An In-Vitro Evaluation of the Bio-Medicus Blood Pump

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Abstract

The Bio-Medicus blood pump was evaluated for possible micro-emboli release and the flow/afterload relationship inherent in any load-sensitive device.

A standard extracorporeal circuit was primed with Plasmalyte A. Microemboli transducers with 7.5 MHz lithium niobate crystals were placed proximal and distal to the Bio-Medicus pump. In Phase I of the study, room air was injected proximally at varying pump flow rates with subsequent embolic activity recorded distally. In Phase II, pump afterload was increased to 750 mmHg in 50 mmHg increments while flow rate and RPM were recorded in the automatic modes.

Microemboli ranging from 32,000 to 280,000 counts/L. were recorded distally at all flow rates after injecting 0.5 cc. of room air. In the manual mode, flow decreased as afterload increased with no change in RPM. In the automatic mode, the flow rate remained constant with a subsequent 105% increase in RPM with a pump afterload of 650 mmHg.

Introduction

The Bio-Medicus Bio-Pump[a] is a centrifugal blood pumping device that achieves flow by utilizing the principle of constrained force vortex. Previous literature has alluded to its safety and ease of operation[1,2,3]. Phase I of this study inspects the potential ability of this device to entrap air emboli in the center of the vortex.

Since the pump is a load sensitive device, changes in flow rate may occur with varying pump outlet resistance during automatic operation. Phase II of the study was designed to determine the reliability of this device in response to changes in arterial line resistance.

Materials and Methods

An extracorporeal circuit incorporating an Interpulse[b] membrane oxygenator, an Intercept[b] arterial line filter, a Travenol[c] compliant reservoir bag, and a Bio-Medicus[a] pump was flushed with 100% carbon dioxide for five minutes and primed with Plasmalyte A[c]. A Bentley Q-220[d] cardiotomy reservoir was used for priming ease and as a purge reservoir. Pressure was measured at the pump outflow with an aneroid manometer with a range of 0 to 760 mmHg (Figure 1).

PHASE I—Microemboli transducers with 7.5 MHz lithium niobate crystals were placed proximal and distal to the pump. A Micropure Model 1100[e] microcontaminant monitoring system was utilized. The pulser component of the system which generates an electrical pulse stimulates the transducer causing it to emit a pressure wave at a resonant frequency of 7.5 MHz. Any contaminant, solid or gas, in the fluid will result in a reflection of

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[b] Extracorporeal Medical Specialties Inc., King of Prussia, PA.

[c] Travenol Laboratories Inc., Deerfield, IL.

[d] Bentley Laboratories Inc., Irvine, CA.

[e] Bio-Medicus Inc., Minneapolis, MN.

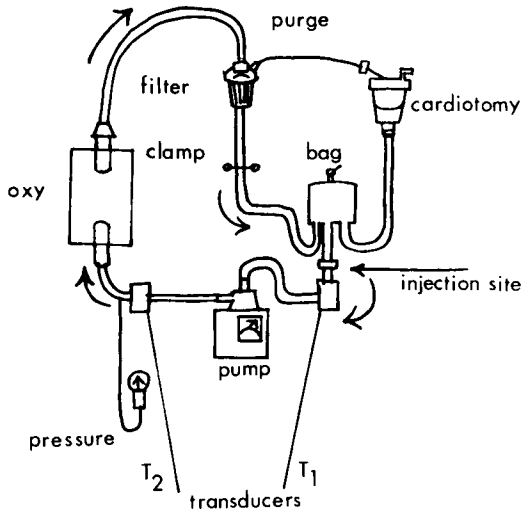

FIGURE 1. Circuit diagram for microemboli study period. T_1 represents the proximal microemboli transducer and T_2 represents the distal microemboli transducer.

the ultrasonic beam which will in turn re-excite the transducer. This results in an electrical signal being returned through the tuned pre-amplifier to the receiver of the microcontaminant monitor. Signals above a certain size (in this case 50 mV = 30 microns) will then be counted by the monitor. The sample rate of the system is adjusted to the flow rate so that each segment of fluid passing the transducer is sampled only once. Actual counts recorded by the system are then converted to counts/Liter using the following formula:

$$\frac{1{,}000 \times \text{Counts}}{\text{Sample Rate} \times \text{Seconds} \times .01 \text{ ml(Sample Volume)}} = \text{Counts/Liter}$$

The circuit was recirculated and debubbled until the inlet and outlet transducers indicated zero contaminant activity. There were three injections of 0.5 ml. of room air made at flow rates of 1 to 6 L/Min. The system was allowed to return to zero baseline prior to each injection. This was accomplished with filtration through the Intercept[b] 20 micron arterial filter.

PHASE II—The effect of afterload on pump flow was studied by increasing arterial line pressure distal to the Interpulse[b] oxygenator at a flow rate of 6 L/Min. This was accomplished by increasing the pressure in 50 mmHg increments beginning at 150 mmHg and peaking at 750 mmHg while observing the Bio-Medicus flow rate and RPM at each pressure.

[b] Extracorporeal Medical Specialties Inc., King of Prussia, PA.

Results

PHASE I—Counts of emboli greater than 30 microns were recorded at all flow rates after room air injections. Determinations at each flow rate are expressed as counts per Liter × 1,000 (Table I).

The highest counts were recorded at 1 L/Min. The average count at this flow rate was 280.6×10^3 Counts/L., ranging from 277.5×10^3 to 284.9×10^3 counts/L.

The number of counts/L. decreased as the flow was increased. The average counts/L. at 6 L/Min. was 55.4×10^3, ranging from 53.3×10^3 to 58.0×10^3 counts/L.

PHASE II—The results of the flow/afterload study are illustrated in Table II. In the auto-flow mode, the 6 L/Min. flow rate was maintained with a corresponding 105% increase in RPM as the arterial line pressure was increased. At 700 mmHg, however, the flow rate decreased to 5.6 L/Min. and subsequently decreased to 4.0 L/Min. at 750 mmHg. RPM increased from 2,150 at 150 mmHg. to 4.500 at 750 mmHg.

Discussion

The microcontaminant monitoring system is capable of accurately discriminating emboli size and number, thereby describing various degrees of embolic activity both quantitatively and qualitatively.

As shown in the results, embolic activity was recorded at all flow rates distal to the Bio-Medicus pump after room air injections.

The decreasing number of counts corresponding to increased flow rate may be attributed to two possibilities: First, the RPM of the rotator cones are higher at increased flow rates. The injected air may be broken up into sizes smaller than 30 mi-

TABLE I

COUNTS X 10^3/LITER - 0.5cc. INJECTION

Flow Rate	Inj. #1	Inj. #2	Inj. #3	Average
1 L/Min.	277.5	279.3	284.9	280.6
2 L/Min.	177.6	173.0	170.0	173.5
3 L/Min.	79.0	79.0	75.9	78.0
4 L/Min.	54.5	57.9	55.0	55.8
5 L/Min.	40.7	41.8	42.6	41.7
6 L/Min.	53.3	54.9	58.0	55.4

* Counts recorded in distal microemboli transducer after 0.5 cc injections of air.

TABLE 2

FLOW - RESISTANCE

mmHg	RPM X 100	Flow L/Min.
150	21.5	6.0
200	25.0	6.0
250	27.5	6.0
300	30.0	6.0
350	33.0	6.0
400	35.0	6.0
450	36.5	6.0
500	38.0	6.0
550	40.5	6.0
600	42.0	6.0
650	44.0	6.0
700	45.0	5.6
750	45.0	4.0

* Effect of increasing resistance on flow rate and RPM in the automode.

crons and, therefore, were not detected by the microemboli transducers. Secondly, higher flows due to higher RPM create a greater centrifugal force, perhaps entrapping more emboli in the apex of the cone.

The afterload sensitivity of the unit was satisfactory up to a pump outlet pressure of 700 mmHg. It is advisable to operate this unit in the automode. Once a flow rate is dialed in, the pump will automatically compensate in RPM for changing arterial line resistance.

Unfortunately, it was not possible to monitor inlet and outlet microemboli activity simultaneously. Undoubtedly, this would have given us more precise information relating to the efficiency of the Bio-Medicus pump to entrap air emboli. However, it is evident that if, for example, 0.5 cc. of air entered this pump at a flow rate of 4 L/Min., the patient will incur an insult of approximately 56,000 separate air emboli 30 microns or greater in one liter. Whether this number is indicative of 1% or 99% efficiency, it will still have the same potentially devastating effect on the patient. Therefore, clinical acceptance of this device should be based primarily on it's potential benefit as an atraumatic blood pump, and not on it's previously reported inherent ability to eliminate air emboli[3].

References

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