)	28.3	43.4	0.105
Invasive mechanical ventilation (%)	67.3	75.5	0.388
Kidney replacement therapy (%)	66.0	24.5	< 0.001
COVID treatments			
Remdesivir (%)	86.8	69.8	0.034
Corticosteroids (%)	100.0	88.7	0.012
Outcomes			
Mortality (%)	32.1	64.2	0.001
Vasopressor-free days, median (IQR)[b]	24.5 (13–28)	14.5 (6–28)	0.022
ICU-free days, median (IQR)	0 (0–19)	0 (0–10)	0.112
Ventilator-free days, median (IQR)[c]	15 (2–28)	5.5 (1–25)	0.077
Hospital length of stay, median (IQR)[d]	21 (9.5–39.5)	17 (11–32)	0.462

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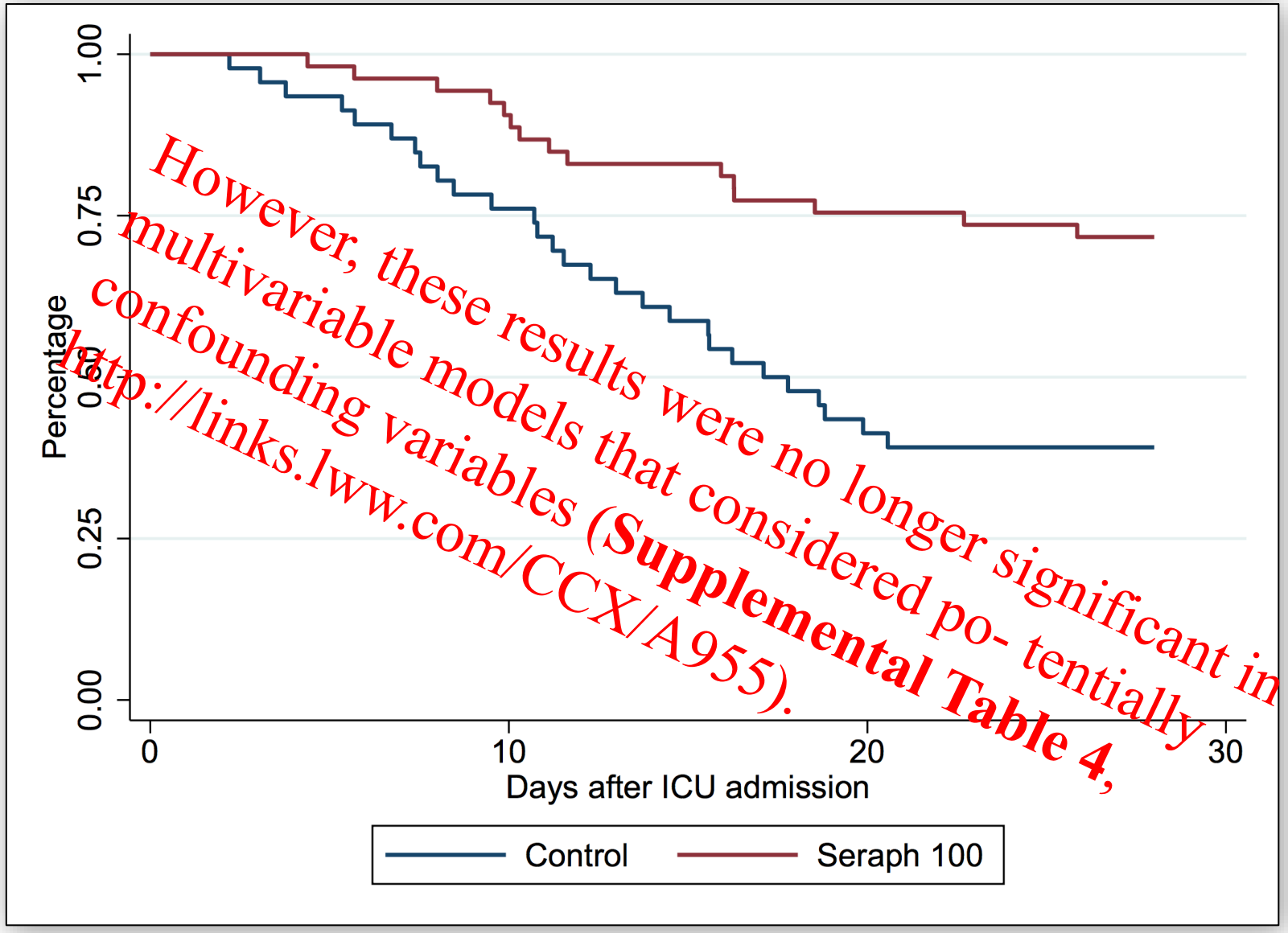
A Multicenter Evaluation of the Seraph 100 Microbind Affinity Blood Filter for the Treatment of Severe COVID-19



However, these results were no longer significant in multivariable models that considered po- tentially confounding variables (**Supplemental Table 4,** http://links.lww.com/CCX/A955).

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A Multicenter Evaluation of the Seraph 100 Microbind Affinity Blood Filter for the Treatment of Severe COVID-19

Characteristics	Prematching			Postmatching		
	Treatment ($n = 53$)	External Control ($n = 337$)	p	Treatment ($n = 35$)	External Control ($n = 39$)	p
Age, median (IQR)	56 (41–65)	62 (50–68)	0.051	56 (41–67)	54 (47–63)	0.626
Sex (%)						
Male	81.1	61.4	0.005	80.0	79.5	0.956
Female	18.9	38.6		20.0	20.5	
Race/ethnicity (%)						
NH White	24.3	23.4	< 0.001	42.9	25.6	0.289
NH Black	24.5	54.3		22.9	41.0	
Hispanic	13.2	10.1		14.3	10.3	
Other	17.0	12.2		20.0	23.1	
Body mass index, median (IQR)[a]	33.1 (28.6–40.7)	30.0 (25.9–36.2)	0.003	32.9 (28.1–38.5)	36.4 (27.6–41.6)	0.420
Modified Acute Physiology and Chronic Health Evaluation II, median (IQR)	12 (9–17)	23 (15–30)	< 0.001	14 (10–19)	13 (10–21)	0.970
Mechanical ventilation (%)	67.9	68.3	0.962	62.9	69.2	0.563

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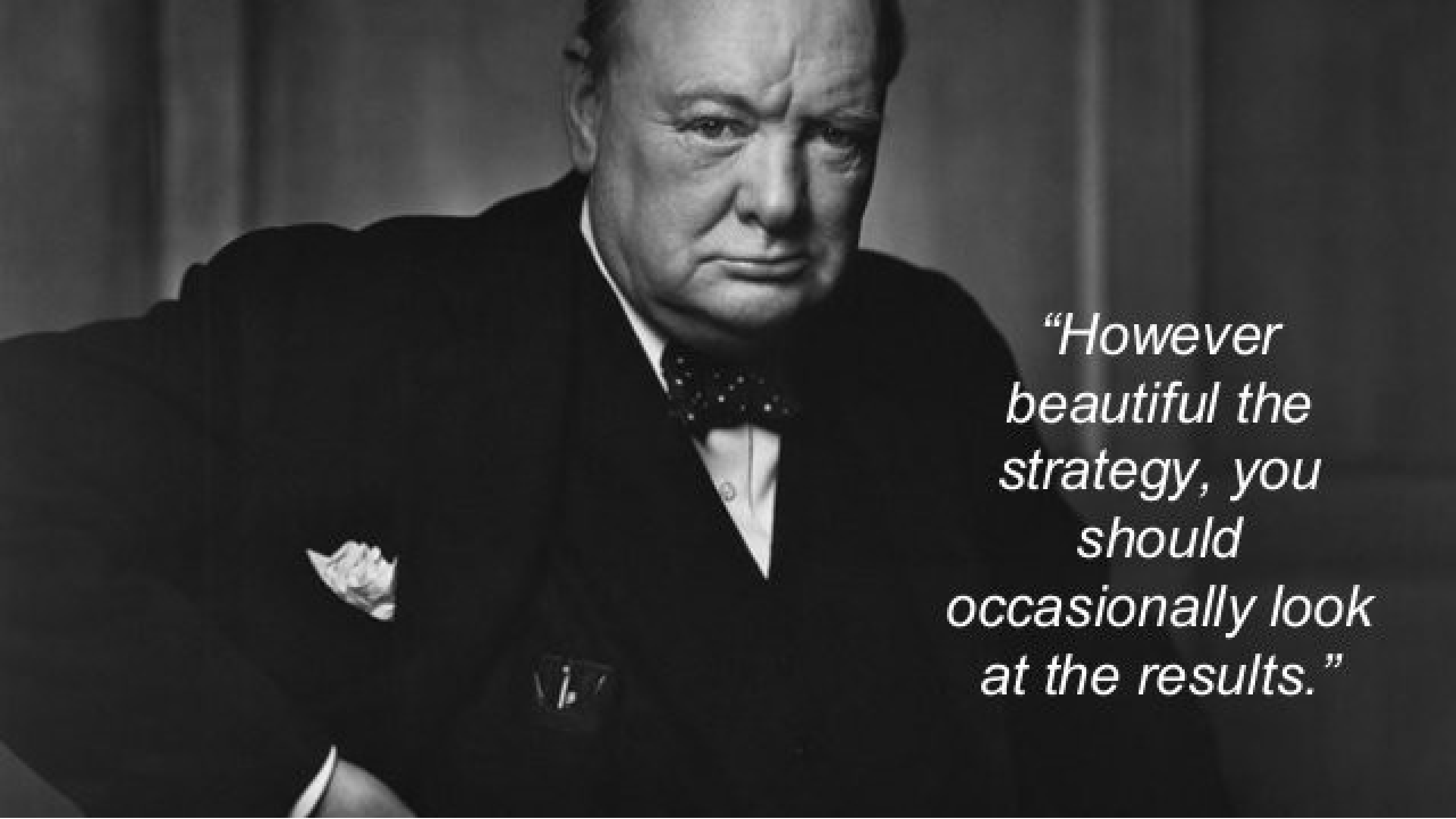
"However beautiful the strategy, you should occasionally look at the results."

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Discover the treatment options…..

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