Clinical Trial of the Shiley Infant Oxygenator, Model S-070

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Introduction

Continued refinements in disposable bubble oxygenators have resulted in extremely efficient devices capable of high levels of performance during cardiopulmonary bypass. Recently such disposable oxygenators designed specifically for use in infants and children have become available.[1] Decisions regarding the reliability of an oxygenator must be based on gas to blood flow ratios, efficiency of the incorporated heat exchanger, and the degree of blood trauma as reflected by hemolysis. A clinical evaluation of the Shiley Infant Oxygenator Model S-070* was carried out at the University of Mississippi Medical Center in 20 patients weighing less than 30 kilograms who were undergoing cardiopulmonary bypass for correction of a variety of congenital heart defects. This report summarizes the performance of this oxygenator.

Construction and Fundamental Characteristics

The Shiley S-070 infant/pediatric oxygenator is a bubble-type oxygenator incorporating an integral venous side heat exchanger (Figure 1). It is composed of the bubble/heat exchange column and an arterial reservoir calibrated to a volume of 1500 cc. Venous blood is drained from the patient by gravity flow and enters the oxygenator through the 1/4 inch venous inlet connector. It immediately passes over the top of the bonded glass bead sparger (3-M Tegraglas™). Oxygen is introduced to the oxygenator and to a manifold directly beneath the sparger and passes through multiple flow paths through the sparger. The result of blood and gas mixture flow upward and around an anodized spiral aluminum heat exchange coil with a surface area of about 430 cm^2. Gas and heat transfer take place simultaneously while the mixture is rising to the top of the bubble-heat exchange column. At the top the flow is directed through a channel, and then into the defoamer. The gas and blood mixture flows into open cell polyurethane foam that has been coated with a silicone antifoam compound. The bubbles break and the blood flows through a final layer of nylon tricot into the arterial reservoir. The resultant gas passes through the upper portion of the reservoir and escapes through a gas vent at the top of the oxygenator. The arterialized blood is pumped back to the patient through either a 3/8 or a 1/4 inch arterial outlet connector.

Materials and Methods

In the period April 1978 to July 1978, 20 infants and children undergoing cardiopulmonary bypass for correction of various congenital heart defects (Table I) were perfused using the Model S-070 Shiley Infant Oxygenator. The protocol for testing this device was first approved by the Human Investigations Committee of the University of Mississippi Medical Center and detailed informed consent was obtained for each patient. Age ranged from 6 weeks to 10 years (mean 4.7 years) and the weight ranged from 4.4 to 28.2 kilograms (mean 15.6 kg). There were 14 females and 6 males. The perfusion circuit included a Pemco pump console,** Tygon tubing,*** Silastic pump head-

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* Shiley Incorporated, Irvine, California.

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*** Norton Industries, Akron, Ohio.

FIGURE 1.

ers,**** Pall***** 40 micron arterial filter, and Bentley 220 F cardiotomy reservoir.****** Water temperature was controlled with a Sarns heater/cooler.******* The gas mixture was 100 percent O_2. The total priming volume was 1000 ml which included 400 ml in the oxygenator and 600 ml in the tubing and filter. Heparinization was controlled by the activated clotting time described by Hattersly.[2] Both vena cavae and aorta were cannulated. Perfusion was at 2.4 L/min/M^2 during cooling and rewarming but was frequently decreased to 1.4 L/min/M^2 or less during actual performance of the surgical procedure. Rectal temperature during hypothermia ranged from 22°C to 37°C. Arterial blood was sampled from the oxygenator and venous blood was sampled from the venous lines. In 10 patients, CBC, platelet count, and plasma hemoglobin were obtained by standard techniques preoperatively, from the priming solution, at the start by bypass, during mid-bypass, and after termination

**** Dow Corning, Midland, Michigan.

***** Pall Corporation, Glen Cove, New York.

****** Bentley Laboratories, Irvine, California.

******* Sarns Inc., Ann Arbor, Michigan.

TABLE I

Procedure	Number
Ventricular Septal Defect	9
Atrial Septal Defect	5
Tetralogy of Fallot	3
Pulmonary Valvotomy	2
Double Outlet Right Ventricle	1
Total	20

Procedures performed using Shiley S-070 Infant Oxygenator.

of bypass. Nineteen patients had intraoperative monitoring of blood and gas flows, esophageal and rectal temperature, and arterial and venous PO_2 and PCO_2 during cooling, during the period of lowest temperature, and during rewarming. Gas flow meter difficulties prevented measurement of oxygen flows in one patient. Heat exchanger efficiency was determined during periods of cooling and rewarming. During rewarming water temperature was not allowed to exceed 41°C.

Results

Gas transfer data is summarized in Table II. More than adequate oxygenation occurred at low gas flow/blood flow ratios at all temperatures. The lowest ratio was obtained during periods of lowest temperatures. Cooling occurred at a rate of .99 degrees per minute while rewarming occurred at .54 degrees per minute. Changes in hematologic indices during bypass are summarized in Table III. All values fell at the beginning of bypass consistent with the degree of hemodilution. After an initial fall to approximately 30 percent of pre-bypass values, platelet counts returned to 47

TABLE II

	Cooling	Maximal hypothermia
Temperature °C (Rectal)	35	26
Gas flow/blood flow ratio	1.3:1	.95:1
Arterial PO_2 (mmHg)	151	168
Arterial saturation	99.7	96.1
Arterial PH	7.45	7.27
Arterial PCO_2 (mmHg)	29.5	34
Venous PO_2 (mmHg)	40	51
Venous saturation	79.6	80.9
Venous PH	7.38	7.26
Venous PCO_2	33	37

Gas flow data obtained using Shiley S-070 Infant Oxygenator. Blood gas data not temperature corrected. 100% oxygen.

TABLE III

	Pre-bypass	Start Bypass	Mid Bypass	End Bypass
RBC ($\times 10^6$/ml)	3.90	2.72	2.50	2.70
WBC ($\times 10^3$/ml)	7.51	4.8	3.1	7.9
Hgb (g/100 ml)	10.9	7.8	7.5	7.7
Hct (vol. %)	33.3	20.9	20.0	21.2
Platelets ($\times 10^3$/mm^3)	270	169	82	126
Plasma Hgb (mg/100 ml)	23	18	26	43

Hematologic data obtained during perfusion using Shiley S-070 Infant Oxygenator.

percent of pre-bypass levels by conclusion of bypass. Plasma hemoglobin gradually increased during bypass from 23 mg/100 ml at the beginning to an average of 43 mg/100 ml at the conclusion. Mean bypass time was 85 minutes. Pressure gradient across the heat exchanger was not measured but we have no reason to suspect that any significant gradient exists.

Discussion

The Shiley S-070 infant/pediatric oxygenator is designed specifically for infants and small children. We have used it in infants and small children undergoing cardiopulmonary bypass for correction of a variety of congenital heart defects. We have not used it in any situation in which projected blood flows calculated preoperatively might exceed 3 L/min. During this evaluation there were no malfunctions with either the oxygenator or its heat exchanger and no manufacturing defects were noted. It is easily assembled and required no special modification in the perfusion set up used in this institution. We are particularly impressed with its low priming volume which represents a decrease of some 38 percent over the previous pediatric oxygenator used in our institution.

The oxygenator performed well with adequate oxygenation being obtained during normothermic and hypothermic conditions at very low gas flow/blood flow ratios (1.3 and .95 respectively). These values are similar to those obtained with the Shiley Adult Oxygenator which is of similar design and are considerably better than those reported with the TMP* venotherm pediatric oxygenator.[1,3,4] Likewise, the changes in hematocrit, platelet count, and other blood indices are similar to those reported by others. We are unable to explain the increase in platelet count from the level noted in mid-bypass to the level at the end of bypass. This was not due to blood transfusion during bypass. The higher plasma hemoglobin at the conclusion of bypass (43 mg/100 ml) is misleading since the plasma hemoglobin in the prime was 23 mg/100 ml due to our tendency to use one unit of blood in the prime itself. Thus the change in plasma hemoglobin during bypass (or ratio of hemolysis) was 20 mg/100 ml (15.1 mg/100 ml/60 minutes) or not significantly different from other reports.[3] The rate of cooling and rewarming was quite good indicating a very efficient integral heat exchanger. Our previous setup required the use of an additional inline heat exchanger to achieve this rate of heating and cooling.

Since this clinical trial was completed an additional 74 infants and children have undergone bypass at the University of Mississippi Medical Center utilizing this oxygenator. Because of the extremely low gas flows made necessary by the small size of the patients and the low gas flow/blood flow ratio described above, recently a much more precise flow meter has been used. This has enabled better control and measurement of gas flow and we have discovered that the gas flow/blood flow ratio is actually much lower than suspected—about 0.8 at normothermia and 0.3 during hypothermia. We advocate the use of such a precise flow meter when utilizing this oxygenator in small infants in order to take advantage of its efficiency. We now use a gas mixture of 97% O_2—3% CO_2 during hypothermia in order to keep the arterial pCO_2 during this time more nearly in the physiologic range.

The performance of the Shiley S-070 infant Oxygenator was extremely good during this initial clinical trial and the subsequent patients in whom it has been used. We are particularly impressed by the low priming volume, the efficiency of gas exchange, and the efficiency of the heat exchanger. At the present time, it is the standard oxygenator used for infants and children in this institution.

* Texas Medical Products, Houston, TX

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