

First experience with the deltastream® DP3 in venovenous extracorporeal membrane oxygenation and air-supported inter-hospital transport

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Abstract

OBJECTIVES: Based on continuous technical innovations and recent research, extracorporeal membrane oxygenation (ECMO) has become a promising tool in the treatment of patients with acute (cardio)pulmonary failure. Nevertheless, any extracorporeal technique requires a high degree of experience and knowledge, so that a restriction to specialized centres seems to be reasonable. As a consequence of this demand, the need for inter-hospital transfer of patients with severely impaired (cardio)pulmonary function is rising. Unfortunately, most of the ECMO devices used in the clinical setting are not suitable for inter-hospital transport because of their size, weight or complexity. In this article, we describe our first experiences with the airborne transport of 6 patients on a new portable, miniaturized and lightweight extracorporeal circulation system, the Medos deltastream® DP3.

METHODS: Six patients suffering acute respiratory failure were taken on venovenous ECMO (DP3) out-of-centre and transferred to the University Medical Center Regensburg by helicopter. All cardiorespiratory-relevant parameters of the patients and the technical functioning of the device were continuously monitored and documented.

RESULTS: Implantation of the device and air-supported transport were performed without any technical complications. The patients were transported from a distance of 66–178 km, requiring a time of 40–120 min. With the help of the new deltastream® DP3 ECMO device, a prompt stabilization of the cardiopulmonary function could be achieved in all patients. One patient was under ongoing cardiopulmonary resuscitation by the time our ECMO team arrived at the peripheral hospital and died shortly after arrival in the central emergency ward.

CONCLUSIONS: Our experience shows that the deltastream® DP3 is an absolutely reliable and safe ECMO device that could gain growing importance in the field of airborne transportation of patients on ECMO due to its unsophisticated, miniaturized and lightweight characteristics.

Keywords: Miniaturized extracorporeal membrane oxygenation • Inter-hospital transport • Acute respiratory distress syndrome • Extracorporeal membrane oxygenation

INTRODUCTION

As a consequence of multiple technical innovations, in recent years extracorporeal membrane oxygenation (ECMO) systems have gained widespread use in patients with acute pulmonary and cardiac failure. Since the first description of a successful ECMO intervention in 1972, systems have become more effective, smaller and even portable [1–3]. Depending on the site of cannulation, it is possible to support patients with pulmonary, cardiac and cardiopulmonary failure. In 1989, this development contributed and resulted in the founding of the Extracorporeal Life Support Organization (ELSO), a scientific platform that provides information, education and guidelines on ECMO therapy.

The intensive-care therapy of patients on ECMO systems today is still complex and ideally should be restricted to specialized centres offering more technical and personnel experience. Patients suffering from severe (cardio)pulmonary failure should therefore be transported to these specialized centres. On the other hand, critically ill patients with acute pulmonary and/or cardiac failure are often so unstable that implantation and initiation of extracorporeal support may be indicated before transport to one of these centres.

Even though transporting patients on ECMO systems is challenging, it proves to be a promising option that increases patient's safety by prompt stabilization of haemodynamics and reduction of hypoxaemia [3].

In this paper, we report on our initial experience in air-supported inter-hospital transports with a completely new, minimized ECMO device for patients with acute (cardio)pulmonary failure.

PATIENTS AND METHODS

Patients

During the last 7 years, we have provided the initiation of out-of-centre ECMO therapy and inter-hospital transport to our institution for >180 patients. Our previous experience included two other portable devices: the Cardiohelp and ELS-system (Maquet Cardiopulmonary AG, Hechingen, Germany). In January 2011, we started to use an even smaller device, the deltastream® DP3 (Medos Cardiopulmonary Solutions, Stolberg, Germany) (Fig. 1). Up to now 6 patients have been transported in a helicopter (Eurocopter, EC 145) with this system. All of these patients were in a life-threatening cardiopulmonary situation by the time of arrival of the transport ECMO team. One of them required cardiopulmonary resuscitation and most were on vasopressor support. In all patients, mechanical ventilation had been started 1–3 days pre-transport. In 3 cases, the indication for ECMO was pulmonary failure according to community acquired pneumonia, pulmonary embolism in 2 cases and a non-specified underlying disease in 1 case. The average time on ECMO ranged between 1 and 42 days. A complete overview of all patient data is given in Table 1.

Materials

Device. As a new minimized ECMO device, we used the deltastream® DP3 in combination with the HILITE 7000 LT (both Medos Cardiopulmonary Solutions, Stolberg, Germany) oxygenator. The deltastream® DP3 is an axial rotation pump, which is driven by a unique diagonally streamed impeller and is approved for 7 days of use. Regardless of its small physical dimension, the pump head achieves a speed of 500–10000 rpm with a consecutive blood flow range of up to 8 l/min, depending on afterload pressure. In

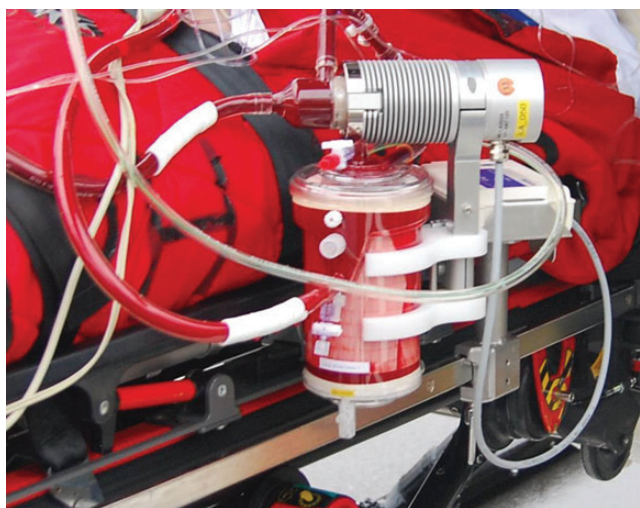


Figure 1: Fixation of the deltastream DP3 to the standard Stryker stretcher via a special metal bracket.

combination with the internal battery system, it offers a power supply of 2 h. The HILITE 7000 LT oxygenator contains a dense membrane (polymethylpentene) with a surface of 1.9 m² for gas exchange. Its blood flow ranges from 1–7 l/min and the static priming volume is 275 ml. The system is completely heparin coated (Reoparine Medos AG) and has a priming volume of ~500–600 ml. All together, the different components built a very compact and easy-to-handle device with a weight of 5 kg. During the complete transport, the ECMO device was safely fixed to the standard stretcher via a special metal bracket (Fig. 1).

Cannula. In 5 patients, a 38 cm long, 21-French cannula (BE-PVS 2138, Maquet CP, Hechingen, Germany) was used for drainage in the right femoral vein, whereas the return of the oxygenated blood was achieved by a 15 cm long, 17-French cannula via the right jugular vein. In 1 patient with a body mass index (BMI) of 65 and ongoing CPR, an Avalon Elite 27 French bicaval dual lumen cannula (Avalon Laboratories, Rancho Dominguez, CA, USA) was placed in the right jugular vein.

Methods

Indication. All patients were referred to our ECMO centre from external hospitals via telephone. According to a standard procedure protocol, all relevant patient data were collected and indication for ECMO therapy was set by a specialized and experienced intensivist. Decision-making was based on the actual guidelines of the ELSO from 2009 [4].

After the patient was deemed suitable for out-of-centre ECMO implantation and inter-hospital transfer, the referring hospital was asked to order two units of blood and have available an ultrasonic device for vascular access evaluation. Immediately, the special ECMO team was informed and further airborne transport organized.

Transport team and equipment. Our team consisted of a cardiac anaesthesiologist and a clinical perfusionist, in order to meet the requirements of ECMO therapy and inter-hospital transfer of critically ill patients. The team was specially educated in the implementation, transportation and provision of care of patients on ECMO systems in the intensive care unit (ICU) [5].

The necessary equipment was prepared in a special backpack and the arrangement of the ECMO device only took a few minutes, so the team could start without any delay. Transport of the ECMO team and patient was carried out by a rescue helicopter type EC 145 (Christoph Regensburg, DRF Stiftung Luftrettung, Filderstadt, Germany).

Patient care. Upon arrival at the referring hospital, the team re-evaluated and confirmed the life-threatening situation and the indication of starting the ECMO therapy. This decision was based on the actual laboratory, cardiac and respiratory findings. If possible, approval of patients or family members was obtained. Furthermore, the mode of extracorporeal life support (single vs double lumen) and the site of cannulation were determined.

Vascular access was achieved using a modified, ultrasound-guided Seldinger technique. An immediate blood gas analysis served as verification of a correct vessel puncture (vein vs artery). According to the patient's coagulation status, a bolus of 5000 I.U. heparin was administered (after placing the guide wire and dilators for the first cannula) to achieve a partial thromboplastin time value between 1.5 and 2 times above the normal range.

Table 1: Patient characteristics (on-scene)

Patient	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Age/gender	49/M	50/F	57/F	49/M	44/F	54/F
BMI (kg/m ²)	33.8	54.7	44.1	23.3	37.2	64.3
Days in-hospital before ECMO (days)	4	2	3	6	6	8
Ventilation before ECMO (days)	2	1	1	1	1	3
Resuscitation before ECMO	No	No	No	No	No	Yes
SOFA score	6	10	8	5	7	
Murray score	2.67	3.67	3.33	2.67	3.67	
PaO ₂ /FiO ₂ -ratio (mmHg)	59	29	87	120	62	43
PaCO ₂ (mmHg)	41	67	52	42	40	72
Lactat (mg/dl)	25	11		10	20	162
Mean arterial blood pressure (mmHg)	61	55	78	81	63	CPR
Norepinephrine (mg/h)	0	3.5	0.5	0	0.5	5.0

ECMO: extracorporeal membrane oxygenation; SOFA: Sequential Organ Failure Assessment.

For all patients requiring venovenous ECMO, the outflow cannula was placed in the right femoral vein with the tip placed in the inferior vena cava and the inflow cannula was placed in the right internal jugular vein with the tip in the superior vena cava. Correct positioning of the cannulas was verified via X-ray or ultrasonic measurement upon arrival at our institution. All cannulas were fixed using the Hollister systems (Hollister, Libertyville, IL, USA) to avoid displacement during the transport. ECMO flow was initiated with blood flow rates ranging between 2.7 and 4.0 l/min. After cardiopulmonary stabilization, an actual blood gas analysis was performed to adapt and optimize the ventilator support. According to generally accepted guidelines of inter-hospital transport, a portable patient monitoring system (Corpulse3, GS Elektromed. Geräte G. Stemple GmbH, Kaufering, Germany) including heart rate, invasive and non-invasive blood pressure, end-tidal CO₂-measurement and continuous oximetry was employed and patients were placed on a standard stretcher (Stryker EMS, Portage, MI, USA) [6]. During the following transport, the peripheral oxygenation saturation was held between 93 and 96% and the mean blood pressure was held >60 mmHg.

RESULTS

Patients

Case 1. A 49-year old male patient developed respiratory failure as a consequence of central pulmonary embolism, following heparin-induced thrombocytopenia. He was treated with VV-ECMO support for 10 days and immediate thrombolysis was performed on the system with recombinant tissue plasminogen activator. After 12 days of intensive care stay he recovered fully. Because of the underlying disease (lung embolism), a venoarterial ECMO approach was considered on scene, but was not performed as transoesophageal echocardiography showed an only slightly impaired right cardiac function without the need for catecholamines.

Case 2. A 50-year old female patient with pre-existing obesity (BMI 54.7 kg/m²) suffered an acute respiratory distress syndrome (ARDS) due to a H1N1-infection. Conventional respiratory support failed, so that by the time of ECMO-team arrival severe hypoxaemia (PaO₂ 29 mmHg) and metabolic disarrangement

were present. She was supported with VV-ECMO for 10 days and survived without any sequelae.

Case 3. A 57-year old female patient also with pre-existing obesity (BMI 44.1 kg/m²) suffered from respiratory failure due to a H1N1-infection. She was supported with VV-ECMO for 8 days. After continuous improvement and successful weaning from respiratory support she could be referred to her home hospital after 15 days.

Case 4. A 49-year old male patient presented severe respiratory failure according to an out-of-hospital acquired bacterial pneumonia. VV-ECMO was initiated and the patient stayed on the system for >1 month, during which he woke up without any neurological pathological findings. Unfortunately, his pulmonary function did not improve due to fibrotic remodelling. As a consequence of the increasing pulmonary resistance, he developed right heart failure and died after 42 days of ECMO therapy.

Case 5. A 44-year old female patient with pre-existing obesity and tick-borne encephalitis developed severe respiratory failure due to a postinfarction pneumonia after recurrent pulmonary embolism. She was connected to VV-ECMO and transported to our hospital. After 7 days on the system, she had to stay on ICU for 3 more days. Finally, she was referred to her home hospital with a favourable neurological and cardiopulmonary status.

Case 6. A 54-year old female patient with pre-existing obesity (BMI 65) suffered ARDS due to unknown reasons. By the time the ECMO team arrived she had to undergo cardiopulmonary resuscitation (CPR) due to severe hypoxaemia. With ongoing CPR and manifest fungal infections in both groins, a double-lumen cannula was placed in the right internal jugular vein and ECMO therapy was started. After immediate stabilization and transport, she died from ventricular fibrillation in the emergency ward.

On average, the patients were transported from a distance of 66–178 km requiring a time of 40–120 min. Initiation of ECMO therapy took between 20 and 45 min. An overview of all transport data is given in Table 2.

Complications

Out-of-centre ECMO implementation and airborne transportation on the delstream® DP3 ECMO device could be performed without any system-related complications.

Table 2: Transport characteristics and results

Patient	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Implementation time (min)	35	40	45	20	25	30
Time on scene (min)	115	90	120	90	100	100
Transport distance (km)	66	148	154	66	159	178
Transport time (min)	40	55	58	40	80	120
Complications during transport	No	No	No	No	No	No
Overall survival	Yes	Yes	Yes	No	Yes	No

DISCUSSION

In this article, we describe the initial experiences with transporting patients on the delastream® DP3 ECMO device by helicopter. All patients were in a life-threatening situation and ECMO implementation on scene could be performed without any problems. Transporting these patients on this new system was safe and no system-related complications occurred.

VV-ECMO as a therapeutic option for severe respiratory failure has gained increasing acceptance over recent years. The indications for implementation of these systems also seem to face a kind of change: VV-ECMO meanwhile is seen as a promising tool to establish and guarantee lung protective or ultra-protective ventilation rather than a pure salvage therapy for refractory hypoxaemia, hypercapnia and acidosis [7]. Though the definite value of keeping the lung at rest still remains uncertain, this approach is at least one option in the treatment of ARDS.

However, the widespread use of ECMO should not suggest that its implementation was trivial and free of potentially life-threatening complications, particularly when performed out-of-centre [8]. Besides, the intensive-care treatment of patients on ECMO systems requires a lot of experience and a highly skilled team. Therefore, the ECMO procedure should be restricted to specialized centres. Unfortunately, the pre-existing diseases that make patients eligible for ECMO therapy often show a dramatic progression over the course of time. As a consequence, transporting these patients to specialized centres is risky, even though implementation of ECMO is indicated. Even within the highly respected CESAR-Trial 3 patients died before they could be transferred and 2 died in transit, so the authors propose the initiation of ECMO therapy at the donor hospital as a promising option [9]. In this context, airborne inter-hospital transport is possibly the most time-saving procedure within a certain distance. Despite its complexity, transporting patients on ECMO is described to be safe, if carried out by an experienced and skilled team [10–15]. At our hospital, we have managed to install a special ECMO team, which is integrated in the clinical routine operation but is available 24/7 in case of emergency [16]. By this, the response time can be kept <20 min during normal working hours. Furthermore, this team consists of anaesthesiologists and clinical perfusionists that have wide experience in all kinds of ECMO therapy, but also in intensive care and emergency medicine. In our opinion, it is exactly this skill level, in combination with an interdisciplinary approach, which guarantees high-quality medicine and subsequently patient safety. Analogous to other clinical settings, ECMO therapy performed by a team of specialists could influence patient outcome [17].

But as the need for inter-hospital transfer of patients on ECMO increases, the demands on these systems are also rising: they should be small, lightweight, easy to handle, secure and absolutely

reliable. Prior research by our group has proposed the *Cardiohelp system* as one of the possible options in similar indications [18]. The newly developed delastream® DP3 described here now presents another alternative. This device appears to be absolutely unsophisticated and robust, with a total weight of ~5 kg. From the moment of the implementation until the handing over of the patient on ICU, we did not face any system-related complications or adverse effects. Potential critical moments like landing or take-off did not result in any changes of blood flow or venous drainage. Besides, the typical helicopter-associated vibrations did not cause any problems. Concerning the expected transport times and distances (Table 2), the battery-driven power supply of ~2 h was sufficient, at least in our setting. Because of patient-safety concerns, the ECMO team had to carry along a replacement battery and a manual drive, but both instruments were never used. Even in 1 case where the time between implementation of the system and the arrival at the destination ICU exceeded 150 min, we did not have to change the power supply. Concerning the efficacy in regard to oxygenation and CO₂-removal, the delastream® DP3 showed excellent performance and was fully equivalent to all the other devices that we used for transportation. As a consequence, the invasive degree of mechanical ventilation could immediately be reduced in all of the described cases to maintain an oxygenation saturation >93%.

By the time of on-scene-arrival of our ECMO team, 1 patient was already under ongoing cardiopulmonary resuscitation. Because of hypoxaemia as the most probable underlying cause, we decided to start VV-ECMO. Unfortunately, this patient presented with a BMI of 65 and fungal infections in both groins, so that a double-lumen Avalon cannula was inserted during CPR. In this situation neither echocardiography, which is our standard procedure, nor radiology was available due to the infrastructure of the external hospital. After a short time of stabilization, the transport could be performed, but the patient died in the central emergency ward from malignant dysrhythmia. The reason for this remained unclear as the relatives refused autopsy. There were no signs of device-malfunction and both constant flow of 4 l/min and an unimpaired oxygenation were present. A possible correlation to the Avalon cannula, as recently published, also remains speculative [19, 20].

CONCLUSION

The delastream® DP3 ECMO device is highly efficient in treating adult patients with pulmonary failure. Its lightweight and compact characteristics make it a promising system for inter-hospital transfer, particularly for transport by air. However, due to our small number of patients, further investigations are required for

evaluating the definite benefit of the deltastream® DP3 in the clinical setting of airborne inter-hospital transfer.

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Conflict of interest: Alois Philipp is Chief Perfusionist at the University Medical Center Regensburg and a member of the technical advisory board of Maquet Cardiopulmonary Care. All other authors have no conflict of interest to declare.

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