Clinical Evaluation of the Eurosets Trilly Oxygenator During Cardiopulmonary Bypass in a Pediatric Population

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ABSTRACT

The equipment selected for cardiopulmonary bypass (CPB) in pediatric cardiac surgery critically influences the safety, efficiency, efficacy and pathophysiological impact in perioperative use and the post-operative outcome. In this report, we present a single-center retrospective analysis of the clinical efficacy, efficiency and safety of the Trilly oxygenator (Eurosets Srl, Medolla, MO, Italy), which has an integrated arterial filter. It has a blood flow capacity of 500 to 3500ml/min, an AAMI index of 4.000ml / min, and a static fill prime (oxygenating module + heat exchanger) of 130 ml. We used this device on 42 pediatric patients who underwent repair of various congenital heart defects with cardiopulmonary bypass. Pre- and intraoperative patient data were collected for the evaluation of gas transfer and metabolic parameters in relation to blood flow, temperature and hematologic profiles.

The mean age of the patients was 8.07 ± 2.9 years. Eight patients had cyanotic heart disease, 7 had chromosomal abnormalities and 9 had previously undergone cardiac surgery. The STAT Mortality Category Score was distributed as follows: Cat. 1 (37.5%), Cat. 2 (35%), Cat. 3 (5%), Cat. 4 (22.5%), Cat. 5 (0%). The mean bodyweight was 29.03 ± 8.25 kg and the blood flow rate was 2664.88 ± 508.43 ml / min. The mean cardiopulmonary bypass time was 95±51.4 min and the cross-clamp time was 37±34.6 min. The mean gas transfer values were as follows:

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partial pressure of oxygen, post oxygenator, 224.7±28 mmHg; partial pressure of carbon dioxide, post oxygenator, 42±4 mmHg; oxygen delivery 356.9± 88.8 ml/min/m^2; carbon dioxide transfer, 52.81± 1.98 mmHg, mixed venous saturation 77.78 %; and mean hematocrit value 29.0±4 %.

The Trilly oxygenator was effective in terms of oxygen uptake, carbon dioxide removal, and heat exchange in a pediatric population undergoing cardiopulmonary bypass. This retrospective analysis showed that the Trilly is both safe and effective in clinical practice without iatrogenic problems.

INTRODUCTION

The development of a membrane oxygenator for use during pediatric cardiopulmonary bypass has been made possible due to technological advancements and the contributions of many investigators over the past two centuries.[1,2] In young patients, cardiopulmonary bypass (CPB) is influenced by the unfavorable relationship between the size of the circuit and the total circulating blood volume.[3,4] A low prime volume is expected to improve blood conservation and decrease donor exposure, prevent problems with transfusion (immunomodulation, infection), increase the likelihood of blood-free surgery in smaller infants, and decrease whole-body systemic inflammation by decreasing the surface of foreign material in contact with blood and inflammation associated with blood transfusion.[5] Adequate oxygenation is fundamental to CPB, since imbalances between oxygen supply and demand can lead to cellular injury, causing profound adenosine triphosphate depletion and nitric oxide generation, which in turn induces several oxidative and apoptotic mechanisms.[6] The equipment selected for cardiopulmonary bypass (CPB) in pediatric cardiac surgery critically influences the safety, efficiency, efficacy and pathophysiological impact in perioperative use and the post-operative outcome. In this context, we introduce the new Trilly pediatric AF oxygenator (Eurosets Srl, Medolla, MO, Italy) (Fig. 1), which was designed for use in patients who are too big for infant oxygenators but too small for adult oxygenators. The small size of the device, the large exchange surface, the reduced calibers of the priming lines, and the integrated arterial filter all make it a very useful tool in clinical practice. Since the beginning of our experience with this oxygenator, the results have been satisfactory. For these reasons, we designed this clinical study to evaluate our first impressions.

Figure 1. Trilly AF pediatric oxygenator. (Eurosets Srl, Medolla, MO, Italy)

MATERIALS AND METHODS

Patients and Methods

This was a single-center, retrospective observational study that included all of the children with congenital heart defects (CHDs) who underwent surgical correction with extracorporeal circulation (ECC) recruited at the Pediatric Cardiac Surgery Department, Giannina Gaslini Children's Hospital (Genoa, Italy) between March 2018 and November 2021.

The inclusion criteria consisted of CHD that needed correction using cardiopulmonary bypass with a nominal flow between 1700ml/min and 3500ml/min. Patients with perfusion flow lower than 1700ml/min or higher than 3500ml/min were excluded.

According to the metabolic needs of the patients and our desire to obtain the lowest possible priming volume, the Trilly pediatric AF oxygenator (Eurosets, Medolla, MO Italy) was used.

Parents gave their consent for the use of their child's anonymized data. The study was approved by the ethics committee (Study n.336/2022, experimentation id 12457) and written informed consent was obtained from all of the patients and/or their parents according to the Declaration of Helsinki.

The primary endpoints were intraoperative Gas Transfer (O_2) and carbon dioxide (CO_2) (calculated as {[(Arterial-Venous Sat.) x 1.34 x Actual Hemoglobin x Blood flow]/100}/FiO_2, and ($PaCO_2$ x Gas Flow rate)/0.863), respectively; partial pressure of oxygen (PO_2) post oxygenator, partial pressure of carbon dioxide (PCO_2) post oxygenator, relative metabolic parameters, including Oxygen Delivery (DO_2), Indexed Oxygen Delivery (DO_{2i}), and Mixed Venous Saturation (SVO_2) in relation to the Blood Flow Rate (BFR), temperature (°C),hematologic profiles, including hematocrit (HTC) values, and the impact of hemodilution according to the results of an arterial blood gas analyzer at 3 time points in ECC: cooling (T0), aortic clamping or central time (T1) and rewarming/ heating (T2).

Secondary endpoints included heat exchange based on the user's experience and the patient's nasopharyngeal temperature after 5 min in relation to the setting on the heat exchanger, in both the cooling and rewarming phases. We describe the performance of the Trilly oxygenator in terms of the following variables from the analysis of blood gas data: venous saturation, lactate, Excess Bases (Be), DO_2 obtained at 3 time-points in ECC (cooling, aortic clamping or central time, rewarming). We also evaluated any adverse events related to product malfunction, such as lack of gas exchange, leaks, breakage, debris, gas embolism, thromboembolism, blood damage, and

failure of the oxygenator which required it to be replaced during ECC.[7]

Ultimately, we included 42 pediatric patients with a median age of 8 years (range 3-15 years) who underwent elective cardiac surgery procedures with ECC. Preoperative and intraoperative patient data were collected and there were no changes to our perfusion practice during the evaluation.

The demographic characteristics, pathologies and preoperative details of the population are shown in Table I.

Anesthesia and surgical procedures

The surgeries were performed with totally intravenous general anesthesia using midazolam, propofol, fentanyl / remifentanil and rocuronium by nasal or oro-tracheal intubation with a tube caliber suitable for the patient. Multi-parameter monitoring involved the use of an invasive pressure line, a central venous pressure line, a probe for monitoring cerebral saturation by NIRS, continuous electrocardiogram in two leads, peripheral saturation / pulse oximetry, and two central temperature monitors (esophageal and bladder or rectal).[6-8]

Other parameters such as Activation Clotting Time (ACT) and blood gas venous and arterial analyses were performed throughout the procedure at 60-minute intervals with an ABL90 FLEX blood gas analyzer (Radiometer, Copenhagen, Denmark). Anticoagulation was performed with intravenous heparin to obtain a working ACT of over 500 seconds. For the prevention of hyperfibrinolysis, a continuous intravenous administration of tranexamic acid was used until the end of surgery.[9]

CPB setting

The hardware consisted of a Stockert S5 heart-lung machine (Livanova, London, UK), Data Management System (DMS) and a HCU40 Heater Cooler System (Maquet, Copenhagen, Denmark). The Trilly AF oxygenator (Eurosets, Medolla, Italy) with an integrated arterial filter was used in all patients. The CPB circuit, coated with phosphorylcholine, was the same for all patients: the arterial line was 180 cm long and 1/4 inch in diameter, the venous line was 120cm long and 3/8 inch in diameter, and the master pump was 3/8 inch in diameter (Eurosets). Arterial and venous cannulas varied according to the flow calculated in CPB: from 12 to 16 Fr for the arterial cannula, from 14 to 22 Fr for the superi-

Table I
Pre-operative and demographic patient data

	Mean value
Age (y)	8.0 ±2.9
BSA (m^2)	1.0±0.2
Weight (kg)	29±8.2
Female patients, n (%)	21 (51.2)
STAT Mortality Categories	
Cat. 1	15 (37.5%)
Cat. 2	14 (35%)
Cat. 3	2 (5%)
Cat. 4	9 (22.5%)
Cat. 5	0 (0%)
Preoperative Hematocrit (%)	40.8±6.6
Calculated Blood Flow (ml/min)	2664.8±508.4
Septal defects	16 (40%)
Valve pathology	15 (37.5%)
Pathology of the right heart	8 (19.5%)
Other	2 (5%)

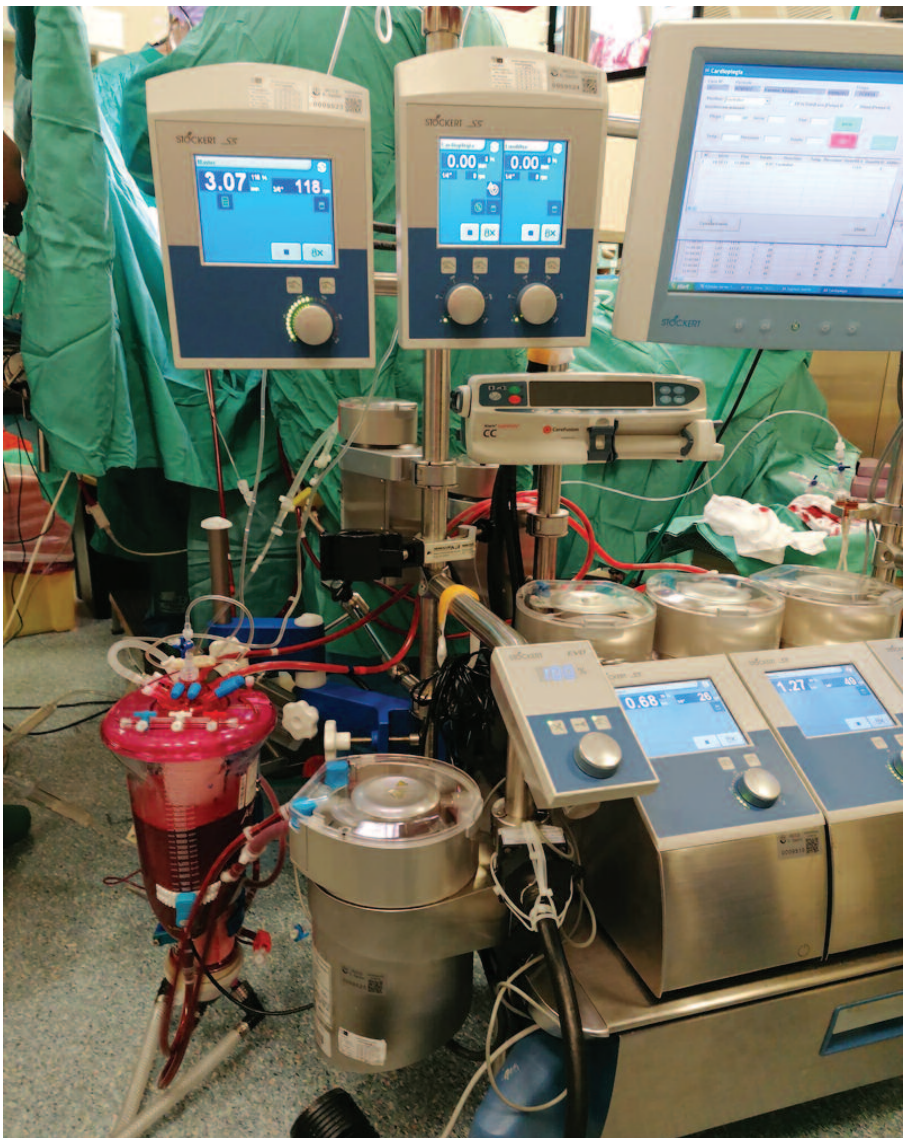

Figure 2. The Trilly AF oxygenator. (Eurosets Srl, Medolla, MO, Italy)

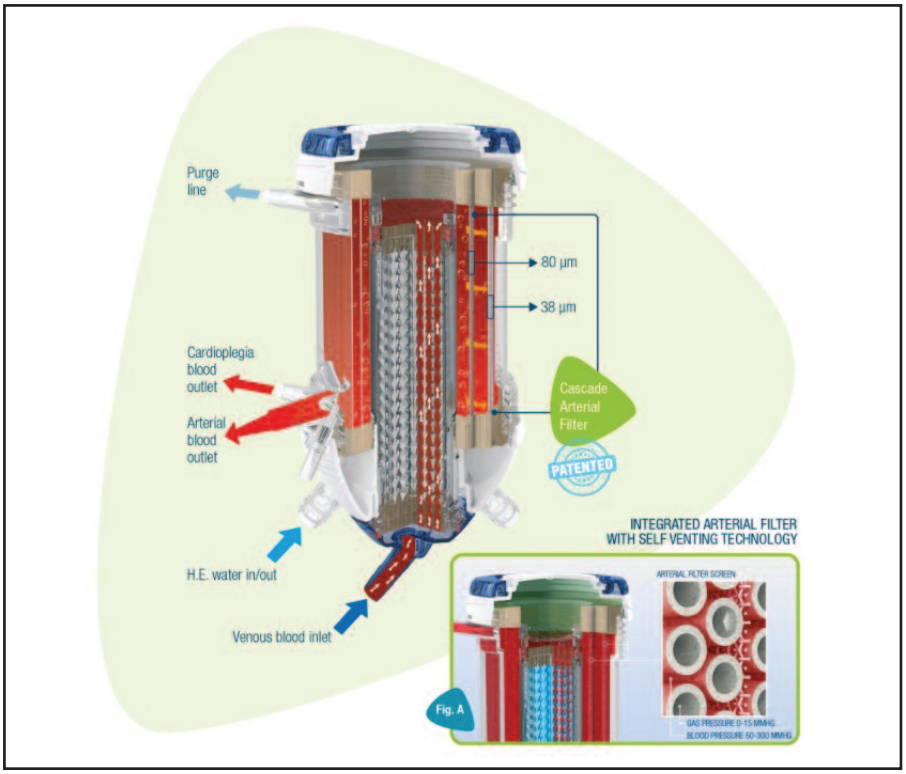

Figure 3. Seizure oxygenator. (Eurosets Srl, Medolla, MO, Italy)

or vascular drainage, and from 14 to 26 Fr for the lower caval drainage.[10] In some patients who required smaller venous cannulas, Vacuum-Assisted Venous Drainage (VAVD) was performed with a negative pressure between 0 and - 30 mmHg, monitored with a Red Box (Medtronic, Dublin, Ireland). The prime consisted of Ringer acetate, Thamesol, 20% albumin and heparin. In children with a low hematocrit, a small amount of packed red blood cells was added to obtain a working hematocrit of not less than 28%. Myocardial protection was performed by antegrade infusion of cold crystalloid cardioplegic solution (Custodiol®, Essential Pharmaceuticals, LLC, Durham, NC) according to our protocol. Metabolic parameters were monitored every 20 minutes using serial arterial samples, and oxygenation saturation and hematocrit were monitored with a Biotrend system (Medtronic)[11,12] according to our institutional protocol.

The Trilly AF oxygenator consists of a rigid venous reservoir with a capacity of 2500ml and two cascade filters with meshes of 80 µm and 38 µm, to help reduce the presence of gaseous microemboli, and is designed to promote drainage of the patient's venous blood by both gravity (difference in height between the reservoir and the patient's bed) and the VAVD technique thanks to the presence of a pressure relief valve. The oxygenating compartment is made of hollow microporous fibers consisting of a gaseous exchange module connected to an integrated heat exchanger and an integrated 38 µm arterial filter that ensures blood filtration and removes microaggregates and microemboli (Fig. 2). It has a blood flow capacity of 500 to 3500 ml / min, where the AAMI index is 4000 ml / min, a static fill prime (oxygenating module + heat exchanger) of 130ml, a membrane surface of 1.1 m^2, and a minimum operating level of 100ml at 3.5 l/min, 80 ml at 2 l/min and 30 ml/min at 0.5 l/min. To allow a sufficient reaction time in case venous flow suddenly stops, thus preventing gaseous emboli from passing to the patient, it is recommended to maintain the operating level at double the minimum operating volume.

The entire system is treated with phosphorylcholine (PC) to improve blood compatibility, which reduces platelet adhesion to the coated surface (Fig. 3).

Table II
Intraoperative data

	Mean value
CPB time (min)	95±51.4
Cross-Clamp time (min)	37±34.6
RBF (ml/min)	2575.5
Htc on CPB (%)	29.0±4.1
Priming volume before CPB (ml)	594.34±50
Diuresis at the end of CPB (ml)	262.95±25
FiO_2 (%)	55.4
Gas Flow (L/min)	1.01

Values are presented as n (%) or mean ± standard deviation. CPB, Cardiopulmonary bypass; Htc, Hematocrit; RBF, relative blood flow.

Statistical analysis

Data are presented as the mean and standard deviation (SD) or median and range for continuous variables, and as absolute and relative frequencies for categorical variables. The statistical analysis was performed using SPSS for Windows (SPSS Inc, Chicago, IL, USA).

RESULTS

From March 2018 to November 2021, we retrospectively collected the data of 42 pediatric patients who underwent elective cardiac surgery at our center for congenital heart diseases, including septal defects: interatrial, interventricular and atrioventricular canals (n=16), pathologies of the mitral valve and/or of the valvular apparatus (n=6), supra-subvalvular and aortic valve diseases (n=9), uni-ventricular heart such as Fontan or replacement of right ventricular-pulmonary artery tube (n=9), and one case each of intracardiac and inferior caval neuroblastoma and a tracheal stenosis. Of these, 1 patient was excluded due to a weight over 40 kg, with a calculated perfusion flow of 3480 ml /min, and because an adult circuit (arterial line 3/8, venous line 1/2) was used. The average age of the patients was 8.07 ± 2.9 years, 8 patients had cyanotic heart disease, 7 had chromosomal abnormali-

ties, and 9 had undergone previous cardiac surgery. With regard to the STAT Mortality Categories Scores, procedures associated with the lowest mortality rates are in Category 1, and those associated with the highest mortality rates are in Category 5. Our patients consisted of 15 patients in Cat. 1 (37.5%), 14 in Cat. 2 (35%), 2 in Cat. 3 (5%), 9 in Cat. 4 (22.5%), and 0 in Cat. 5 (0%). One patient was not suitable for this categorization (neuroblastoma). The mean bodyweight was 29.03 ± 8.25 kg and the perfusion flow was 2664.88 ml / min ± 508.43. Intra-operative data are shown in Table II.

The mean priming volume was 594.34 ml ± 63.78 and crystalloid was used in 35 patients. In 7 children with a mean bodyweight of 20.3 kg who had a pre-CPB hematocrit value of 34.2%, packed red blood cells were added to the priming. Five patients were transfused shortly before or during ECC due to a hematocrit below 26.1%, with a low operating level (50 ml), which didn't allow the device to work safely, provided an insufficient blood volume to fill the patient's heart, and did not give adequate contractility for weaning from the ECC. Three of these transfused patients had undergone a third sternotomy for the correction of congenital heart disease. Also, in 5 patients, continuous ultrafiltration (CUF) was used to reduce the water volume, concentrate the blood, and consequently increase the hematocrit. The mean ECC time was 95±51.4 min and the mean cross-clamp time was 37±34.6 min. The mean gas values on ECC were PO_2 post oxygenator 224.7±28 mmHg, PCO_2 post oxygenator 42±4 mmHg, SVO_2 77.78 %, mean HTC value 29.0±4%, mean DO_2i 353.07± 62.84 ml/min/m^2, and mean CO_2 transfer 52.81± 5 mmHg. Intra-operative data on gas transfer are shown in Table III.

Table III
Perioperative data

	Mean value
CPB time (min)	95±51.4
Cross-Clamp time (min)	37±34.6
RBF (ml/min)	2575.5±25.4
Htc on CPB (%)	29.0±4.1
pO_2 (mmHg)	224.7±17.2
pCO_2 (mmHg)	42.0±5.3
FiO_2	55.4±3.2
Gas Flow (L/min)	1.01±0.64

Values are presented as n (%) or mean ± standard deviation. CPB, Cardiopulmonary bypass; Htc, Hematocrit; RBF, relative blood flow; pO_2, oxygen partial pressure; pCO_2, carbon dioxide partial pressure.

When monitoring PO_2, we considered 150-280 mmHg to be normal; at T0 (5 min to start of CPB), 25 patients (61%) were within this normal range, 11 (26.8%) were below normal (68.4-144 mmHg) and 5 were above normal (287 to 365 mmHg) (Table IV). At T1 (clamping or central time), only 8 patients (19.5%) were outside the normal range (7 above and 1 below), and at T2 (warming time), 12 patients (29.2%) were outside the normal range.

When monitoring PCO_2, the normal range was considered to be 35-50 mmHg. At the first blood gas analysis (T0), only 6 patients (14.6%) were outside of this range (5 patients were at 30 to 33 mmHg and one was at 51 mmHg). At T1, 5 patients (12.1%) were outside the normal range (at 50-52 mmHg). At T2, only 2 cases (4.9%) were outside the normal range.

In our experience with this device, we have not witnessed any potential failures, such as lack of gas exchange, leaks, breakage, debris, gas embolism, thromboembolism, blood damage or failure of the oxygenator that required a replacement of ECC.

DISCUSSION

In pediatric patients, cardiopulmonary bypass is based on a miniaturized ECC circuit to reduce the priming volume. Usually, blood products are used to maintain a safe level of hematocrit and colloid osmotic pressure to ensure adequate oxygen delivery to avoid an imbalance between oxygen supply and demand causing cellular injury involving deep adenosine triphosphate depletion and nitric oxide generation, which induces an

Table IV
Perioperative data

	Starting CPB	During Cross-Clamp	During warming (from 28°C to 36°C)
SaO_2	99.61±0.2	99.86±03	99.92±0.1
SvO_2	76.24±0.1	80.82±0.1	76.04±0.2
RBF (ml/min)	2646.82±45	2575±0.145	2523.90±0.135
FiO_2	57.80±0.4	54.61±0.4	58.46±0.5
DO_{2i}	140.61±20	112±15	131.74±17
PCO_2 post oxygenator	39.30±0.3	44.36±0.4	42.41±0.7
PCO_2 transfer	51.91±0.6	55.09±0.5	51.45±0.4
Priming volume before CPB (ml)	594.34±50		
Diuresis at the end of CPB (ml)	262.95±25		

Values are presented as n (%) or mean ± standard deviation. CPB, cardiopulmonary bypass; SaO_2, post-oxygenator arterial saturation; SvO_2, mixed venous saturation; RBF, relative blood flow; pO_2, oxygen partial pressure; pCO_2, carbon dioxide partial pressure; FiO_2, oxygen fraction; DO_{2i}, indexed oxygen delivery.

oxidative process.[10,13,14] However, blood transfusion may trigger a series of inflammatory reactions, increasing the risk of organ dysfunction, especially lung and right ventricular function.[15]. This is associated with a risk of early postoperative hyperthermia and allergies, which affects the prognosis in children.[16,17]

Therefore, in pediatric cardiac surgery, selection of the proper CPB components and devices is essential, with respect to safety, efficiency, efficacy and pathophysiological impact, both intra- and post-operatively. In this report, we have described our clinical case experience with the Eurosets Trilly Pediatric AF oxygenator, which was designed for use in patients who are no longer children but not yet adults.

As shown in Table IV, the PO_2 values that were outside the normal range were probably due to our initial lack of confidence with the oxygenator, which led us to manage the exchange of FiO_2 moderately, especially during cooling and warming.

On the other hand, a lower percentage of PCO_2 values were outside the normal range because we did a better job of managing the exchange of CO_2 than that of O_2. Consequently, we can conclude that the oxygenator was very efficient at removing CO_2, which is demonstrated by the low gas sweep required to maintain our range of normality. Regarding the high and low values that we experienced, we think that a period of learning may be needed to understand how to manage gas flow in patients of different sizes, in different types of heart disease and at different working temperatures. While the Trilly oxygenator appeared to show good performance, with good oxygen and carbon dioxide transfer, it's very difficult to offer any definitive conclusions due to the lack of evidence and the fact that reference ranges in the adult population cannot be used to guide practice in pediatric patients.[18,19]

Our interpretation can be supported by comparing clinical performance trends with the manufacturer's in vitro data.

Overall, the size of the device, the exchange surface, the reduced need for prime and the integrated arterial filter make the Trilly oxygenator a very valid option in clinical practice. However, this study had some limitations. For example, retrospective data were collected from a small population, with a particular focus on our clinical experience with the oxygenating module in terms of safety and efficiency, which isn't correlated with survival or mortality. In addition, the lack of clear standards regarding pediatric critical DO_{2i} and the lack of evidence regarding normal ranges of oxygen and carbon dioxide transfer in the pediatric population may limit our conclusions. In future studies, it would be interesting to evaluate clinical outcomes prospectively with a greater number of patients.

Regarding heat exchange, in all oxygenators, the temperature probes on the oxygenator for monitoring the blood temperature are considered to be unreliable, since they underestimate the actual temperature of the patient,[20] and measuring heat-exchange performance presents a particular challenge. Overall, we can say that, in our experience, the Trilly AF pediatric oxygenator performs adequately.

In conclusion, our experience with the Trilly oxygenator (Eurosets) has proven that it is effective in terms of O_2 uptake and CO_2 removal, blood fluid dynamics, metabolic compensation and heat exchange in a pediatric population, and it showed adequate safety and performance in a clinical setting without iatrogenic problems. **STI**

AUTHORS' DISCLOSURES

IC is a consultant for Eurosets Srl (Medolla, MO, Italy).

AUTHORS' CONTRIBUTIONS

ST, MP, SG and MF contributed equally to this work.

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