Perfusion 1991; 6: 175–181

Logistics of an ECMO programme

Mark Kurusz and **Joseph B Zwischenberger** Department of Surgery, Division of Cardiothoracic Surgery, University of Texas Medical Branch, Galveston, Texas

Introduction

Among three possible uses of extracorporeal circulation proposed by John Gibbon Jr in 1939, one was temporary support for acute cardio-respiratory failure.[1] While the primary use of the heart-lung machine as envisioned and developed by Gibbon was for short-term circulatory support in the operating room during open cardiac surgery, his extensive laboratory work presaged the current widespread (and growing) use of artificial oxygenators and mechanical pumps for prolonged circulatory support in the intensive care unit (ICU) setting.

Extracorporeal oxygenation for respiratory failure in a newborn was first attempted by Rashkind and co-workers using a bubble oxygenator in 1965.[2] Hill performed the first successful prolonged extracorporeal membrane oxygenation (ECMO) case in an adult in 1972.[3] This was followed by clinical trials in infants by Bartlett and co-workers, with the first successful case reported in 1976.[4] A multicentre prospective randomized trial of ECMO in adults with acute respiratory failure was reported in 1979.[5] The survival rate with ECMO was 9.5% compared with 8.3% using conventional ventilatory management, which led to general disinterest in the technique for adults.

In 1985 Bartlett and his associates conducted the first prospective randomized study demonstrating the success of ECMO in neonates.[6] O'Rourke and co-workers subsequently conducted another prospective randomized study comparing ECMO to conventional medical therapy; again the outcome with ECMO was superior with 28 of 29 infants surviving compared to six out of ten with conventional management.[7] ECMO is currently the treatment of choice for term newborns with severe respiratory failure unresponsive to maximum medical management.

Until 1983, ECMO was limited to neonates at only a few centres. However, open communication between these centres helped promote the technique and make it become widely available. Our programme in Galveston began in 1986 as the twenty-first established in the United States. The growth of ECMO programmes has been most dramatic in the last five years (see Figure 1). In 1987, the number of programmes doubled from the previous year. According to the Extracorporeal Life Support Organization (ELSO) in Ann Arbor, Michigan, there are currently 81 programmes, eleven of which are located outside the United States.

The purpose of this paper is to review our

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The purpose of this paper is to review our

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experience in establishing an ECMO programme with an emphasis on the organizational and technical aspects. Additionally, recent survey data regarding equipment, monitoring and personnel currently used for neonatal ECMO will be summarized. Finally, the common mechanical complications that can occur will be briefly discussed along with measures that have been taken by us and others to minimize the risk of the technique.

Organizational logistics

The complex and challenging care of patients treated with ECMO requires a highly trained and skilled team of professionals comprising physicians, perfusionists, nurses and ECMO technicians ('specialists'). One of the most pressing considerations with ECMO is meeting the personnel requirements. Figure 2 compares the number of cases and personnel hours between cardiopulmonary bypass and ECMO as performed at our hospital during a 12-month period. There were 306 cardiopulmonary bypass cases with an average pump time of 131 minutes; adding all cases, the total pump time was 672 hours. In contrast, there were 12 ECMO cases during the same time with an average duration of ECMO support of 118 hours, or a total 'on pump' time of approximately 1400 hours. Thus, it is evident that ECMO is highly labour intensive and in this example 12 ECMO babies required twice the number of hours of pump management than did 300 open-heart surgical patients. Unless there is an overabundance of perfusionists at a hospital, one of the primary logistical considerations is that the perfusion team cannot sit ECMO shifts in addition to their operating room duties.

Virtually every employee of the hospital is affected by the decision to establish an ECMO programme (see Figure 3). In our programme, policy and important decisions are made by a 'triumvirate' composed of the ECMO Medical Director, ECMO Co-ordinator and Chief Perfusionist. This group has met regularly since the inception of our programme to discuss ECMO issues and ensure adequate communication is maintained among the three disciplines. The 'triumvirate' also has been largely responsible for training critical care nurses to become ECMO

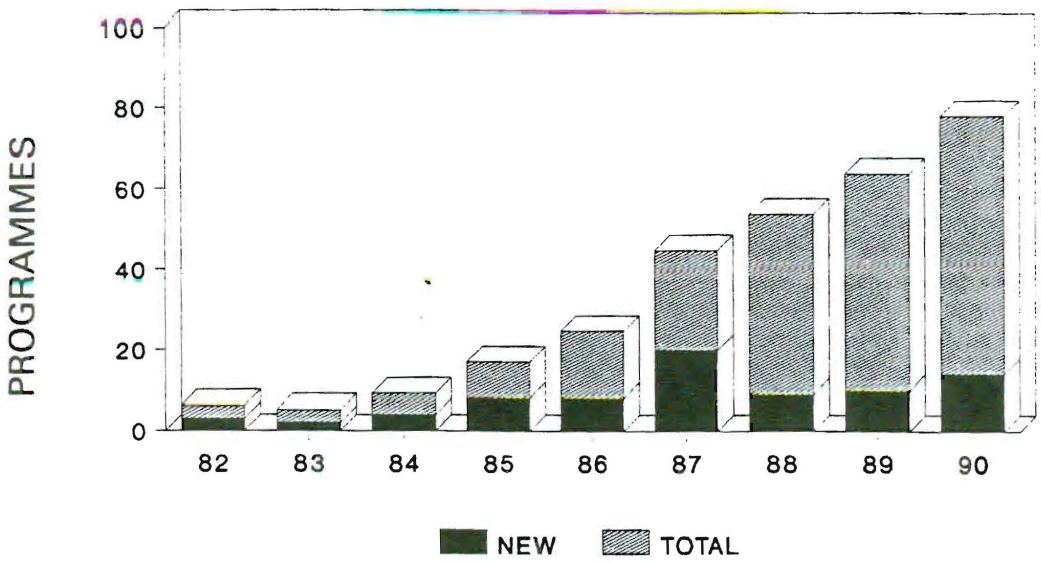

Figure 1 Growth of programmes since 1982. (Data courtesy of Extracorporeal Life Support Organization, Ann Arbor, MI, USA.)

CPB	12 MONTHS	ECMO
306	Patients	12
131 min	Mean Pump Time	118 hours
672 hrs	Total Pump Time	1418 hrs

Figure 2 Cardiopulmonary bypass (CPB) hours versus ECMO hours during a 12-month period at the University of Texas Medical Branch.

specialists who manage the circuit at the bedside whenever a patient is on ECMO. Such management is governed by formal protocols and daily orders determined by the responsible physician(s). There are a variety of organizational options used by other programmes; however, all agree that physicians, nurses, perfusionists and respiratory therapists must work together to ensure a successful ECMO team.

The level of involvement of our perfusion team is to set up and prime the ECMO circuit and provide expertise for any technical problems such as changing out an oxygenator. The perfusionists provide advice regarding circuit design, including use of specific equipment and monitoring devices. The perfusionists, in conjunction with the ECMO nurse co-ordinator, also help develop technical protocols and check lists. Perfusionist 'back-up' in the hospital while a patient is on ECMO was only used early in our experience. However, a few programmes do maintain this level of involvement, particularly if the co-ordinator is a perfusionist.

The ECMO co-ordinator in more than 70% of programmes is a Registered Nurse with critical care experience; however, certified perfusionists or registered respiratory therapists also function as co-ordinators at several programmes. The medical director and co-ordinator must interact frequently and establish good working relationships with several hospital departments and services including the blood bank, operating room, radiology, paediatric cardiology, respiratory therapy, clinical laboratories, transport team, emergency room, paediatrics, neonatology, the intensive care units and housekeeping. As noted earlier, an ECMO programme has a profound effect on a hospital at all levels of primary and ancillary services.

In our experience, an ECMO programme can serve as an incentive to retain critical care nurses at a university hospital. They are already familiar with the care of seriously ill patients and after training and laboratory experience they become quite proficient at managing the ECMO circuit. Bedside assessment of the patient on ECMO is an important responsibility of the ECMO specialist and nurses by their training are skilled at this job. We initially trained between 10 and 15 nurses each year who were obligated to cover three 12-hour ECMO shifts per month. However, recently we have established a permanent ECMO team with six full-time ECMO nurses. When a patient is not on ECMO they perform regular critical care nursing duties.

The team composition reported in a national survey[8] confirms this approach. The majority of programmes (89%) employ a Registered Nurse (RN) with ICU experience as the ECMO specialist to provide bedside management of the extracorporeal circuit and patient anticoagulation. Fifty-seven per cent have exclusively RNs, while the other programmes employ a combination of personnel. One programme used exclusively perfusion assistants and one exclusively respiratory therapists. For the 16 programmes (36%) that used a combination of personnel, they most often consisted of RNs or respiratory therapists.

Training of ECMO specialists is the primary responsibility of the hospital that establishes an ECMO programme. Nurses, respiratory therapists and perfusionists all function as ECMO specialists and their inherent deficiencies can be corrected with specialized training. Training consists of didactic instruction, animal laboratory experience, water drills and clinical supervision or preceptorship. The average length of didactic instruction reported in the survey[8] was 25 hours and ranged from 12 to 48 hours.

We spend 20 hours in the classroom with lectures from the three members of our ECMO 'triumvirate'. Next, several hours are spent in the laboratory actually doing ECMO on animals. In our case it has been sheep or piglets. Water drills are used primarily to teach about circuit complications and are part of a yearly refresher course. Finally, no ECMO specialist is permitted

to function alone until she or he has been observed clinically during a preceptorship with either the co-ordinator or another trained ECMO specialist.

There is a wide range of hours for clinical preceptorships nationally, ranging from none to 150 hours. Some programmes have discontinued animal laboratory experience and this may account for the long number of hours spent to qualify their ECMO specialists. Annual ELSO meetings at the University of Michigan and by other groups review basic ECMO physiology, circuit design, patient selection and management, research and associated ECMO issues. A standardized training manual for ECMO specialists is in preparation by ELSO and should be available shortly.

The cost of establishing an ECMO programme in Galveston in 1986 using some available perfusion equipment was approximately $45000 and included new equipment purchases and classroom and laboratory training. A reasonable estimate of startup costs in 1991 would be at least $100000. The current patient charges for ECMO

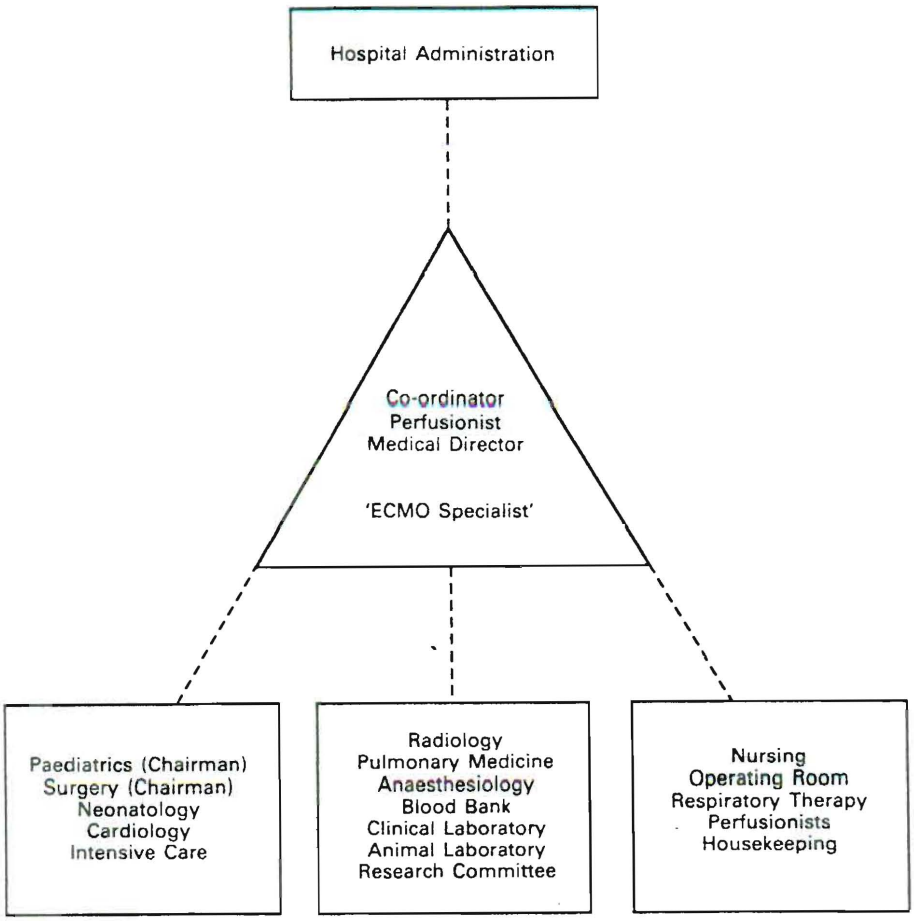

Figure 3 Organization of an ECMO team. Note that major policy and operational decisions are made by the ECMO 'triumvirate' (middle of diagram) after approval and funding of hospital administration (top) to establish an ECMO programme. Support is required from numerous hospital departments and services (bottom) every time a patient is put on ECMO.

in our hospital to cover supplies and the ECMO specialists' time is approximately $3000 per day. While these expenses may seem high, analysis by other groups have shown that ECMO may cost less than conventional treatment.[9] Reimbursement for ECMO is accepted by most third party insurers and by government-backed insurance in the United States.

Technical aspects

While ECMO has been called 'prolonged bedside cardiopulmonary bypass',[10] fundamental differences exist. Unlike conventional cardiopulmonary bypass, ECMO is performed using extrathoracic cannulation of the great vessels at normothermia with no cardiotomy suction, vents or cardioplegia. Basic circuit components for ECMO include a venous blood drainage reservoir, a servo-regulated roller pump, a membrane oxygenator to exchange oxygen and carbon dioxide and a heat exchanger to maintain temperature. The most commonly used configuration is venoarterial: that is, venous blood flows by gravity from a cannula inserted into the right internal jugular vein to the small (<50cc) venous reservoir mounted in a bladder box that servo-regulates the roller pump in the event of decreased blood volume. A roller pump pumps blood through a Sci-Med membrane oxygenator (Sci-Med Life Systems Inc., Minneapolis, MN), a Sci-Med tubular heat exchanger, then into the aortic arch via the right common carotid artery.

Because ECMO is done for several days, servo-regulation of the circuit is necessary to ensure adequate venous flow for a given pump rate. Both the patient and circuit are checked by the ECMO specialist at regular intervals, which includes neurologic, respiratory and cardiovascular assessment. Circuit checks include cannula-to-cannula inspection for circuit integrity (e.g. absence of blood leaks or foam/air). The oxygen concentration and flow of gas entering and exiting the oxygenator is checked routinely. Monitors and alarms are recalibrated and verified to be operational. Correct roller pump occlusion is verified periodically by momentarily clamping the inlet to the bladder box reservoir to observe collapse of the bladder reservoir. Heparin anticoagulation is adjusted according to the activated clotting time (ACT) performed at least hourly. The entire time the patient is on ECMO an ECMO specialist is in attendance at the pump and for most cases the duration of support is technically uncomplicated.

Because the Sci-Med membrane is the only US Food and Drug Administration-approved oxygenator for long-term use, all programmes surveyed[8] currently use it. Pre- and postoxygenator pressures can be measured to continuously assess pressure drop across the membrane. The monitors will alarm if excessive line pressures are detected.

Most programmes use a dual roller pump; we prefer the Polystan (Polystan A/S, Ballerup, Denmark) because it has a direct drive motor. Centrifugal pumps often are used on paediatric patients greater than 20kg. The most widely used pumphead tubing is a modified polyvinyl chloride ('Super Tygon', Norton Performance Plastics Inc., Akron, OH). We have run samples continuously in the laboratory for 15 days with no failures and never have had any clinical failures with one-quarter inch internal diameter, one-sixteenth inch wall thickness. Several tubing segments have been examined after more than 250 hours of continuous pumping with negligible wear.

Circuit configurations vary slightly from programme to programme, but all use a portable cart which can be transported easily to different areas of the hospital. In Galveston we perform ECMO in three different ICUs and occasionally have had to transport patients to or from the operating room. A battery provides electrical power and is kept online in the ICU in case of interruption of wall power.

Because of the frequency of ACT measurements, using a device that requires a small (<0.4cc) sample volume can minimize blood loss. We have used the ACTester device (Trimed Inc., Huntington Beach, CA) but have experienced several instances of consumptive coagulopathy requiring circuit change-outs more than other programmes in the ELSO database. We have recently switched to the Hemochron device (International Technidyne Corp., Edison, NJ) favoured by most programmes. The ACT values are consistently about 50 seconds lower with the Hemochron when compared to the

ACTester, suggesting that our heparin dose will be increased to achieve protocol ACT values of 200–240 seconds.

Mechanical considerations

Minimizing the risk of mechanical complications is a goal during any long-term extracorporeal support. The ELSO database lists ECMO complications with the most common (10%) classified as 'other', indicating that in addition to identifiable components, the entire ECMO circuit is subject to failure. Cannula problems occur 8% of the time and oxygenator failure 5% of the time. Tubing rupture, pump failure, or heat exchanger malfunctions occur infrequently. The mean aggregate survival associated with any mechanical complication during 4221 ECMO cases was 75% (as compared to 83% overall), but causality is not documented nor implied by these data.

Obviously, backup equipment is important in the event that a major component in the ECMO circuit fails. We have adopted certain devices and practices to minimize the risk of mechanical complications. Preassembled sterile roller pump tubing is available in a supply cart kept next to the ECMO cart. Also included on this cart are drugs, syringes, needles and duplicate circuit components that might be needed urgently. ECMO specialists are required to demonstrate familiarity with emergency procedures such as hand-cranking the roller pump, removing air from the circuit, changing connectors and/or tubing (including the pumphead segment) and placing the patient on ECMO.

Appropriate equipment and circuit modifications can decrease the risk of ECMO. A simple plastic tubing holder which can be secured under the patient's mattress stabilizes the pump lines and cannulae. To facilitate an oxygenator change-out a double 'Y' connector before and after the oxygenator permits maintaining blood flow through one leg while the other is double-clamped and divided for insertion of the new membrane oxygenator.[11] Less than one minute off ECMO support for recirculation minimizes haemodynamic alterations during this manoeuvre.

Another simple, yet valuable monitoring device consists of a Doppler probe as is typically used to assess vascular blood flow. When attached to the ECMO circuit tubing just before the bladder reservoir, an audible continuous 'swishing' sound is heard.[12] If there are any drastic changes in flow, or if gross air bubbles pass the sensor, the ECMO specialist hears it immediately and can take corrective action. Other monitors include an in-line blood oxygen saturation probe in the venous line, a ventilating gas oxygen concentration monitor and a blood temperature probe to warn of potential problems before they become life-threatening.

Arterial air bubble detectors are not widely used during neonatal ECMO, primarily because of lack of availability and compatibility with existing pumps. For neonatal ECMO the heat exchanger, which is placed after the roller pump, also functions as a gross air bubble trap. Because of the potentially devastating consequences of air embolism, we are soon purchasing an air bubble detector for ECMO. These devices have a long successful track record in haemodialysis and conventional cardiopulmonary bypass which has led to our decision to use an air bubble detector servo-regulated to the roller pump.

In summary, the major logistical issue of ECMO is the personnel requirements. Establishing an ECMO programme requires a multidisciplinary team and a strong commitment on the part of the hospital.[13] The ELSO group has become established as a forum for active ECMO programmes and it will soon publish specific consensus guidelines for an ECMO programme.

Acknowledgement

Patricia L Allison RN, CCRN, Head Nurse of the ECMO programme at The University of Texas Medical Branch reviewed the manuscript and provided helpful input.

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