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MAIN TEXT

Iodinated Contrast Adsorption in Cartridges With Styrene-Divinylbenzene Sorbent

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Received: 23 November 2024 | **Revised:** 27 December 2024 | **Accepted:** 3 January 2025

Funding: The authors received no specific funding for this work.

Keywords: adsorption | blood purification | cartridges | hemoadsorption | iodinated contrast

ABSTRACT

Background: Contrast-associated acute kidney injury (CA-AKI) is frequent in patients with chronic kidney disease who are submitted to cardiac endovascular procedures using iodinated contrast. In hemoadsorption, cartridges containing styrene-divinylbenzene sorbent resin are applied to remove substances from the blood through an extracorporeal circuit. Importantly, iodinated contrast is also removed via adsorption. We aimed to determine the adsorptive kinetics of the iodinated contrast medium iohexol using a 1:3 scale model of the HA380 cartridge.

Methods: An experimental in vitro study utilizing a closed-loop extracorporeal circuit with an interposed sorbent cartridge. A solution spiked with iohexol was recirculated for 60 min. Samples for the measurement of iohexol were drawn at 0, 5, 10, 15, 20, 30, 40, and 60 min. The experiment was carried out twice.

Results: In experiments 1 and 2, the reduction ratio after 60 min was 53.0% and 53.1%, respectively. In experiment 1, iohexol clearance was 46.79 mL/min during the first 5 min and decayed to 3.57 mL/min during the last 20 min. In experiment 2, iohexol clearance was 46.72 mL/min and decayed to 3.87 mL/min during the last 20 min. The ratio of adsorbate/sorbent was 155 mg/g.

Conclusion: A 1:3 scale model of the HA380 cartridge efficiently removes iodinated contrast in a clinical-scale in vitro circuit. These findings provide a rationale for hemoadsorption as an intervention in clinical trials to prevent or attenuate CA-AKI.

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1 | Introduction

Contrast-associated acute kidney injury (CA-AKI) is a frequent complication in patients with chronic kidney disease (CKD) receiving intra-arterial iodinated contrast for cardiac procedures such as coronary angiography/angioplasty, ventriculography, and transcatheter aortic valve replacement [1, 2]. Up to 14% of patients with CKD stage ≥ 4 (i.e., estimated glomerular filtration rate < 30 mL/min/1.73 m^2) present acute kidney injury (AKI) following these percutaneous procedures [3]. Additionally, persistent kidney dysfunction, defined as a sustained reduction in the estimated glomerular filtration rate below 25% of the baseline, occurs in 12% of these high-risk individuals [3]. In light of the established deleterious long-term outcomes in the continuum process of AKI, acute kidney disease, and CKD, [4, 5] it is logical to investigate interventions to prevent or mitigate CA-AKI. Notwithstanding, to date, pharmacological interventions and hemodialysis have been ineffective in preventing CA-AKI [6–8]. The current recommendations for the prevention or mitigation of CA-AKI comprise the discontinuation of potentially nephrotoxic medications and administration of isotonic intravenous crystalloid prior and following the contrast-enhanced procedure [6].

Hemoadsorption is an extracorporeal blood purification technique [9–13] in which blood permeates a solid material (sorbent), and some substances are retained on its surface due to physicochemical interactions, a mass-transfer mechanism defined as adsorption [14]. The first reports of the use of crosslinked divinyl-benzene copolymers sorbents for hemoadsorption in the context of drug intoxication were published in the 1970s [15]. Kellum and co-workers tested the adsorptive properties of a specific divinyl-benzene sorbent for iodinated contrast in two different in vitro models [16, 17]. The results of these proof-of-concept experiments were encouraging. Indeed, iodinated contrast was efficiently removed. Nonetheless, an experimental model emulating an extracorporeal circuit in a closed-loop configuration, using commercially available elements (e.g., cartridge, sorbent resin, peristaltic pump, blood tubing), with iodinated contrast doses and solution flow applied in clinical practice, was never built. Therefore, information such as adsorptive efficiency over time after exposure to a commonly used contrast dose, contrast clearance, and sorbent saturation are lacking.

Some studies have demonstrated a dose–response association between the volume of iodinated contrast and CA-AKI in percutaneous cardiac procedures [18, 19]. Accordingly, there is biological plausibility in exposing high-risk patients to the smallest possible amount of contrast to prevent CA-AKI. Some strategies are already applied to minimize contrast exposure, such as using biplane angiography to acquire two images for each injection, automated injectors, and thinner catheters (e.g., 4 Fr or 5 Fr). The removal of iodinated contrast by hemoadsorption could be envisioned as an additional tool to reduce the risk of CA-AKI. A conceivable clinical scenario comprises high-risk patients submitted to complex procedures in which a higher contrast volume will likely be required.

We constructed a closed-loop extracorporeal circuit with components and setup parameters used in clinical practice. A cartridge filled with sorbent resin was interposed downstream of a peristaltic pump, and a solution with iohexol was recirculated. The aim of this study was to assess the impact of adsorption on the kinetics of an iodinated contrast medium using a cartridge with sorbent material. We expect that the study results will establish the basis for conducting preclinical and clinical studies exploring whether contrast removal through adsorption can attenuate or prevent CA-AKI.

2 | Methods

2.1 | Study Design

The authors carried out an in vitro experimental study emulating an extracorporeal circuit applied for hemoadsorption. The aim of the study was to determine the adsorptive capacity of a styrene-divinylbenzene cartridge for the iodinated contrast medium iohexol. The main variables explored were the solute reduction ratio, solute clearance, and sorbent saturation. The elements in the circuit were a blood tubing circuit for hemodialysis, a peristaltic pump, a glass reservoir, and a cartridge packed with sorbent resin (Figure 1a,b). The cartridge was interposed in the circuit downstream of the peristaltic pump. A solution containing iohexol was propelled into the closed-loop circuit. Samples of the solution were collected from the reservoir at different time points. We performed the experiment twice.

2.2 | Iohexol Solution

A 0.9% NaCl solution (Baxter Gambro S.p.A., Medolla, Italy) was spiked with iohexol (OMNIPAQUE 350, GE Health Care S.r.l., Milano, Italy), which contains 755 mg of iohexol equivalent to 350 mg of organic iodine per mL. Iohexol—Bis(2,3-dihydroxypropyl)-5-[N-(2,3-dihydroxypropyl)-acetamido]-2,4,6-triiodo-isophthalamide is an iodinated, water-soluble, nonionic monomeric contrast medium (Figure 2a,b).

Iohexol's molecular weight is 821 Da, [20] categorized as a small-middle molecule according to the current classification of middle molecules [21].

We prepared a solution with 40 mL of OMNIPAQUE 350 dissolved in 960 mL of 0.9% NaCl, aiming for a final iohexol concentration of 30.2 g/L. The authors decided to use the dose of 40 mL because the mean iodinated contrast volume in complex procedures such as selective coronary arteriography combined with ventriculography or during transcatheter aortic valve replacement is around 100 mL [18, 22]. Considering that the blood volume of a 70-kg person is 4200 mL (60 mL/kg of body weight), if the hematocrit is 40%, plasma volume (i.e., 1—hematocrit) equals 2520 mL [23]. In these conditions, the theoretical concentration of the contrast medium would be similar to the concentration in plasma in clinical settings. The solution was recirculated into the closed-loop circuit for 60 min.

2.3 | Circuit

The circuit was applied to the GALILEO platform (IRRIV Foundation, Vicenza, Italy), in which a peristaltic pump

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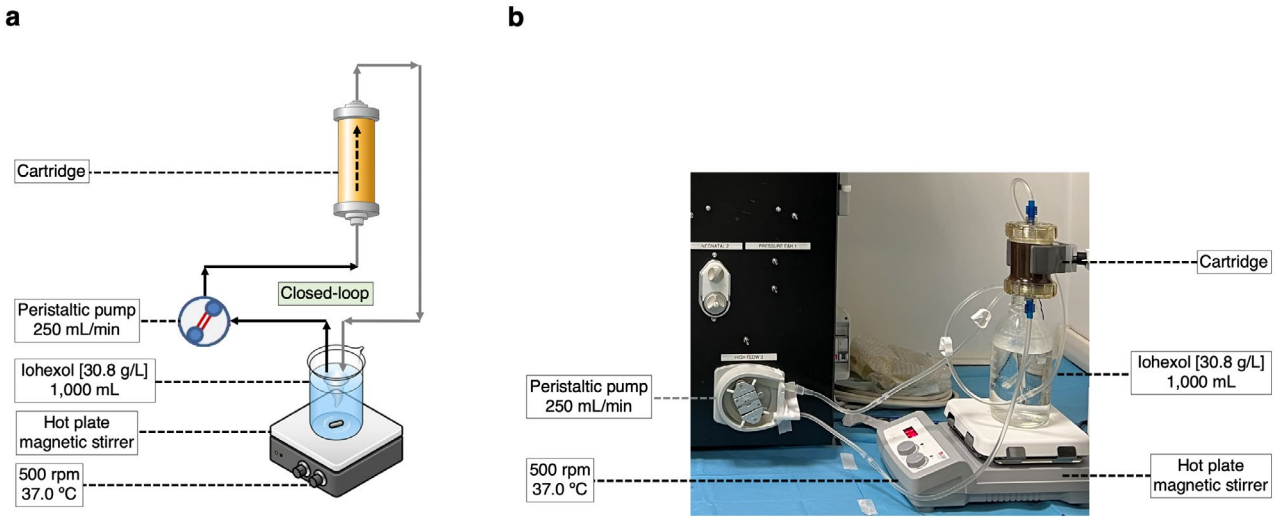

FIGURE 1 | Experimental circuit setup. A peristaltic pump propels a saline solution containing iohexol from a reservoir through a cartridge. This device contains 125 mL (105 g) of mesoporous sorbent resin (double crosslinked styrene-divinylbenzene copolymers) in beads with an average diameter of 800 μm. The circuit emulates an extracorporeal circuit from blood purification in a closed-loop configuration. (a) Schematic graphic representation of the components and parameters configurations. (b) Picture of the components and parameters configurations during the execution of the experiment.

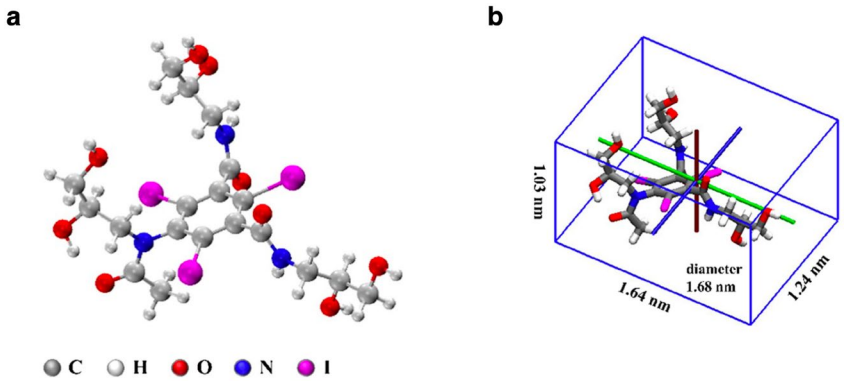

FIGURE 2 | Iohexol properties. (a) Tridimensional molecular structure. (b) Molecular size.

for extracorporeal circulation propels the solution, see Figure 1a,b. A 1000 mL glass reservoir (Schott 1000 DURAN, Sigma-Aldrich, Darmstadt, Germany) with a stir bar contained the solution. The reservoir remained over a hotplate magnetic stirrer (VELP Scientifica S.r.l., Usmate Velate, Italy). A customized blood tubing system for the extracorporeal circuit had its inlet and outlet extremities connected to the reservoir. The modified cartridge was connected downstream of the peristaltic pump and was held in an upward position, with the inlet port facing downwards. The circuit was primed with saline solution.

2.4 | Cartridge

The authors utilized a mini-module cartridge (1:3 scale model) filled with the sorbent resin of the HA380 commercial cartridge (Jafron Biomedical, Zhuhai City, China) [24]. The cartridge contains 125 mL (105 g) of mesoporous [25] sorbent resin (double crosslinked styrene-divinylbenzene copolymers) in the form of beads with an average diameter of 800 μm. The cartridge's technical data are described in Table 1.

2.5 | Iohexol Sampling and Measurement

The solution was pumped at 250 mL/min at a constant temperature of 37.0°C. The sampling of 2 mL aliquots of the solution occurred at eight time points (0, 5, 10, 15, 20, 30, 40, and 60 min). The samples were diluted 1:250, and the results were obtained after the correction for the dilutional factor. Dilution was necessary to adjust the results within the linearity range of the ultraviolet–visible detector, preventing its saturation and underestimation of iohexol concentration. The analysis of the samples was performed in duplicate at the Biological Sales Network headquarters in Castellone.

The method for the iohexol concentration measurement was high-performance liquid chromatography with ultraviolet (HPLC-UV) detection [20] using the FloChrom kit (Biological Sales Network—B.S.N., Castellone, Italy). The analytes are separated by isocratic chromatography. Notably, iohexol has two structural isomers (i.e., endo- and exo-isomers). The test results in the chromatogram comprise two distinguishable peaks representing the endo and exo forms. Therefore, the total concentration is the sum of the isomers' individual concentrations.

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TABLE 1 | Device (HA380 mini-module) technical data.

Adsorbent material	Double crosslinked styrene-divinylbenzene copolymers
Mass	105 g
Adsorbent volume[a]	125 mL
Priming volume[a]	100 mL
Mean pore size	3.34 nm
Mean bead diameter	~800 μm
Cartridge volume, length, and radius	200 mL, 9 cm, and 2.66 cm
Housing, net rack, end cover, cap nut, and cap material	Polycarbonate
Filter mesh	Polyester
O-ring seals	Silicone
Blood flow range	100–700 mL/min
Effective adsorption area	18.000–20.000 m^2
Sterilization	Gamma irradiation
Manufacturer	Jafron

[a]Information provided by the manufacturer.

2.6 | Parameters and Calculations

The reduction ratio is derived from the following formula:

$$RR_{(t)} = \frac{C_i - C_{(t)}}{C_i} \quad (1)$$

where C_i is the initial concentration, $C_{(t)}$ is the concentration at different time points (t), and consequently, $RR_{(t)}$ is the reduction ratio in the specified time points. The formula to calculate the iohexol mass adsorbed ($Mass_{ads}$) was:

$$Mass_{ads} = C_i \bullet V \bullet RR_{(t)} \quad (2)$$

where C_i is the initial concentration, V is the solution volume, and $RR_{(t)}$ is the reduction ratio at different time points (t).

Finally, iohexol clearance was calculated based on this formula:

$$\text{Clearance (mL/min)} = \frac{\text{Elimination rate (g/min)}}{\text{Concentration (g/mL)}} \quad (3)$$

where the elimination rate is the iohexol $Mass_{ads}$ in a time interval. Thus, the clearance can be calculated as follows:

$$Clearance_{(t1,t2)} = \frac{Mass_{ads\ (t1,t2)}}{[C]_{(t1)} \bullet (t2 - t1)} \quad (4)$$

where the clearance between two time points represented as ($t1$) and ($t2$) equals the mass adsorbed during this time interval divided by the solute concentration or [C] in ($t1$) and by the time interval between ($t1$) and ($t2$).

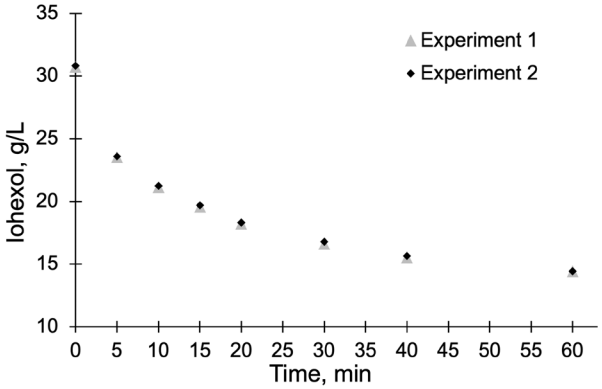

FIGURE 3 | Iohexol concentration at the defined time points.

2.7 | Data Analysis

Due to the experiment's simple descriptive design, specific statistical analyses were unnecessary. Data were plotted in Excel (Microsoft, Redmond, Washington, USA).

3 | Results

3.1 | Reduction Ratio

In experiment 1, after 60 min of recirculation, the iohexol concentration measured by HPLC-UV decreased from 30.73 to 14.44 g/L (Figure 3), with a reduction ratio of 53.0%. In experiment 2, after 60 min of recirculation, the iohexol concentration decreased from 30.82 to 14.44 g/L (Figure 3), with a reduction ratio of 53.1% (Table 2).

3.2 | Iohexol Clearance

Iohexol clearance decay over time for both experiments is represented in Figure 4. In experiment 1, the iohexol clearance was 46.79 mL/min during the first 5 min, decaying to 3.57 mL/min during the last 20 min. Similarly, in experiment 2, the iohexol clearance was 46.72 mL/min during the first 5 min, decaying to 3.87 mL/min during the last 20 min (Table 3).

3.3 | Sorbent Saturation

In both experiments, after 40 min, the reduction in the iohexol concentration was marginal, denoting the sorbent's saturation. At 60 min, the total mass adsorbed was 16.29 g and 16.37 g in experiments 1 and 2, respectively (Table 2). Since each cartridge contained 105 g of sorbent, the ratio of adsorbate/sorbent is approximately 155 mg/g. Therefore, each gram of the sorbent can remove roughly 155 mg of iohexol dissolved in a saline solution at 37.0°C.

4 | Discussion

This in vitro study demonstrates that iohexol is efficiently removed from a saline solution via adsorption with a styrene-divinylbenzene resin. The two experiments yielded almost identical results.

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TABLE 2 | Iohexol kinetics in an in vitro adsorption closed-loop circuit.

Time (min)	Reservoir (g/L) experiment 1—mean	Reservoir (g/L) experiment 2—mean	Reduction ratio (%) experiment 1	Reduction ratio (%) experiment 2	Mass adsorbed (g) experiment 1	Mass adsorbed (g) experiment 2
0	30.73	30.82	—	—	—	—
5	23.54	23.60	23.4	23.4	7.19	7.21
10	21.12	21.23	31.3	31.1	9.62	9.56
15	19.57	19.70	36.3	36.1	11.15	11.13
20	18.21	18.30	40.7	40.6	12.51	12.51
30	16.63	16.78	45.9	45.6	14.10	14.05
40	15.55	15.65	49.4	49.2	15.18	15.16
60	14.44	14.44	53.0	53.1	16.29	16.37

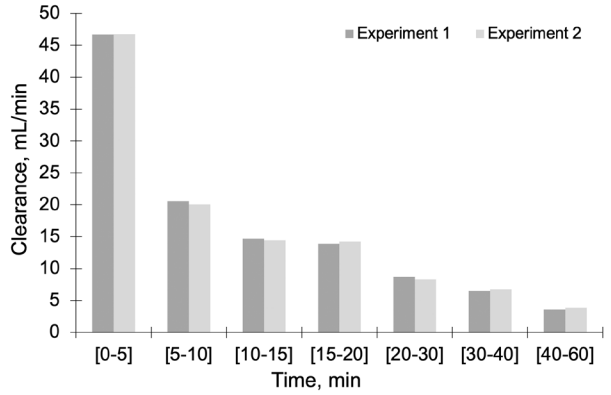

FIGURE 4 | Iohexol clearance at the defined time points.

Approximately half of the total iohexol mass was cleared from the solution during the experiment, which comprised 60 min of recirculation. Of note, roughly 50% of the removal occurred during the first 5 min, whereas only about 4% occurred during the last 20 min. From a clearance perspective, during the first minutes, the iodinated contrast clearance was 47 mL/min, while it decayed to around 4 mL/min from 40 min onwards.

The rapid removal of the solute during the first minutes is consistent with similar in vitro experiments evaluating the removal of medications such as ticagrelor, [26] factor Xa inhibitors (anticoagulants), [27, 28] anticonvulsants, [29] and antimicrobials [30–32]. In these other experiments with distinct target solutes, the bulk of removal also occurred in the first 60 min.

The use of saline as the solvent is a limitation of our study. The presence of other solutes in plasma or whole blood could decrease adsorption efficiency. Therefore, the assessment of efficacy in vitro using saline cannot be extrapolated for the clinical context. Probably, the efficiency in clinical use is not as much as pointed out by our results. This can occur because of competition for adsorptive sites in the resin and unintended protein (e.g., fibrinogen) deposition and pore obstruction in the beads, preventing the interaction between solutes and the sorbent outer and inner surfaces. The pump flow was set at 250 mL/min, impeding explorations related to flow variations. Remarkably, in clinical practice, because of vascular access constraints or patient characteristics (e.g., pediatric setting), a blood flow of 250 mL/min is not always attainable. Indeed, it would be relevant to explore this variable because one foreseeable application of hemoadsorption to mitigate CA-AKI would use a 7 French peripherally inserted central dual-lumen catheter as the vascular access. This less invasive strategy prevents the placement of a hemodialysis catheter. At lower solvent flows, there is more time for interaction between the fluid phase and the sorbent, at the cost of taking a more extended period to circulate all the solution through the cartridge, which can impact the adsorption kinetics. Another independent variable we did not explore was the initial solute concentration. A higher initial concentration may intensify the clearance decay over time.

Our data show that each gram of resin can adsorb approximately 155 mg of iohexol. The commercially available cartridge HA380 has 310 g of resin. Hence, ~50 g of iohexol can be adsorbed in this cartridge, equivalent to the amount present in 66 mL of OMNIPAQUE 350. In complex procedures such as transcatheter aortic valve replacement, the mean volume of contrast administered is 100 mL [18]. This implies that roughly two-thirds of the iohexol mass in this volume could be removed in a 1 to 2-h hemoadsorption session with the HA380 cartridge before saturation [18]. From a clinical perspective, two consecutive treatments, each using one HA380 cartridge, could enhance contrast elimination and minimize the exposure of body tissues to the contrast medium.

Currently, guidelines advocate against the use of hemodialysis following exposure to iodinated contrast to prevent or mitigate AKI. Furthermore, for patients on maintenance dialysis, there is also a recommendation to discourage anticipation of a dialysis session after contrast administration to preserve residual kidney function [33, 34]. One randomized clinical trial failed to demonstrate the usefulness of hemodialysis in reducing acute kidney disease following contrast medium exposure in chronic kidney disease patients [35]. Owing to the fact that the extraction of iodinated contrast by adsorption seems quicker than what has been demonstrated with hemodialysis, [36] clinical trials with hemoadsorption could yield beneficial

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TABLE 3 | Iohexol clearance by adsorption.

Time (min)	Elimination rate (g/min) experiment 1	Elimination rate (g/min) experiment 2	Clearance (mL/min) experiment 1	Clearance (mL/min) experiment 2
0–5	1.438	1.440	46.79	46.72
> 5–10	0.484	0.474	20.56	20.08
> 10–15	0.310	0.306	14.68	14.41
> 15–20	0.272	0.280	13.90	14.21
> 20–30	0.158	0.152	8.68	8.31
> 30–40	0.108	0.113	6.49	6.73
> 40–60	0.056	0.061	3.57	3.87

results concerning the occurrence of AKI. Besides, other conditions induced by iodinated contrast, such as iodide sialadenitis [37–39], and encephalopathy, [40] might be obviated with hemoadsorption.

5 | Conclusion

A 1:3 scale model of the HA380 cartridge containing 105 g of styrene-divinylbenzene resin efficiently removes iohexol in an experimental extracorporeal blood purification circuit setup. In proportion, the mass removed would represent roughly two-thirds of the amount administered in major cardiac endovascular interventions. These findings provide a rationale for exploring hemoadsorption as an intervention in clinical trials to prevent or mitigate CA-AKI in high-risk patients.

Author Contributions

Thiago Reis: conceptualization (lead); methodology (lead); writing – original draft (lead); writing – review and editing (lead); investigation (equal); visualization (lead). **Gonzalo Ramírez-Guerrero:** investigation (equal); writing – original draft (supporting); writing – review and editing (equal). **Roberto Pecoits-Filho:** writing – original draft (supporting); writing – review and editing (equal). **Anna Lorenzin:** investigation (equal), writing – original draft (supporting); writing – review and editing (equal). **Massimo de Cal:** investigation (equal); writing – original draft (supporting); writing – review and editing (equal). **Valentina Corradi:** investigation (equal); writing – original draft (supporting); writing – review and editing (equal). **Gerd Klinkmann:** writing – original draft (supporting); writing – review and editing (equal). **Federico Ronco:** conceptualization (equal); writing – original draft (supporting); writing – review and editing (equal). **Francisco A. R. Neves:** writing – original draft (supporting); writing – review and editing (equal). **Rinaldo Bellomo:** writing – original draft (supporting); writing – review and editing (equal). **Claudio Ronco:** conceptualization (lead); methodology (lead); writing – original draft (equal); writing – review and editing (equal); investigation (equal); visualization (lead); resources (lead); supervision (lead); project administration (lead).

Acknowledgments

The authors have nothing to report.

Conflicts of Interest

TR has received funding for lectures and has been consultant or advisory board member for Alexion, AstraZeneca, B. Braun, Baxter, bioMérieux, Boehringer Ingelheim, Contatti (CytoSorbents), Eurofarma, George Clinical, Jafron, Lifepharma, Medcorp, Nipro, and Nova Biomedical. GK has received funding for lectures for Artcline and CytoSorb Europe and has received research grants from the German Research Foundation and the German Society of Anaesthesiology and Intensive Care. RB has been on advisory boards or speaker's bureau for Baxter and Jafron. CR has been on advisory boards or speaker's bureau for AstraZeneca, Aferetica, Asahi, B. Braun, Baxter, bioMérieux, CytoSorbents, GE, Medica, Medtronic, and Jafron. The other authors has no conflicts of interest.

Data Availability Statement

Data are available on request due to privacy or other restrictions.

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