A Look at the BOS-10 and H-1500 Oxygenators

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Abstract

Having experienced difficulty, from time to time, in obtaining certain oxygenators from manufacturers for various reasons, we were prompted to investigate the convenience and possibility of using two oxygenators on a routine basis. An evaluation of the Bentley Spiraflo BOS-10 and Harvey H-1500 oxygenators was undertaken to determine the ease of use and compare the performance of each in the areas of blood gases, flows, and heat transfer. The BOS-10 oxygenator and the H-1500 oxygenator were each used for fifty perfusions on patients requiring cardiopulmonary bypass for the correction of cardiac/coronary disease.

While there was no statistical difference in blood flow between the two oxygenators, there was a significant difference in gas flow employed. The Bentley BOS-10 was able to adequately oxygenate at a lower total gas flow, but unable to adequately remove the CO_2 at these lower gas flows. There was no statistical difference in the arterial blood pO_2. The BOS-10 outperformed the H-1500 oxygenator when warming times were compared. For this reason we have discontinued the use of the H-1500 in favor of the S-100A and BOS-10S.

No problems were experienced in the routine use of two different bubble oxygenators. We believe that it is advantageous for an institution performing open-heart surgery to have at least two oxygenators available to the surgical team.

Introduction

Due to the occasional inavailability of certain oxygenators caused by various manufacturing problems, we felt it advantageous to be able to stock and use two brands of oxygenator. To determine whether the use of two oxygenators on an alternating basis is possible and convenient and produces similar results, a study was undertaken to use and compare the performance of the Bentley Spiraflo BOS-10[a] oxygenator and the Harvey H-1500[b]. Blood gases, blood and gas flow rates, rewarming times, and ease of use were documented and compared. Both the Bentley BOS-10[1,2] and the Harvey 1500[3] have been described in detail previous to this report.

Materials and Methods

A total of 100 patients underwent cardiopulmonary bypass for cardiac surgery. Fifty patients were perfused using the Bentley BOS-10 oxygenator, and fifty patients were perfused using the Harvey H-1500 oxygenator. Table I summarizes the procedures performed and demonstrates a comparable patient population. The average body weight of the BOS-10 group was 78.6 kg with an average BSA of 1.91 m². The H-1500 group had an average weight of 77.7 kg with an average BSA of 1.91 m². Those patients perfused using the BOS-10 oxygenator had a mean age of 58.1 years while those perfused on the H-1500 oxygenator had a mean age of 56.7 years (Table II). The BOS-10 group had an average bypass time of 118.7 minutes and the H-1500 group had an average bypass time of 129.4 minutes. The mean blood flow rate while cool was close to 4.0 LPM for both oxygenators and the warming/warm flow rate was about 4.3 LPM for both units (Table III). The cool gas flow rate for the BOS-10 was 2.6 LPM and 3.1

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[b] William Harvey, Santa Ana, CA 92705

TABLE I
Procedures

Procedures	BOS-10	H-1500
ACB × 1	1	1
ACB × 2	13	7
ACB × 3	15	24
ACB × 4	14	11
ACB × 5	2	5
ACB × 6	0	1
ACB × 7	1	0
AVR	3	0
MVR	1	1
TOTAL	50	50

ACB = Aorto-coronary Bypass Grafts, AVR = Aortic Valve Replacement, MVR = Mitral Valve Replacement

LPM for the H-1500. The warming/warm gas flow rate was 3.3 LPM and 3.6 LPM for the BOS-10 and H-1500, respectively (Table III).

The cardiopulmonary bypass circuit was identical while evaluating both the BOS-10 and H-1500 oxygenators. This circuit included a Bentley Q-120 cardiotomy reservoir[a] a Swank CA-100[c] cardiotomy filter, and Tygon S-50-HL[d] tubing supplied in a custom tubing pack made by Cobe[e]. The gas source used was 100% O_2 and 98/2% O_2/CO_2.

The prime consisted of 20 ml./kg. of patient body weight of Lactated Ringers (LR). To this was added 10mEq. of sodium bicarbonate per 500 ml. of LR to buffer the prime, and 2500 U. of beef lung heparin per 1000 ml. of LR. The patient's bypass hematocrit was calculated and if it fell below 30%, reconstituted CPD packed cells or whole blood was added to the prime.

A patient dose of 20% Mannitol is calculated from the patient's weight ((10(Kg. + 10)/2) and was given at the onset of bypass. If necessary, phenylephrine hydrochloride or sodium nitroprusside was administered to maintain a mean arterial blood pressure of 70–90 mmHg. When necessary, additional sodium bicarbonate was given to adjust the pH. If additional volume was required, whole blood or packed cells were used in the place of 5% Dextrose in 0.2% Sodium chloride to maintain a hematocrit above 29%. Three hundred units per kg. of body weight of beef-lung heparin was given to systemically heparinize each patient prior to cannulation and re-heparinization was administered as calculated by Activated Clotting Times (ACTs). ACTs were kept between 400–500 seconds.

Moderate hypothermia (30–32°C.) was maintained during bypass as measured by an esophageal temperature probe. Blood temperatures were not taken. Blood flows remained at 2.0 LPM/M^2 while the patient was cool, and increased up to 2.4 LPM/M^2 during the warming process. The water was supplied to the oxygenator's heat exchanger via the American Optical[f] Heating/Cooling Module Model #16725A. The water flow delivered by this unit is 11 LPM at a pressure of 4psi. The

[c] Pioneer Viggo, Inc., Beaverton, OR 97005

[d] Norton Company, San Jose, CA 95120

[e] Cobe Laboratories, Inc., Lakewood, CO 80215

[f] American Optical, Bedford, MA 01730

TABLE II
Patient Data

Data Description	BOS-10		H-1500	
Body Weight (Kg.)	range	55–122	range	54–109
	mean	78.6	mean	77.7
	S.D.	14.86	S.D.	9.89
Body Surface Area (M^2)	range	1.54–2.41	range	1.52–2.28
	mean	1.91	mean	1.91
	S.D.	0.20	S.D.	0.16
Age (years)	range	38–76	range	40–76
	mean	58.1	mean	56.7
	S.D.	9.19	S.D.	8.23

S.D. = Standard Deviation

TABLE III
Perfusion Data and Warming Times

ITEM	BOS-10 range	BOS-10 mean	BOS-10 S.D.	H-1500 range	H-1500 mean	H-1500 S.D.	p-value
BYPASS TIME (minutes)	50–249	118.7	43.48	55–221	129.4	40.79	n.s.
BLOOD FLOW RATE (LPM)							
Cool:	3.0–5.0	3.90	0.42	3.0–4.8	4.06	2.13	n.s.
Warming/warm:	1.2–5.5	4.33	0.65	3.1–5.5	4.34	0.53	n.s.
GAS FLOW RATE (LPM)							
Cool:	0.4–4.5	2.63	0.96	1.0–6.0	3.09	0.92	0.001
Warming/warm:	1.5–6.0	3.27	1.26	2.0–6.0	3.56	0.82	0.05
WARMING TIMES (minutes)	8–28	16.2	4.08	12–34	20.9	5.72	0.001

S.D. = Standard Deviation; n.s. = not significant

water temperature during the warming process never exceeded 42°C[4(p. 278)]. The water inflow and outflow temperature at the oxygenator was not measured.

The induction of anesthesia was achieved with sodium pentathol and succinylcholine. The level of anesthesia desired was maintained with nitrous oxide, halothane or Enflurane, and muscle relaxants, none of which were administered by the perfusionist.

Ten minutes after the initiation of cardiopulmonary bypass, the first arterial/venous blood gas sample was drawn. The second sample was drawn twenty minutes after the start of bypass and blood samples were taken every twenty minutes thereafter unless otherwise indicated.

The patient's aorta was not routinely cross-clamped, but rather partial bypass was maintained allowing the aortic valve to open during the suturing of the proximal anastomosis. While working on the distal anastomosis, intermittent fibrillation was often used. Total bypass was not used on any of the coronary bypass procedures, nor was any cold slush or cardioplegic solution used. Total bypass was used on all of the valve replacements. The aorta was cross-clamped and blood coronary perfusion used on all of the aortic valve replacements. One of the mitral valves in the BOS-10 group was replaced under cardioplegic arrest.

A two-tailed t-test[5] was used to analyze variance on the warming times between the BOS-10 group and the H-1500 group. Similarly analyzed were the gas flow rates, pH and $paCO_2$ values.

Results

The patients in this study were similar with respect to body weight, body surface area, and age. There was no statistical difference in the length of bypass, blood flow rates, arterial/venous (A/V) pO2, or patient hematocrits. There was statistical difference demonstrated in the warming times, gas flow rates, arterial pH and $paCO_2$.

The warming times were compared (BOS-10 16.2 ± 0.6 vs. H-1500 20.9 ± 0.8) and found to be statistically significant ($p < 0.001$) in that the BOS-10 group had faster warming times. The cool gas flow rates were compared (BOS-10 2.63 ± 0.64 vs. H-1500 3.09 ± 0.59) along with the warming/warm gas flows (BOS-10 3.27 ± 0.12 vs. H-1500 3.56 ± 0.08), and it was found that the BOS-10 adequately oxygenated the blood at a significantly lower ($p < 0.001$ and $p < 0.05$, respectively) gas flow than the H-1500.

The same test was applied to both the arterial pH and $paCO_2$ for both oxygenators. The cool values for arterial pH were compared (BOS-10 7.38 ± 0.014 vs. H-1500 7.42 ± 0.004) and the warm pH values were compared (BOS-10 7.35 ± 0.006 vs. H-1500 7.38 ± 0.005), and it was found that the BOS-10 group had significantly lower pH values ($p < 0.01$ and $p < 0.001$, respectively). The

TABLE IV
Blood Gas Data and Hematocrits

ITEM	BOS-10 range	BOS-10 mean	BOS-10 S.D.	H-1500 range	H-1500 mean	H-1500 S.D.	p-value
Arterial pH							
Cool:	7.26–7.55	7.38	0.21	7.27–7.58	7.42	0.06	0.01
Warming/warm:	7.19–7.50	7.35	0.06	7.28–7.48	7.38	0.05	0.001
Arterial pCO_2							
Cool:	25–52	36.97	5.54	22–45	33.73	5.13	0.01
Warming/warm:	28–60	40.59	7.11	25–48	36.72	4.97	0.001
Arterial pO_2							
Cool:	53–364	179.76	63.81	45–492	169.19	78.5	n.s.
Warming/warm:	66–470	203.83	94.98	54–492	216.49	105.28	n.s.
Venous pO_2							
Cool:	24–126	39.01	11.15	23–92	39.08	11.16	n.s.
Warming/warm:	31–93	46.98	11.18	32–72	47.47	9.28	n.s.
Hematocrit	21–37	30.59	2.50	18.36	30.39	2.55	n.s.

S.D. = Standard Deviation; n.s. = not significant

cool and warm pCO_2 values were compared also (BOS-10 35.97 ± 0.37 vs. H-1500 33.73 ± 0.33 and BOS-10 40.59 ± 0.70 vs. H-1500 36.72 ± 0.50, respectively), and found to be significant (cool $p < 0.01$ and warm $p < 0.001$) in that the H-1500 oxygenator was better able to "blow off" the CO_2 during cardiopulmonary bypass while maintaining an adequate pO_2.

The 98% O_2/2% CO_2 gas mixture was not employed in the BOS-10 group and blended in as needed in 16 patients of the H-1500 group.

Discussion

Our perfusion protocol calls for a $paCO_2$ between 150–200 mmHg. The BOS-10 oxygenator was able to adequately give these results at a significantly lower total gas flow than that of the H-1500 oxygenator. But along with the lower gas flows came the difficulty of CO_2 removal. The H-1500 had significantly lower pCO_2 values, and, in turn, higher pH values. It was easier to control blood gases while using the H-1500 oxygenator. Others have reported difficulty in CO_2 removal at low gas flows while using the BOS-10 also.[6] In the past it has been desirable to have an oxygenator with a very low gas-to-blood flow ratio with the thought that there will be less trauma to the bubbled blood[4(p.111,165,166)]. Yet it has been demonstrated that the majority of hemolysis is caused by the suction system[4(p.111,134,224,248)]. With the present generation of low gas-to-blood flow oxygenators, we are finding it more difficult to balance the pCO_2 and pO_2.

The warming times for the BOS-10 (average of 16.2 minutes) were faster than the times for the H-1500 (average of 20.9 minutes) (Table III). Disappointment in the slower warming capabilities of the H-1500, prompted an increase in both the water flow and pressure through the heat exchanger in an effort to speed-up the warming times. Therefore, a Hemotherm[g] unit was used for six additional H-1500 oxygenators but produced no difference in warming times (20.9 minutes with the American Optical unit vs. 20.5 minutes using the Hemotherm unit). The warming times for the BOS-10 while using the Hemotherm were slightly better than those times observed while using the American Optical (16.2 minutes with the American Optical vs. 14.7 minutes with the Hemotherm). The Hemotherm cooler/heater unit provides 19 LPM water flow at a pressure of 15 psi.

Cooling times are not included in this study for several reasons: 1) we are not aggressive in our cooling process and cool the patient slowly to reduce the chance of premature fibrillation; 2) we have not utilized a disposable hardshell oxygenator that cannot adequately cool a patient to 30°C

[g] Cincinnati Sub-Zero, Cincinnati, OH 45206

within ten minutes; 3) a downward drift in the patient's temperature is often seen prior to the initiation of cardiopulmonary bypass, and at the start of bypass before cooling is initiated; 4) the difficulty in judging when to shut off the cooling device in time not to undershoot or overshoot the desired temperature, results in some temperature drift before a stable cool temperature is reached.

The BOS-10 oxygenator allowed a reduction in prime, lines included, to 1200 ml. of volume, whereas 1500 ml. were needed in the H-1500. A lower priming oxygenator is seen as an advantage, but it has been observed that those oxygenators which require larger primes and have a larger volume of dynamic hold-up prove to be more effective in defoaming.[7]

Both oxygenators functioned well and have their advantages and disadvantages. The visibility of the arterial reservoir with the H-1500 is superior to that of the BOS-10 oxygenator. Since the writing of this report, Bentley has introduced the new BOS-10S oxygenator which we are now using on a routine basis. Bentley has improved the visibility of its arterial reservoir with this modified Spiraflo oxygenator. Because total gas flow was higher with the H-1500 oxygenator, we were better able to blow-off CO_2 and had better control of blood gases as a result. The H-1500 has better gravity drainage and less venous resistance. The BOS-10 oxygenator is easier to set-up because all of the ports come off the same side and there is no need to be running around the pump connecting lines. The warming times seen with the BOS-10 group were superior to those of the H-1500 group. We were disappointed with the warming times of the H-1500, and have elected to use the Shiley S-100A[h] in its place along with the BOS-10S at our institution. The priming and debubbling of both units were easily achieved.

Keeping an inventory of two or more oxygenators will insure their routine use and acquaint the perfusionist with each units' peculiarities. If, for any reason, one oxygenator cannot be obtained, there is another ready to go with its accompanying hardware. Using two oxygenators on an alternate routine basis presented no inconveniences to the perfusionist involved in this evaluation. Therefore, we believe that it is an advantage to have two units available at our institution.

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[h] Shiley, Inc., Irvine, CA 92714