Comparison of Four Stainless Steel Heat Exchangers for Neonatal ECMO Applications

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ABSTRACT

Conventional neonatal extracorporeal membrane oxygenation (ECMO) circuits utilize a heat exchanger distal to the oxygenator to replace ambient heat loss and maintain patient normothermia. A secondary function of the ECMO heat exchanger is to act as an arterial line bubble trap to protect the patient against accidental air embolism. Using an asanguinous recirculating test circuit, we measured and compared heat transfer properties, pressure drop, air trapping capabilities, and priming characteristics of four commercially available stainless steel heat exchangers currently being used in neonatal ECMO circuits: AVEco ECMOtherm, Gish HE-3, Gish HE-4, and Electromedics D1079. Manufacturers’ product specifications were also compared.

The pressure drop across all four heat exchangers was less than 10 mmHg with flow rates up to 500 ml/min. The Gish HE-3 and HE-4 were the easiest to prime and de-air, while the Electromedics D1079 was the most difficult. The heat exchangers with integral bubble traps (D1079 and HE-4) have superior air trapping capabilities. The ECMOtherm provided moderate air trapping capabilities (>7.3 ml ± 1.5 ml) at flow rates under 300 ml/min. The low prime HE-3 was the poorest at trapping air; less than 1 ml at a 400 ml/min pump flow rate. Thermal analysis indicated that the D1079 had the highest performance factor, though all four heat exchangers had similar heat transfer rates and were capable of warming perfusate from 34° to 37°C on a single pass at pump flow rates of 500 ml/min. We conclude that all four heat exchangers can adequately maintain patient normothermia in neonatal ECMO applications. There are, however, significant differences in priming volumes, air trapping capabilities, and manufacturers’ recommended maximum use time.

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INTRODUCTION

Though the conventional neonatal extracorporeal membrane oxygenation (ECMO) circuit has retained the same fundamental design that was introduced by Bartlett and Gazzaniga in 1977 (1), there have been numerous modifications and improvements to each of the components of the circuit. Specifically, improved cannulae, more durable PVC tubing, lower prime bladders with better flow characteristics, approved oxygenators that are individually tested rather than lot tested, and the use of stainless steel instead of aluminum as the thermal core material of the heat exchanger. Use of aluminum in the ECMO heat exchanger fell into disfavor when aluminum emboli, presumably originating from the heat exchanger, were found in organ beds of neonates treated with ECMO (2). Evidence of aluminum contamination by heat exchangers during cardiopulmonary bypass has also been reported (3).

In contrast to the usual pre-oxygenator placement of heat exchangers in cardiopulmonary bypass circuits, the heat exchanger in the neonatal ECMO circuit is positioned distal to the oxygenator (Figure 1). There are two reasons for this configuration. First, at the low flow conditions during ECMO there can be significant blood heat loss across the membrane which is ventilated with cool gas. Secondly, the heat exchanger can act as an arterial line bubble trap in this position. The concerns of generating gaseous microemboli caused by thermal gradients are minimal in normothermic ECMO applications.

According to a 1993 ECMO equipment survey (4), the A vecor ECMOtherm heat exchanger is used by 79% of reporting ECMO centers, with heat exchangers from Gish (4%), Electro medics (9%), Dideco (1%) and other (6%) comprising the remainder. In this study, we made bench top comparisons of pressure drop, air trapping capacity, priming characteristics, and thermal performances of four stainless steel heat exchangers that are currently being used in neonatal ECMO circuits: A vecor ECMOtherm, Gish HE-3, Gish HE-4, and Electro medics D1079 (Figure 2).

MATERIALS AND METHODS

DESCRIPTION OF HEAT EXCHANGERS

A vecor ECMOtherm: The ECMOtherm has a tube-in-shell design that is 18.5 inches long. Blood flow is diverted inside seven stainless steel tubes with water circulating in a counter-current fashion around them. Inside each tube is a steel rod insert to reduce priming volume and promote blood mixing. The blood contact surface of the stainless steel is coated with an adherent layer of silicone polymer. The water and blood paths are separated at the ends by a pair of seals between which is a vented air space. This reduces the possibility of a water-to-blood leak.

Gish HE-3: The Gish HE-3 has a “double pipe” configuration utilizing a convoluted steel tube as a thermal core which is enclosed by a polycarbonate shell (5). Blood flow is directed around the thermal core while water passes on the inside of the tube. Reinforced O-rings seal the blood path from atmosphere. The device is 12 inches in length.

Gish HE-4: Like the HE-3, the HE-4 utilizes a “double pipe” configuration with an 18 inch convoluted steel tube with blood on the outside, water on the inside. The HE-4 incorporates a bubble trap at the top of the device with a luer connector to vent the trap. Reinforced O-rings seal the blood path from atmosphere. The HE-4 also has a temperature monitoring port at the blood outlet site.

Electro medics D1079: The D1079 is a cylindrical heat exchanger with a blood inside/water outside fin-type steel thermal core enclosed by a clear polycarbonate shell. The D1079 incorporates a bubble trap at the inlet side. Water and blood paths are separated by potting material at each end. The D1079 has a luer connector at the top of the bubble trap for venting and has both inlet and outlet temperature monitoring ports.

THE TEST CIRCUIT

A recirculation test circuit was assembled using 1/4” PVC tubing, a Sarns 500 ml bag reservoir, and a Shiley Stöckert roller pump. The circuit was primed with 500 ml of lactated ringers solution. The test heat exchangers were placed distal to the roller pump, mounted vertically in the circuit with the blood inlet on the...
top and the outlet on bottom (with the exception of the HE-4, the
blood inlet is on the bottom). The following tests were per­
formed:

PRESSURE DROP

Using disposable transducers, the circuit line pressure was
measured proximal and distal to the heat exchanger. The hydro­
static pressure difference between proximal and distal sites was
corrected by zeroing inlet and outlet transducers in the test
position. The difference between inlet and outlet static pressure
(pressure drop across the device) was measured in triplicate from
flows of 100 ml/min to 2000 ml/min.

AIR TRAPPING CAPACITY

Air trapping capacity was measured at different pump flow
rates by injecting air at a rate of 1 ml/sec into a pre-heat exchanger
port in the circuit. When air was detected post-heat exchanger by
a Shiley© Stöckert ultrasonic air emboli detector, the injection
was stopped and the volume of injected air recorded. The bubble
detector was set at its most sensitive setting which is capable of
detecting 0.02 ml bubbles.

THERMAL PERFORMANCE

Temperature probes were placed in the circuit distal and
proximal to the test heat exchangers, and in the water bath line at
the heat exchanger inlet. A Sarns® Heater/Cooler was used to
maintain a water bath temperature of 40°C. At set pump flow rates of 100, 300, and 500 ml/min,
the circuit prime was warmed and inlet and outlet temperatures recorded. Heat exchanger
performance factors (PF) were calculated at
flow rates of 100, 300, and 500 ml/min using the formula:

\[ PF = \frac{T_{bo} - T_{bi}}{T_{wi} - T_{bo}} \]

where \( T_{bo} \) is the blood outlet temperature,
\( T_{bi} \) is the blood inlet temperature, and \( T_{wi} \) is the
water inlet temperature.

Total heat transfer rates in British Ther­
mal Units (BTU)/min across the devices was
also determined during steady-state, steady-flow
conditions. Assuming that the specific heat trans­
er is equal to the change in enthalpy across the
devices, the heat transfer rate (BTU/min) was
calculated using the following derived equation:

\[ Q_{cv} = m\Delta h \]

where \( Q_{cv} \) is heat transfer rate, \( m \) is the
mass transfer rate (density of fluid x pump flow
rate) through the heat exchanger in pound mass
(lbm)/min, and \( h \) is the specific enthalpy in
BTU/lbm (6). Enthalpy terms were obtained
from a saturated steam table (6) at the appropri­
ate blood exit and inlet locations.

PRIMING

Heat exchanger priming volumes were
determined by completely filling the devices
from inlet to outlet with fluid and then draining
into a graduated cylinder for measurement.

Using dry heat exchangers, we assessed
priming characteristics by the ease and speed of
de-airing the devices. The heat exchangers were
not CO₂ flushed prior to priming.
RESULTS

The heat exchangers' priming volumes, maximum blood flow rates, manufacturers' recommended use times, and relative ease of priming are shown Table 1. Measured priming volumes differed significantly, ranging from a low of 17 ml (HE-3) to a high of 75 ml (HE-4 with the bubble trap filled). The ECMOtherm and D1079 primed with volumes of 46 ml and 48 ml, respectively. The Avecor ECMOtherm was developed specifically for long-term ECMO applications, though the manufacturer does not assign a specific “maximum use time” to the device. The manufacturer's recommendation for use time of the HE-3 and HE-4 is 144 hours. The D1079 was developed for cardioplegia delivery systems and is not rated for long-term use. All of the devices have maximum flow ratings which exceed flow requirements for neonatal ECMO applications. The D1079 offers the highest rated flow (3 L/min) while all the other devices are rated to 2 L/min. The D1079 was judged to be the most difficult device to prime and de-air. The ECMOtherm was determined to be easier to prime than the D1079, but more difficult than either the HE-3 or HE-4.

Thermal performance factors of the test heat exchangers for pump flow ranges up to 500 ml/min are shown in Figure 3. All devices showed the anticipated trend of decreasing performance factors with increased pump flow rates. The D1079 had the highest performance factors at each of the flow rates examined, while the Gish HE-3 had the lowest performance factors at the measured flow rates. Performance factors at 100 ml/min were 0.81, 0.85, 0.90, and 0.92 for the HE-3, HE-4, ECMOtherm, and D1079 respectively. At flow rates of 500 ml/min the performance factors were 0.64, 0.70, 0.72, and 0.86 for the HE-3, HE-4, ECMOtherm, and D1079 respectively.

Total heat transfer rate in BTU/min is shown in Figure 4 and indicates similar heat transfer response for all four test heat exchangers. It was noted that each heat exchanger was capable of warming perfusate from 34°C to 37°C with a single pass (water bath temperature at 40°C) at flow rates of 500 ml/min.

Pressure drop across the heat exchangers (Figure 5) was not significantly different at flow rates up to 500 ml/min; less than 10 mmHg for each device. At a flow rate of 2000 ml/min, however, differences between heat exchangers became evident. The D1079 had the lowest pressure drop at all flows measured.

The heat exchangers with integral bubble traps (the D1079 and HE-4) showed the greatest capability to trap air and were
least affected by increased pump flow (Figure 6). The HE-4 trapped 35.3 ± 0.6 ml and 33.0 ± 1.7 ml at flow rates of 100 ml/min and 500 ml/min, respectively. The D1079 trapped a maximum of 41.0 ± 1.0 ml at a 100 ml/min pump flow rate. A gradual reduction in trapping capacity in the D1079 occurred as the pump flow rate was increased. At pump flow rates of 500 ml/min, 32.7 ± 2.5 ml was trapped. The ECMOtherm heat exchanger trapped 29.3 ± 1.2 ml and 20.3 ± 1.5 ml at pump flow rates of 100 and 200 ml/min, respectively. The ECMOtherm showed a rapid drop in air trapping capacity from 20.3 ± 1.2 to 7.3 ± 1.5 ml when flow rates were increased from 200 to 300 ml/min. The low prime HE-3 had the poorest air trapping capacity, with a maximum trapping capacity of 10.3 ± 1.5 ml at a 100 ml/min pump flow rate. At a pump flow rate of 300 and 500 ml/min, the HE-3 would trap 1.6 ± 0.3 and 0.23 ± 0.21 ml of injected air, respectively.

DISCUSSION

The thermal requirements of heat exchangers for neonatal ECMO are limited to maintaining normothermia. Our studies as well as the clinical experience at other centers indicate that despite clear differences in performance factors, all four of the test heat exchangers are capable of achieving this primary purpose. Accordingly, the heat transfer rates are similar at ECMO flow ranges for all four test heat exchangers, which may demonstrate the shortcomings of weighing performance factors too heavily when choosing heat exchangers. Pressure drop across the four test heat exchangers was not appreciably different from one another within neonatal ECMO flow rate ranges. Therefore, other characteristics must be examined when evaluating heat exchangers for ECMO applications.

The priming volume of the heat exchanger can represent up to 15% of the total circuit volume. The Gish HE-3 has the advantage of being the most compact heat exchanger with the least priming volume (17 ml - nearly one third of the ECMOtherm volume) and smallest blood contact surface area of the four devices we tested. Our measured priming volume of the Gish HE-4 was markedly higher than the manufacturer's stated priming volume; 75 ml measured versus 60 ml stated (Table 1). We measured the volume of the HE-4 with the bubble trap full to avoid any blood/air interface, whereas the manufacturer may have measured the volume with the bubble trap only partially filled.

Devices used in ECMO circuits need to function for prolonged periods. The ECMO registry data indicates that the average ECMO time course for the neonatal respiratory failure patient population (n=8136) is currently 140.58 hours, or 5.9 days (7). The ECMOtherm heat exchanger was developed and approved specifically for long-term ECMO applications and has an advantage of not having a maximum use time assigned to the device. The Gish HE-3 and HE-4 heat exchangers have maximum use ratings of 144 hours, or 6 days. After 6 days of use the manufacturer's recommendations would be in violation. The Electromedics D1079 was developed for cardioplegia systems and is not approved for long-term use, nor is it promoted for ECMO applications by the manufacturer.

All four devices utilize a stainless steel thermal core. Despite having an inferior heat transfer coefficient and more difficult fabrication characteristics when compared to aluminum, stainless steel provides better relative tissue compatibility in long term use (8). In addition, the ECMOtherm has an adherent layer of silicone polymer coating the blood contact surfaces to enhance biocompatibility. This coating has been previously implicated as a possible source of silicone emboli which may occur from erosion off the aluminum mixing rods in the SciMed P-7-14 heat exchanger (the ECMOtherm precursor used extensively on ECMO circuits until 1988) (9,10). Avecor, in repeating these experiments, has been unable to duplicate this silicone erosion phenomenon (personal communication). There is no data on silicone erosion from the stainless steel ECMOtherm.

Our data indicates substantial differences in the air trapping capacities of the four devices. The trapping capacity of the ECMOtherm has been previously investigated by Kurusz, et al, who showed that the ECMOtherm could effectively trap up to 5 ml air at flow rates less than 400 ml/min (11). Similarly, in the ECMOtherm, our tests showed a trapping capacity of 4.3 ± 0.6 ml at a flow rate of 400 ml/min. In addition, we found a rapid reduction in total air trapping capacity from 20.3 ± 1.5 ml at 200 ml/min to 7.3 ± 1.5 ml at 300 ml/min in the ECMOtherm. The Gish HE-3 had little, if any, air trapping capacity at flow rates above 300 ml/min. As expected, devices with integral bubble traps, the HE-4 and D1079, had the greatest ability to trap gross air (at 300 ml/min, 34 and 36 ml respectively) and showed the least drop off in trapping capacity at higher flow rates.

Historically, the heat exchanger has been regarded in ECMO circuits as an air embolism safety device by acting as a gross bubble trap, especially when positioned vertically with the blood inlet on the top and the outlet on the bottom. As a result of the variations observed in air trapping capabilities between the devices, total reliance on the heat exchanger for air embolism protection may not be warranted. Bubble detectors are available for extracorporeal pumps and should be considered for ECMO applications. Currently, the use of air bubble detectors on neonatal ECMO circuits has not been embraced: as of 1993, only 13% of all ECMO centers were using bubble detectors on neonatal circuits, a decline from 17% in 1990 (4,12).

We were concerned over the possibility of stasis and fibrin formation in the devices with integral bubble traps, especially in the low flow, minimal anticoagulation environments found in ECMO procedures. Also, we had questions regarding management of the integral bubble trap - whether to keep the purge port opened or closed on the bubble trap.

Each of the devices has certain key advantages and disadvantages. The Gish HE-3 and HE-4 have a visible blood path which was considered an advantage over the ECMOtherm and D1079, in which blood passes through stainless steel tubes or fins and, therefore, cannot be viewed. Additionally, the Gish HE-3 has the benefits of an easy-to-prime configuration and a low
prime volume/low blood contact area, but because of its ineffectiveness at trapping air cannot be recommended without another form of air embolism protection. The ECMOtherm has historical reliability, no time use limits, and is a fair bubble trap at flows under 300 ml/min. The silicone enhanced biocompatibility is an advantage, but the possibility of erosion should be investigated. Heat exchangers with an integral bubble trap can be considered in programs that are currently using separate bubble traps in their circuits. Lastly, medical legal issues must be evaluated in using any device outside of the manufacturer’s recommendations. Further studies of these devices under the special conditions that exist in long-term neonatal ECMO procedures are necessary to fully evaluate their performance for this application.

REFERENCES


ADDENDUM

DERIVATIONS OF TOTAL HEAT TRANSFER

In addition to investigating the so called “performance factor” so often quoted in the research and sales literature, it was decided to perform a more rigorous analysis. A classical approach employing the concepts from the first law of thermodynamics, continuity and heat transfer was employed to provide the total heat transfer rate in BTU/min.

This technique was believed to alleviate what the authors felt were shortcomings of the performance factor format of data presentation. The heat transfer capability of a single pass concentric cylinder heat exchanger employing counter-current flow is the algebraic product of the log - mean temperature distribution (analogous to performance factor) wetted area available for heat transfer and the overall heat transfer coefficient which is a function of the material from which the heat exchanger is composed and the fluid mechanical flow properties on the inside and outside of the heat exchanger. In equation form this becomes: $Q = UA_{w} \Delta T_{m}$, where $U$ is the overall heat transfer coefficient, $A_{w}$ is the wetted area, $\Delta T_{m}$ is the log - mean temperature difference, and $Q$ is the heat transfer rate. It can be noted that while $\Delta T_{m}$ may be significantly better for one particular heat exchanger as compared to another, the geometry and flow characteristics may be much different and, therefore, the actual thermal energy that is transmitted to the blood path and used to warm or cool the patient may or may not be much different as well. In other words, it was felt that in order to truly evaluate a heat exchanger the actual heat transfer rate should be determined.

Applying the first law of thermodynamics to a stationary control volume operating at steady-state, steady-flow conditions, the following assumptions are valid: i) the control volume is...
stationary relative to the non-inertial reference frame; ii) the state of mass does not change with time within the control volume, i.e., mass does not accumulate within the control volume); and iii) the state of mass at each discrete entrance and exit across the control surface of the control volume and the mass flux are invariant with time.

The continuity consideration yields:

\[ \frac{d}{dt} \left( \int \rho \, dv \right) + \int \rho U_n \cdot ds = 0 \]

Assumption ii) yields:

\[ \frac{d}{dt} \int \rho \, dv = 0 \]

\[ \int \rho U_n \cdot ds = \dot{m}_i = \dot{m}_e = \dot{m} \]

The first law of thermodynamics yields:

\[ \dot{Q}_r = \frac{d}{dt} \left( \int \epsilon p \, dv \right) + \int \left( h + \frac{V^2}{2g} + \frac{Z \mu}{g} \right) \rho U_n \cdot ds + W_{fr} \]

But the time dependent energy term vanishes for steady-state and the only work that is done by the control volume on the fluid is the flow work contained in the enthalpy convection terms. Therefore, \( W_{fr} = 0 \) as well. Also since the control volume is evaluated in the horizontal position and the inlet and exit blood path flow velocities are essentially equal the change in the potential and kinetic energy flux terms are negligible. Therefore the heat transfer equation reduces to the much simplified form:

\[ \dot{Q}_r = \int \rho U_n \cdot ds \]

or

\[ \dot{q}_r = \frac{\dot{Q}_r}{m} = h_e - h_i \]

\[ \dot{Q}_r = \dot{m} \Delta h \]

Therefore the specific heat transfer is equal to the change in specific enthalpy and the heat transfer rate is the product of the mass flow rate and change in specific enthalpy. This assumes that the flow work component of the specific enthalpy is the product of specific volume and static pressure as compared to specific volume and the normal stress tensor. For water and for comparative purposes this difference is negligible.