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ORIGINAL ARTICLE

Extracorporeal membrane oxygenation for interhospital transfer of severe acute respiratory distress syndrome patients: a 5-year experience

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ABSTRACT

Purpose: *Transfer of severely hypoxic patients is a high-risk procedure. Extracorporeal Membrane Oxygenation (ECMO) allows safe transport of these patients to tertiary care institutions. Our ECMO transportation program was instituted in 2004; here we report results after 5 years of activity.*

Methods: *This is a clinical observational study. Criteria for ECMO center activation were: potentially reversibile respiratory failure, PaO_2 <50 mmHg with FiO_2 >0.6 for >12 hours, PEEP >5 cmH_20, Lung Injury Score (LIS) ≥3 or respiratory acidosis with pH <7.2, no intracranial bleeding, and no absolute contraindication to anticoagulation. If eligible, a skilled crew applied ECMO at the referral hospital. Transportation was performed with a specially equipped ambulance.*

Results: *Sixteen patients were possible candidates for ECMO transfer. Two patients were excluded while 14 (mean±SD, age 35.4±18.6, SOFA 8.4±3.7, Oxygenation Index 43.7±13.4) were transported to our institution (distance covered 102±114 km, global duration of transport 589±186 minutes). Two patients improved after iNO-trial and were transferred and subsequently managed without ECMO. The remaining 12 patients were transferred on veno-venous ECMO with extracorporeal blood flow 2.7±1 $L \cdot min^{-1}$, gas flow 3.8±1.8 $L \cdot min^{-1}$, and FiO_2 1. Data were recorded 30 minutes before and 60 minutes after initiation of ECMO. ECMO improved PCO_2 (75±23 vs. 53±9 mmHg, p<0.01) thus improving pH (7.28±0.13 vs. 7.39±0.05, p<0.01) and allowing a reduction in respiratory rate (35±14 vs. 10±4 breaths/min, p<0.01), minute ventilation (10.1±3.8 vs. 3.7±1.7 $L \cdot min^{-1}$, p<0.01), and mean airway pressure (26±6.5 vs. 22±5 cmH_2O, p<0.01). No major clinical or technical complications were observed.*

Conclusions: *ECMO effectively enabled high-risk ground transfer of severely hypoxic patients.*

KEY WORDS: *ARDS, Severe Acute Respiratory Syndrome, Extracorporeal Membrane Oxygenation, Transportation of patients, Mobile emergency units, Severe hypoxia*

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INTRODUCTION

Inter-hospital transportation of critically ill patients to tertiary care hospitals is required when local resources and technology are insufficient for adequate management (1, 2). Unfortunately patients requiring transfer are often too unstable to undergo conventional transport, and the risk may exceed the immediate benefit. This is particularly true for severely hypoxemic-hypercapnic acute respiratory distress syndrome (ARDS) patients (1). Extracorporeal membrane oxygenation (ECMO) makes the transportation of these high-risk, critically ill patients feasible under stable vital gas exchange conditions (3-6).

ECMO remains a complex and expensive procedure, as

it requires specific technical knowledge and equipment. As a consequence, only a few selected centers utilize it. Over the years most of these specialized institutions have arranged flight/ground transportation protocols. Since Cornish et al (7) first reported in 1986 the successful flight transportation of a neonate with severe respiratory failure on ECMO, many specialized institutions extended their ECMO program with a mobile ground-air ECMO team. In recent years a substantial number of critical patients have been transported by these institutions with relatively low complication rates (3-15).

Monza (Italy) San Gerardo Hospital (SGH) has 900 beds with 23 ICU beds. SGH is a tertiary care center for critically ill patients, with the significant exception of pediatric and major burn patients. We started our ECMO-transfer program in 2004, following 15 years of local ECMO activity. Here we report our first 5-year experience of inter-hospital transfer on ECMO.

METHODS

From December 2004 to November 2009 we collected data concerning the activity of our ECMO transfer team. Clinical records and ad hoc data sheets were retrospectively reviewed. Due to the retrospective observational design of the study, informed consent was waived, according to Italian Regulations (AIFA Directive of March 20, 2008). All patients were transferred from local hospitals to SGH and subsequently admitted to our 10-bed general ICU. National health insurance covered all the expenses of all the transfers.

Referral and patient selection

Referral of patients to our center is initiated by telephone contacts: the intensivist in charge collects clinical information and evaluates entry and exclusion criteria for ECMO. Entry criteria are: potentially reversible respiratory failure, PaO_2 <50 mmHg with FiO2 >0.6 for >12 hours, PEEP >5 cmH_20, Lung Injury Score (LIS) (16) ≥3, or respiratory acidosis with pH <7.2. Exclusion criteria are: intracranial bleeding, contraindications to heparinization, presence of a distinct pathology associated with poor prognosis, or body weight ≥130 kg (due to logistic restrictions).

If the patient is judged eligible, the referring center is asked to make relatives fully aware of the procedure and transportation, check the availability of blood products and, if feasible, to have a fluoroscope and an ultrasound at the bedside. The mobile ECMO team consists of two ICU physicians, one ICU nurse, and an ECMO specialist, plus trainees (one ICU physician and one ICU nurse) and ambulance personnel.

Plan of action

Ground transport is performed by means of a specially equipped ambulance, endowed with enlarged oxygen (6400 liters) and two power inverters, which provide 1800+800 watts at 220 volts. This ambulance is loaded with a high performance ICU ventilator, an ICU portable monitor, infusion pumps, suction equipment, additional oxygen, and an iNO tank. An additional vehicle transports the team and the rest of the equipment.

All the equipment required for cannulation, circuit set-up, and transportation is pre-packed in 3 backpacks. Additional items are ECMO cannulas (Medtronic, Anaheim, CA, USA), circuit elements (Jostra PLS® system; Maquet Cardiopulmonary AG, Hirrlingen, Germany), and the ECMO pump (Rotaflow®; Maquet Cardiopulmonary AG, Hirrlingen, Germany). Table I lists the backpack contents and additional equipment.

Arrival at referral hospital

Once at the referral hospital, the ECMO crew receives clinical handover and re-evaluates the patient. Re-evaluation is a stepwise process, which includes, in progression, optimization of ventilator therapy, recruiting maneuvers, and iNO administration. The aim of this procedure is to assess the safety of a conventional transport: if judged unsafe, the ECMO cannulation procedure is started.

After ultrasound measurement of the transverse diameter of the femoral and jugular veins, cannulation is performed percutaneously with the aid, if available, of direct fluoroscopic view. In the meantime, the ECMO specialist sets up and primes the ECMO circuit. Priming solution is heated to body temperature by means of a water heater pump.

Once cannulated, the patient receives a bolus of unfractionated heparin 50-100 units/lean body weight (kg); then, a continuous heparin infusion is started based on the activated clotting time (ACT). As ECMO begins, minute ventilation is gradually tapered by reducing the respiratory rate according to end-tidal CO_2 and repeated arterial blood gas

TABLE I - EQUIPMENT, DEVICES, AND SPARE MATERIALS

Backpack 1: cannulation material	
Percutaneous venous (25, 23, 21, 19 Fr) and arterial (15, 17) cannulas (2 for each diameter)	
Sterile surgical set, sheets, gowns, gloves	
Vessel dilators 6-28 Fr (3 for each caliber)	
Needles for vascular cannulation 18 Ga	
Connectors 3/8''x3/8''	
2x300 cm stiff vascular guidewires	
4x150 cm vascular guidewires	
4x80 cm vascular guidewires	
Backpack 2: extracorporeal circuit material	
Sterile surgical set, sheets, gowns, gloves	
2x ECMO membrane lung and circuit (pre-assembled)	
ECMO (heparin coated) additional tubing (3 m)	
Sterile priming solution (Ringer lactate)	
Three-way stopcocks	
US special gel for centrifugal pump flowmeter	
Backpack 3: emergency support material	
Disposable face masks, ET tubes (6-8.5 mm), laryngeal mask airway (3-5), connectors	
Laryngoscope and blades	
CRP material + emergency drugs	
Vascular arterial, venous catheters, connectors	
Percutaneous thoracic draining set and connectors	
IV fluids (colloids and crystalloids)	
Additional support material	
Spine board	Gas connector for the ambulance
Steel cart	Oxygen tanks
ICU portable monitor	Nitric oxyde tank
ICU ventilator	Activated clotting time portable analyzer
ECMO centrifugal pump	Infusional pumps
ECMO water heater	ECMO emergency (manual) drive

(ABG) analysis. PEEP and inspiratory/expiratory cycling is set to avoid dangerous sudden reductions in mean airway pressure.

Patient preparation

After a short stabilization period the patient is positioned on a spine board. A stainless steel rack (Fig. 1), firmly secured on the spine board, supports the ECMO pump, the heater, the ventilator, and the syringe pumps. Artificial lung and drive unit holders are secured on their vertical posts, allowing easier mobilization of the patient.

Data collection

Electrocardiogram, invasive blood pressure, central venous pressure, pulmonary pressure (when available), bladder temperature and urinary output, pulse oximetry, and end-tidal CO_2 were monitored. We recorded parameters and the ABG analysis 30 minutes before and 60 minutes after the beginning of ECMO. Coagulation was assessed by means of standard lab testing (PT, aPTT) and by bedside measurement of activated clotting time (ACT) (Hemochron Junior®; Cremascoli & Iris, Milan, Italy).

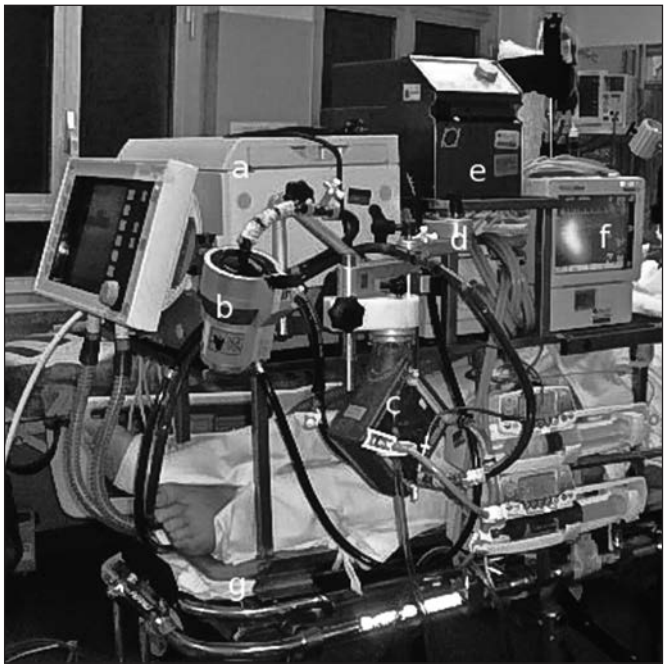

Fig. 1 - *Before departure equipment is loaded on a specially designed steel cart.* ***a*** *= intensive care ventilator;* ***b*** *= extracorporeal membrane oxygenation (ECMO) pump head;* ***c*** *= ECMO artificial lung;* ***d*** *= of note, a holder bearing b and c is fixed to the cart;* ***e*** *= ECMO pump;* ***f*** *= intensive care portable monitor;* ***g*** *= spine board.*

Statistical analysis

Data are presented as mean±standard deviation. Recorded data were compared using the two-tailed paired data t-test (PASW18, SPSS inc., Chicago, USA). Differences were considered significant when $p<0.05$.

RESULTS

Among 16 eligible patients, 14 (9 males, 35.4±18.6 years old, BMI 26.9±6.2 kg·m^{-2}) were transported to our institution: one patient's relatives refused transfer and one patient died before re-evaluation. The average distance covered to reach the referral hospital was 102±114 km (median 39 km). The time elapsed between crew activation and transport end was 589±186 minutes (median 540 minutes).

Table II lists characteristics of the enrolled population. Median time from intubation to enrollment was 5 days (IQ range 3-11 days). Disease severity scores on first evaluation were sequential organ assessment failure score (SOFA score) 8.4±3.7 and Oxygenation Index (OI) 44±13.4. Two patients improved after iNO trial and were transferred via conventional transportation; they were subsequently managed without ECMO. Twelve patients were placed on veno-venous ECMO at the referring institution and then transported to our center. These patients represent 29% of the total amount of veno-venous ECMO performed at our ICU over the considered time period. Diagnosis, prior days of ventilation, mode of ventilation, cannulation characteristics, and inter-hospital distance are shown in Table II. Main ventilatory and physiologic parameters, registered 30 minutes before and 60 minutes after ECMO institution, are reported in Table III. All patients were sedated, intubated, and in controlled mechanical ventilation. As ECMO began (BF 2.7±1 L·min^{-1}, 1.6±0.4 L/min per m^2), gas flow through the artificial lung (GF 3.8±1.8 L min^{-1}, FiO_2 1) allowed a significant reduction in arterial pCO_2 and resolution of respiratory acidosis. Respiratory rate (RR) was reduced and, accordingly, minute ventilation (MV) decreased.

All patients had stable hemodynamic status before ECMO, but 7 of them were on vasoactive drugs. ECMO did not cause variation in heart rate. Mean arterial pressure decreased and vasopressor infusion rates were rapidly tapered in 6 of the 7 patients. Only 5 patients had a pulmonary artery catheter in place at time of cannulation; this data is therefore not reported.

We did not encounter any major complications during the transfers. Among minor problems, we faced two ventilator malfunctions: in one case the battery pack was unable to maintain the charge and the ventilator switched off during ICU ambulance transfer; in the other one the touch-screen malfunctioned. In both cases we were able to manually assist the patients for several minutes while solving the problems. We recorded one magnetic decoupling of the centrifugal pump head due to street roughness, which resulted in an ambulance emergency stopover. The pump was immediately restarted without additional problems.

Upon arrival at SGH 8 patients were transferred to the CT facility to perform a head-thorax computed tomography (CT) before entering the ICU. This decision was made on a case-by-case basis, taking into account the amount of information acquired at the referring hospital and the risk involved in a possible additional transfer from the destination ICU to the CT scan suite.

Among ECMO patients, length of stay in the ICU was 24±24.6 days; six patients were successfully weaned from extracorporeal support and survived to discharge from hos-

TABLE II - POPULATION CHARACTERISTICS

Pt no.	Age (years)	Sex	BMI	Distance (Km)	Global duration (min)	CT on arrival	Disease	Vent days prior ECMO	Mode of ventilation prior ECMO	PaO_2/FiO_2 prior ECMO	OI[b]	Type of ECMO	Route	ICU LOS[c] (days)	Outcome
Patients transferred on ECMO															
1	32	F	18	351	995	Y	Bacterial pneumonia	43	PCV	56	23.4	VV[d]	FF[e]	88	Exitus
2	41	M	20	24	450	N	Bacterial pneumonia	6	CPPV	62	30.5	VV	FF	22	Hospital Discharge
3	66	F	22	26	450	Y	Bacterial pneumonia	1	CPPV	66	42.4	VV	FF	2	Exitus
4	52	M	26	38	540	Y	Bacterial pneumonia	3	CPPV	63	48.7	VV	FF	11	Exitus
5	36	M	31	318	880	Y	Toxic pneumonia	8	CPPV	70	40	VV	FF	3	Exitus
6	49	M	37	8.3	465	N	Bacterial pneumonia	1	CPPV	67	31.3	VV	FF	14	Hospital Discharge
7	58	M	26	40	600	N	Bacterial pneumonia	4	PCV	54	57.2	VV	FF	18	Hospital Discharge
8	2	M	--	47	485	Y	Liver transplantation	9	HFO	50	72	VV	JDL[f]	39	Exitus
9	25	M	24	142	522	Y	Viral pneumonia	3	CPPV	54	49.6	VV	FF	34	Hospital Discharge
10	2	F	--	36.9	600	N	Viral pneumonia	2	PCV	42	52.3	VV	JDL	30	Hospital Discharge
11	28	F	26	196	630	Y	Bacterial pneumonia	7	PCV	80	37.5	VV	FF	26	Hospital Discharge
12	43	M	38	150	720	N	Pneumonia	15	CPPV	66	42.2	VV	FF	3	Exitus
Patients Transferred Without ECMO															
13	26	M	31	30	315	N	Trauma	2	CPPV	50	52	--	--	9	Hospital Discharge
14	36	F	23	24	NA[a]	Y	Pneumonia	4	CPPV	91	30.8	--	--	9	Exitus

[a]not available; [b]oxygenation index; [c]length of stay; [d]veno-venous; [e]femoro-femoral veins; [f]jugular double lumen.

pital (Tab. II). Six died during bypass (2 intracranial bleeding, 2 septic shock, 1 unresolving pneumonia, 1 acute right heart failure). Intracranial bleeding was diagnosed by head CT within 24 hours of ECMO initiation. Among variables investigated at baseline, no significant differences were found between survivor and non-survivor patients.

DISCUSSION

In severe ARDS, ECMO allows clinicians to support acutely failing lungs while providing additional time for diagnosis and treatment. It also enables reductions in dangerous high-pressure, high-oxygen ventilation, thus providing lung rest (17, 18). Two former randomized trials on adults failed to establish an advantage for ECMO-treated patients (19, 20), but enrollment and ventilatory treatment were extremely different from the current standard approach. ECMO technology has indeed changed markedly during the last two decades. In 1996 the UK Collaborative ECMO Trial Group (21) demonstrated among 185 mature newborn infants a greater improvement of survival in the ECMO group (59% vs. 32%). In adult populations, published survival data of ARDS patients treated with ECMO ranged from 51% to

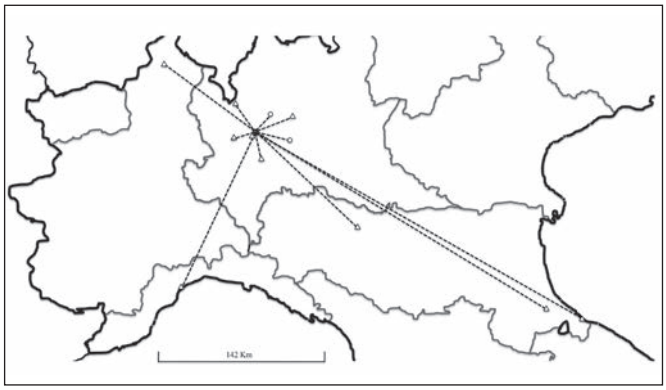

Fig. 2 - *Schematic representation of the north of Italy: circles indicate institutions that referred two patients while triangles indicate institutions that referred one patient.*

76.5% (22-25). A randomized trial has recently been conducted in the UK including 180 patients. Patients enrolled in the ECMO group were transferred to a single institution where 68 out of 90 received ECMO. As compared to the conventional treatment group, the ECMO group demonstrated a significantly higher survival rate (63% vs. 47%) (18). Of note, in the treatment group no ECMO was instituted at the referring center; 3 patients died before transportation and 2 patients died during transfer.

In 1989, when we began to treat severe ARDS patients with veno-venous ECMO at our center, this procedure was technically very complex; instruments were heavy, large, and delicate, therefore even the in-hospital transfer of patients on ECMO (e.g., to perform CT) was demanding and risky. Since then considerable technological improvement, such as biocompatibility and miniaturization of the equipment (26), has been achieved. In 2004 we managed to add to our referral program the possibility of applying ECMO at the referring ICU, with the aim of substantially increasing the possibility of successful transfer of the most severe patients.

Our initial choice was ground transportation because our experience with air transportation was scarce. However, due to a very favorable geographical position (Fig. 2) ambulance allowed us to cover most of the northern regions of Italy, the farthest destination being 350 kilometers from our institution.

Major complications during cannulation and transportation (fatal cardiac arrest during cannulation, severe hypocarbia requiring CO_2 ventilation of the artificial lung, and severe bleeding) are rare, as reported in larger case series (6, 8-9, 12-15). We did not encounter major complications; however, we faced some minor complications, such as electrical

TABLE III - VENTILATOR SETTINGS AND ARTERIAL BLOOD GAS ANALYSIS AT BASELINE AND AFTER ECMO

	Baseline	ECMO	*P* Value
	Mean±SD	Mean±SD	
Ventilator setting			
FiO_2	0.99±0.03	0.98±0.04	NS
PEEP (cmH_2O)	16.8±5.3	17.6±4.9	NS
PIP (cmH_2O)	35.5±6.8	33.2±4.8	NS
PAW (cmH_2O)	25.9±6.5	21.6±5	p<0.01
MV (L min^{-1})	10.1±3.8	3.7±1.7	p<0.01
RR (breaths min^{-1})	35±14	10±3.5	p<0.01
TV/Kg (mL kg^{-1} PBW)	4.5±1.1	5.5±2.4	NS
ABG			
PaO_2 (mmHg)	60±10.17	79±25.6	p<0.05
$PaCO_2$ (mmHg)	75.1±19.8	52.6±8.7	p<0.01
pH	7.28±0.13	7.39±0.05	p<0.01
BE	6.4±7.4	5.8±7.2	NS
Hemodynamics			
HR (beats min^{-1})	118±22	108±19	NS
MAP (mmHg)	86±12	79±8	NS

ABG = arterial blood gas analysis; Baseline = 30 minutes before ECMO; ECMO = at 60 minutes after initiation.

failure of the ventilator, which is consistent with published data (17).

Transportation of critically ill patients is a high-risk procedure; therefore recently published guidelines (1) emphasize the importance of obtaining optimal clinical stabilization before departure. ECMO application leads to significant improvement in clinical parameters such as respiratory acidosis and hypoxemia (6-10, 12-15). In hemodynamically compromised patients, a veno-arterial ECMO may also successfully support the failing circulation (9, 11, 14). In our experience, as in previously published clinical series, the use of veno-venous ECMO enables "safe" transfers of severe ARDS patients with a very low rate of associated complications. Respiratory acidosis was partially corrected by ventilating the artificial lung. We set sweep gas flow rate as high as needed to correct acidosis while lowering respiratory rate on the ventilator. This allowed us to decrease airway pressure to safer levels. Changes in gas flow rate are made empirically by keeping end-tidal CO_2 at the same level and by the means of serial ABGs before departure. This is accomplished only when acid-base balance, hemodynamic status, and coagulation are stabilized. During transportation, FiO_2 of the sweep gas was set to 100% to allow for easier management of gas supplies. According to the draining cannula size and the atient's hemodynamic status, extracorporeal blood flow was set to achieve relatively safe arterial pO_2 levels. Indeed, a substantial contribution to oxygenation may still be accomplished by the patient's own lung, therefore an intensive care ventilator, which can guarantee PEEP levels above 20 cmH_2O, is warranted. In our population, despite a decrease in mean airway pressure, oxygenation through the artificial lung slightly increased arterial pO_2. Though no specific guidelines exist about the best ventilator and pump settings in this clinical scenario, other authors apply similar strategies (6, 12).

None of our patients had a significantly impaired cardiac function, allowing us to use the venovenous ECMO setting. If needed a veno-arterial ECMO setting could have also been employed. Hemodynamics were managed to assure a mean arterial pressure above 65 mmHg and urine output above 0.5 $mL \cdot kg^{-1} \cdot h^{-1}$.

Two patients died from intracranial bleeding. This is the most serious ECMO-related complication and carries a poor prognosis. The incidence of intracranial bleeding is high, ranging from 2.6% to 4.9% in the adult and pediatric populations, respectively (17). Heparin anticoagulation is a known risk factor, but hypoxia, sepsis, and thromboembolic events leading to focal cerebral ischemia also play a role in its pathogenesis. Recent intracranial bleeding or recent stroke are exclusion criteria for ECMO. Thus a complete neurological assessment and/or head CT evaluation is advisable before ECMO implementation. Unfortunately, in the clinical setting of an extremely hypoxic patient, these evaluations are often impossible to perform. In our patients, brain hemorrhage was diagnosed within 24 hours of ECMO implementation and we could not ascertain if any brain injury was present before heparin anticoagulation. Actually, one of the two patients had atrial fibrillation with hemodynamic impairment several hours before ECMO institution, while the other one had severe septic shock. Another patient, who had a short episode of supraventricular tachycardia, was diagnosed with multiple cerebral infarctions at first CT scan; a patent foramen ovale was subsequently diagnosed by transesophageal echocardiography. In our opinion these outcomes highlight the necessity of thorough neurological evaluations in these patients as quickly as possible.

Other authors applied pumpless arterial-venous iLA to ARDS patients for transportation: this system is cheaper, less complex, and allows safe flight transportation without major complications (10, 14). Though very effective in removing CO_2, pumpless artificial lungs are characterized by a low oxygenation performance, as the blood entering the artificial lung is arterial and thus already oxygenated. Moreover, extracorporeal blood flow is low and totally dependent on the patient's hemodynamics. Therefore when patients are severely hypoxemic this technique may carry additional risks compared to ECMO, since it cannot warrant the same stability of gas exchange provided by an effective ECMO set up. Certainly, however, the simple technology involved might constitute an intrinsic advantage.

The SOFA score (27) before cannulation was low, particularly in view of the very high oxygenation index (OI). This may be explained by the selected characteristics of our population: many patients were affected by a pure respiratory disorder.

Furthermore, due to the young age, most had no comorbidities. Basal OI, a strong mortality risk indicator for pulmonary diseases (28), was very high, predicting an elevated risk of death. In spite of this high mortality risk, 50% of our patients survived.

This study has some limitations, the most important being that our population does not represent a homogeneous

sample of eligible patients. This is due to the fact that in 2009 our program was not included in a national/regional framework and many cases were not referred to our center. Based on our results, we conclude that ECMO allowed safe ground transportation of severe ARDS patients to our tertiary care institution. According to recent scientific evidence (3), this mode of transport allowed more advanced care of these patients and probably improved survival. In order to provide the best clinical care for these severely ill patients, an interhospital national network was set up in Italy in November 2009.

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