

controlled clinical trials are hardly feasible, among others because of the substantial administrative and financial burden on the required patient recruitment. In addition, rare acute diseases are usually outside the interest of research-based pharmaceutical industry, because, unlike rare chronic illnesses, medication is limited in time and sales revenue is not guaranteed. In contrast, registry observations allow an almost complete picture of the target population and insight into potential treatment options.

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International registry on the use of the CytoSorb®-Adsorber in ICU patients (NCT02312024)

Schein M (1), Bahr V (1), Reißner F (1,2), Jakob M (1), Schumacher U (1), Brunkhorst FM (1,2)

(1) Center for Clinical Studies Jena (ZKS), Jena University Hospital, Jena, Germany, (2) Center for Sepsis Control and Care (CSCC), Jena University Hospital, Jena, Germany.

Introduction: Clinical registries are valuable tools for assessing long term benefits of medical applications. The efficacy of treatment methods and medical devices can be evaluated and compared. In addition, registries are supportive of the transfer new technologies into clinical routine.

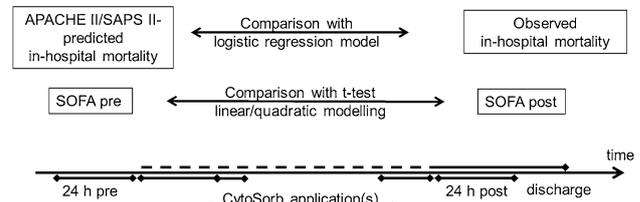
Objectives: The aim of this registry is to record the use of CytoSorb® under real life conditions in as many cases as possible (preferably all or, at least, in a representative sample). All CytoSorb® applications in different clinical settings and in all patients who are treated with this technology are planned to be included (Study website: <http://www.cytosorb-registry.org/>).

Methods: The objectives of the registry are collection of real-life data on a broad scale, their centralized, structured and comprehensive documentation, and a controlled data exchange. The gathered information will be used to augment the knowledge on the clinical efficacy of the technology, to optimize the quality of its therapeutic application, and to identify and promptly handle possible complications related to the use of CytoSorb®. The registry will record all relevant information in the course of product use, e.g. diagnosis, comorbidities, course of the condition, treatment, concomitant medication and clinical laboratory parameters. The registry will inform physicians of different medical specialties about the range of possible applications of CytoSorb® and invite them to contribute their own experiences to the registry. This is done by giving them access to their own data and to the results of periodic analyses (for contributing participants), and via publications of the results (for participants and external interested parties)

Results: The CytoSorb® registry will provide the data base for justified and optimized decisions. An active form of data collection where data is prospectively collected by qualified staff is particularly suited for this purpose. Registry data might help closing knowledge gaps and open practical issues. Due to the patient group's heterogeneity, the registry can identify sub-groups, assess their risk–benefit-profile and examine their safety profile. Registry data are absolutely essential for assessing a therapy's significance within the healthcare landscape.

Institutions that contribute data to the registry benefit in several ways: They will obtain a continuous retrospective feedback of their own results, their data will be periodically compared with data from other participating sites, and they will get access to regularly published analyses of the results of all participants. On the basis of these data, they can establish a quality monitoring and optimize their use of CytoSorb®.

Conclusions: The planned endpoints allow for a comprehensive description of CytoSorb® efficacy in terms of several indication-relevant aspects. Together with the monitoring of application safety, these data build the basis for establishing benchmarks that promote a higher treatment quality.



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Case report of 1 Patient with multiorgan failure due to severe SIRS in cardiac failure treated additional with Cytosorbents haemadsorption as adjunctive therapy

Kogelmann K (1), Drüner M (1), Jarczak D (2)

(1) Department of Anesthesiology and Intensive Care Medicine, Klinikum Emden, Germany, (2) Department of Intensive Care Medicine, University Hospital Hamburg, Germany.

Introduction: In several studies and in in vitro data is demonstrated that the additional treatment with an extracorporeal cytokine adsorption filter (CytoSorb®) may be helpful not only in patients with septic multiple organ failure but also e.g. in severe pancreatitis or other critical diseases due to an excess of cytokines (1). The effect is based on biocompatible, highly porous polymer beads able to capture and adsorb cytokines and other middle molecules (1, 2, 5, 6, 9, 11, 12). CytoSorb® therapy has meanwhile been used in over 200 hospitals worldwide in more than 5500 patients and is well tolerated and safe.

Methods: We treated one patient with severe SIRS and multiorgan failure in cardiogenic shock due to refractory cardiac arrhythmia. Hospital admission of our patient took place after she collapsed several times at home. Glasgow Coma scale was 11, heartrate was ~20 bpm, hypothermia was measured with 30 °C, metabolic acidosis with pH 7.2, no blood pressure measurable. Immediately resuscitation followed and after that, the patient developed severe SIRS and multiorgan failure in cardiogenic shock due to refractory cardiac arrhythmia. Patients history results in peripheral arterial obstructive disease, arterial hypertension and former minor stroke.

Initial ultrasound of the heart function shows diffuse hypokinesia and an ejection fraction at about 45 % with a heartrate by 36 bpm. After 24-h conventional treatment (differentiated catecholamine therapy with combined norepinephrine and adrenaline, ultrasound guided volume therapy, lung-protective ventilation, administering temporary cardiac pacemaker), CytoSorb® therapy and CRRT was initiated because of no decline in catecholamine demand associated with a persistent renal failure. Ultrasound control showed diffuse dysfunction and hypokinesia with an ejection fraction at about 50 %. Chest X-ray at admission shows Fig. 4. Laboratory and electrocardiography at admission showed neither myocardial infarction nor infectious items but high elevated liver enzymes and creatinine (Table 1).

Before treatment, during treatment and after treatment with CytoSorb® we calculated or collected SAPS II-Score, SOFA-Score, mean arterial pressure, requirement of norepinephrine, and blood lactate level. Furthermore we calculated the demand of norepinephrine (µg/h vs. mm Hg MAP) during therapy. The

duration of therapy with CytoSorb® was 72 h, the filter was changed every 24 h.

Results: During CytoSorb® therapy we determined a decrease in catecholamine demand from more than 95 %, 72 h after therapy the patient had been free of catecholamines. SOFA Score didn't change, SAPS II-Score was divided in halves. Blood lactate decreased from 46.9 to 21.4 mg/dl. GOT max 5355 U/L, 3 days later 431 U/L. GPT from 4858 U/L down to 888 U/L. LDH from 6859 down to 242 U/L (Table 1; Fig. 3). 12 days after treatment the liver enzymes declined to normal values. Chest X-ray 10 days after admission showed only slightly effusions, 6 days later we could finish ventilation and our patient was alert, vigilant and in stable clinical condition without any catecholamine demand. During therapy we determined blood natriuretic peptide level tenfold increased with 1959 pg/ml as a marker from left ventricular dysfunction.

In coronary angiography there was shown a three vessel coronary artery disease with ischemic cardiomyopathy as a reason for patients refractory cardiac arrhythmia which leads to severe SIRS.

Collected data during therapy showed in Table 1 and Figs. 1, 2, and 3. Figures 4 and 5 showed initial and end-of-therapy chest X-ray.

Table 1: Descriptives, scores, laboratory values

	Pre CYTO	Cyto day1	Cyto day2	Cyto day3	24 h Post CYTO	12 days post Cyto
SAPS II-score	73	68	52	53	41	25
SOFA score	16	18	14	18	17	4
MAP (mmHg)	35	50	70	65	75	70
μNOR vs MAP (μg/h * mmHg)	114.2	50	11.4	9.2	6.7	0
Lactat (mg/dl)	55	50	46.9	43.4	29.9	10
Creatinin (mg/dl)	2.48	3.2	1.84	1.36	1.29	1.8
CK (U/L)	227	1694			577	41
LDH (U/L)	3140	6859			242	264
GOT (U/L)	2698	5355			431	27
GPT (U/L)	2195	4858			888	38
Leuko (1000/μl)	15.2	10.1	4.74	5.36	11.2	10.3
PLT (1000/μl)	157	99	68	44	36	250
PCT (ng/ml)					0.67	0.47

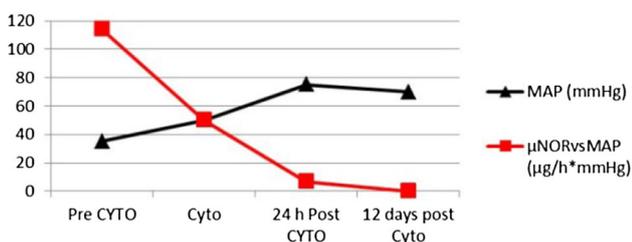


Fig. 1 μg Norepinephrine/h * mm Hg MAP

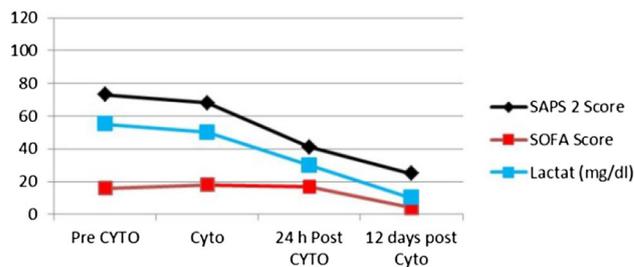


Fig. 2 SAPS II-Score, SOFA-Score, Lactate (mg/dl)

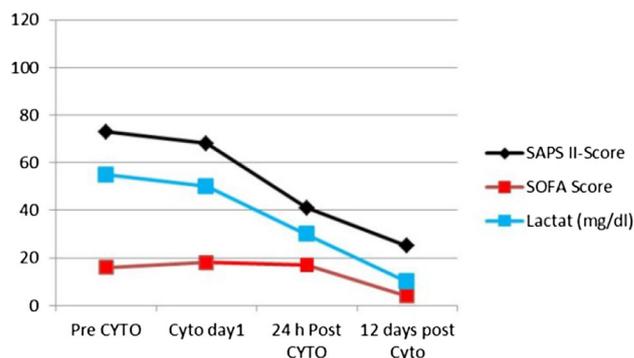


Fig. 3 Laboratory values

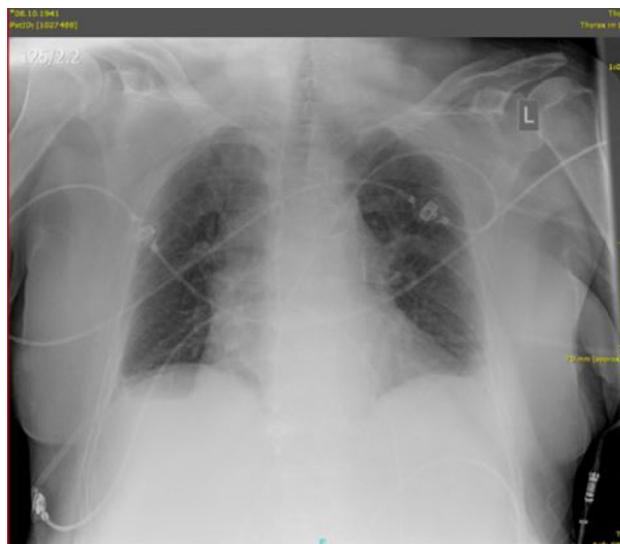


Fig. 4 Chest X-ray at hospital admission

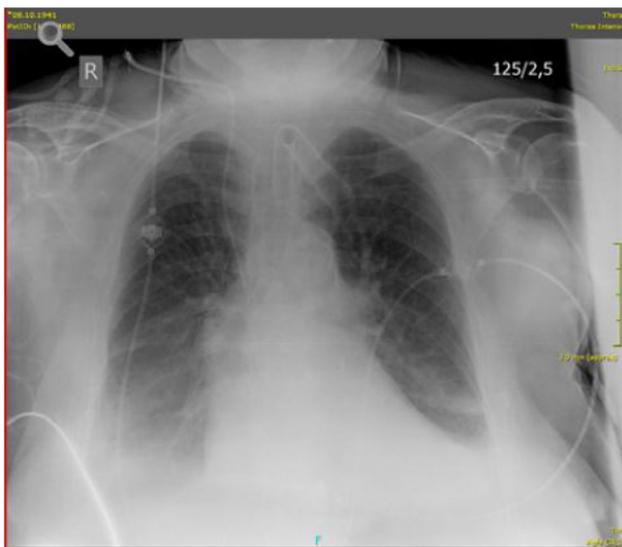


Fig. 5 Chest X-ray at end of CytoSorb® therapy

Conclusions: In this case report from one patient with severe cardiac failure due to ischaemic cardiomyopathy one effect we could see was a pronounced decrease in catecholamine demand. SAPS II-Score decreased into halves, SOFA-Score in treatment period and within 72 h after CytoSorb® therapy didn't change. As a second effect, liver enzymes, blood lactate and creatinine decreased fast and normalized after 2 weeks. Treatment with CytoSorb® adsorption filter in this patient had shown great effect, been safe and without any noticed side effects.

We found that CytoSorb® therapy was helpful even in a patient with severe cardiac failure and thereby initiated severe SIRS.

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Sepsis Prevention and Pediatric Sepsis Research

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The effect of daily skin decolonization with chlorhexidine on hospital-acquired infections in the ICU

Kulpa K, Nieckula-Szwarc A, Duszynska W, Lentka K, Adamik B, Kübler A

Department of Anaesthesiology and Intensive Therapy, Wrocław Medical University, Borowska St. 213 50-550 Wrocław, Poland.

Introduction: Hospital acquired infections (HAI) are associated with significant morbidity, mortality, and increased healthcare costs. Skin is a major reservoir of bacterial pathogens in intensive care unit (ICU) patients and decolonization with antiseptic chlorhexidine may reduce the incidence of HAI s.

Objectives: Our objective was to evaluate whether daily bathing of patients with chlorhexidine would reduce the rate of bloodstream infections (BSI), ventilator acquired infections (VAP), and urinary tract infections (UTI) in ICU patients.

Methods: The study setting was 14-bed ICU at the tertiary care hospital in Wrocław, Poland. This prospective, observational study consisted of two periods: (1) three-month baseline period when all patients admitted to the ICU underwent routine daily baths with soap and water, (2) four-month interventional period, when all patients admitted to the ICU received daily skin cleansing with 2 % CHG-impregnated washcloths (Sage 2 % CHG cloths; Sage Products Inc, Cary, Illinois). The overall rate of HAI and rates of hospital-acquired BSI, VAP, and UTI were compared between the two periods.

Results: 104 ICU patients were included during the 1st period (control group) and 147 patients were included during the 2nd period (intervention group). In the control group the overall rate of HAIs was 36.5 % and the HAIs density was 36.2/1000 patients days; the rate of BSI was 17.8 cases/1000 CVC days, of VAP 16.7 cases/1000 ventilator days, and of UTI 9.3 cases/1000 UC days. In the intervention group the overall rate of HAIs was significantly lower—20.4 % ($p = 0.002$) and the HAIs density was 19.5/1000 patients days ($p = 0.01$); the rate of BSI was 8.3 cases/1000 CVC days ($p = 0.02$), VAP 9.3 cases/1000 ventilator days ($p = 0.25$), and UTI 5.3 cases/1000 UC days ($p = 0.31$). There were no adverse events observed related to the method studied.

Conclusions: In our study daily skin decolonization with chlorhexidine-impregnated washcloths reduced significantly the rate of hospital acquired infections, particularly the rate of bloodstream infections, in ICU patients. This approach is easy to implement, safe and efficient for the prevention of hospital-acquired infections.

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Infection 2015

Cost benefit analysis of interventions for prevention of hospital acquired infections: a systematic review

Arefian H (1,2), Vogel M (3), Hartmann M (1,2)

(1) Center for Sepsis Control and Care (CSCC), Jena University Hospital, Jena, Germany, (2) Hospital Pharmacy, Jena University Hospital, Jena, Germany, (3) Center for Clinical Studies, Jena University Hospital, Jena, Germany.