Left Ventricular Assist with the New Bio-Pump 80

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Abstract

Six male mongrel dogs were studied on left ventricular bypass (left atrium to femoral artery) for twenty-four hours without anti-coagulation. The circuit consisted of standard perfusion cannulae, polyvinylchloride tubing, polycarbonate connectors, and the new Bio-Pump 80. Bypass flows averaged 2.2 l/min. Hematologic and biochemical parameters were measured according to protocol.

The coagulation profile during the 24 hours remained normal. The prothrombin time, partial thromboplastin time, and fibrinogen values were not statistically different from preoperative control values. Fibrin split products were consistently negative and hemoglobin, hematocrit, and platelets were stable over the 24 hour period. Serum hemoglobin levels were negligible over the course of the experiment. The biochemical results also remained at normal levels, with the exception of creatinine, which was significantly lower.

All dogs were electively sacrificed at the end of the 24 hour assist period. Autopsy revealed minor renal infarcts in two animals; all other organs were found to be grossly intact. There were no technical problems with the Bio-Pump 80. Thrombi were seen at approximately twenty per cent of the connector/tubing junctions. Four of the Bio-Pumps had no thrombus accumulation in any part of the pump, while two pumps had small amounts of thrombus present around the center shaft.

Introduction

In March 1981, at the 19th International AmSECT Conference, we reported our initial results using the Bio-Pump 600 in seven patients who required long-term left ventricular support. Since that time we have continued to expand our application of this unique device to include long-term right ventricular support, extracorporeal membrane oxygenation, and shunting blood during repairs of traumatic tears of the thoracic aorta.

The Bio-Pump 600 has remained essentially unchanged since its introduction in 1973. However, the Bio-Medicus company has recently developed a new version of the Bio-Pump designated the Bio-Pump 80 (BP 80). The new BP 80 has approximately one half the priming volume of the BP 600 and will be significantly less expensive. The purpose of this study was to test the new BP 80 in vivo, to determine whether or not it would perform satisfactorily as a long-term blood pump in areas of blood trauma and mechanical reliability.

Materials and Methods

Six conditioned male mongrel dogs weighing 22–28 kg. were used in this study. Each animal was anesthetized with IV Pentothal, 20 mg/kg, intubated, and endotracheal anesthesia maintained with halothane, nitrous oxide, and oxygen. Urinary output and electrocardiogram were monitored continuously. Fluid losses (urinary output and chest tube drainage) were replaced with balanced electrolyte solution. Sterile technique was maintained during all surgery. The right femoral artery and vein were cannulated for arterial pressure (AP) and central venous pressure (CVP) respectively. Blood samples were drawn at this time for baseline measurements and for ventilator management. The left femoral artery was exposed and isolated with umbilical tapes, and a left thoracotomy was performed in the fourth intercostal space. The pericardium was opened parallel to the phrenic nerve just over the left atrial appendage. A 3-0 purse string suture was placed around the tip of the appendage and passed through a tourniquet in preparation for cannulation.

The perfusion circuit consisted of 3/8” x 3/8” polyvinyl tubing and 3/8” polycarbonate connectors. The arterial cannulae were 16 french straight arterial cannulae and the left atrial cannulae were 32 french bas-
ket-tipped cannulae. The circuit was primed with a balanced electrolyte solution. The Bio-Medicus disposable flow probe was inserted into the circuit just distal to the BP 80.

After the perfusion circuit was primed and all air removed, the femoral artery was cannulated and connected to the outlet side of the BP 80. Then in rapid succession the left atrial appendage was clamped, the tip amputated, and the 32 french cannula inserted into the left atrium and secured in place by the string suture previously placed. The left atrial cannula was connected to the input side of the BP 80 and the dog placed on left ventricular assist. A chest tube was inserted, the chest and both femoral incisions were closed. The dogs were closely attended for the next 24 hours.

Blood samples were drawn just prior to surgery for a preoperative baseline measurement, immediately after going on assist, designated T = 0, and at 2, 4, 8, 12, 16, 20, and 24 hours. The hematologic data obtained were red blood cell count, hemoglobin, hematocrit, platelets, fibrinogen, fibrin split products, serum hemoglobin, prothrombin time, and partial thromboplastin time. The biochemical data obtained consisted of sodium, potassium, chloride, blood urea nitrogen, creatinine, serum osmolality, calcium, total bilirubin, total proteins. The hemodynamic data were collected hourly and included arterial pressure, central venous pressure, BioPump revolutions per minute, and blood flow. Data were checked for significance by analysis of variance.

At the end of the 24 hour assist period the animals were heparinized, sacrificed, and an autopsy performed. The perfusion circuit was removed from the animal, gently rinsed and photographed.

Results

All six animals survived the twenty-four hour procedure without difficulty. The electrocardiograms remained unchanged during the assist period. The chest tube drainage in each animal during the 24 hours was less than 50 ccs. Blood gases were maintained within normal limits and the urinary output ranged from 40 to 247 ccs per hour. Mean aortic blood pressure ranged from 77 to 105 mm Hg while the CVP ranged from 0–2 mm Hg. The BP 80 revolutions per minute ranged from 1600–2500 which produced blood flows ranging from 1.6–2.8 liters per minute (Figure 1).

There were no statistically significant changes in any of the hematological data collected (Table 1). The hemoglobin, hematocrit (Figure 2) and platelet count (Figure 3) fell slightly during the assist period, but the change was not statistically significant. The prothrombin time remained at baseline levels throughout the assist period (Figure 4). The partial thromboplastin time rose slightly during the assist period (Figure 5), however the rise was not statistically significant. The fibrin split products were negative on all animals throughout the experiment. The fibrinogen level (Figure 6) rose in some animals and fell in others, however the changes were not statistically significant. The average serum hemoglobin was at a level of 0.00 mg%. All biochemical parameters (Table 2) were maintained within normal limits, with the exception of serum potassium which was supplemented as needed by IV boluses, and creatinine which fell from a preoperative average of 0.68 + 0.06mg% to 0.38 + 0.03mg%, p<.01, which is a statistically significant change.

Examination of the assist circuit revealed clot for-

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Table 1

<table>
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<tr>
<th>RBC</th>
<th>HGB</th>
<th>HCT</th>
<th>PLAT.</th>
<th>PT</th>
<th>PTT</th>
<th>FIBRIN.</th>
<th>FSP</th>
<th>SERUM HEMO.</th>
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<td>Pre</td>
<td>4.93 ± .43</td>
<td>11.2 ± 1.1</td>
<td>31.8 ± 3.0</td>
<td>217 ± 33</td>
<td>7.17 ± .17</td>
<td>16.5 ± .08</td>
<td>248 ± 38</td>
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<td>4.27 ± .33</td>
<td>9.6 ± 0.8</td>
<td>27.5 ± 2.3</td>
<td>160 ± 24</td>
<td>7.33 ± .33</td>
<td>16.7 ± .05</td>
<td>194 ± 21</td>
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<td>28.4 ± 2.4</td>
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<td>7.50 ± .22</td>
<td>17.2 ± .04</td>
<td>198 ± 25</td>
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<td>29.4 ± 2.0</td>
<td>179 ± 20</td>
<td>7.50 ± .22</td>
<td>16.2 ± .07</td>
<td>209 ± 32</td>
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</tr>
<tr>
<td>8</td>
<td>4.34 ± .20</td>
<td>9.6 ± 0.6</td>
<td>27.9 ± 1.7</td>
<td>176 ± 17</td>
<td>7.67 ± .21</td>
<td>16.8 ± 1.3</td>
<td>190 ± 28</td>
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<td>4.28 ± .26</td>
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<td>27.6 ± 2.1</td>
<td>171 ± 16</td>
<td>7.38 ± .17</td>
<td>18.0 ± 1.4</td>
<td>194 ± 24</td>
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<tr>
<td>16</td>
<td>4.12 ± .19</td>
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<td>26.5 ± 1.5</td>
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<td>19.0 ± 1.3</td>
<td>216 ± 27</td>
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<tr>
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<td>8.60 ± .22</td>
<td>23.7 ± 1.9</td>
<td>207 ± 19</td>
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</tr>
</tbody>
</table>

All values are expressed as mean ± standard error of the mean.

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f Sarns, Inc., Ann Arbor, MI 48103
g Bio-Medicus, Inc., Minneapolis, MN 55344
Table 2

<table>
<thead>
<tr>
<th></th>
<th>NA+</th>
<th>K+</th>
<th>CL−</th>
<th>BUN</th>
<th>CREAT.</th>
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<td>.68±.05</td>
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<td>115.2±1.9</td>
<td>10.4±2.8</td>
<td>.63±.05</td>
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<tr>
<td>16</td>
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<td>116.7±1.5</td>
<td>12.6±2.2</td>
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<td>3.90±.20</td>
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<td>12.3±2.2</td>
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<td>24</td>
<td>138.0±1.8</td>
<td>3.90±.20</td>
<td>116.3±1.7</td>
<td>12.3±2.2</td>
<td>.38±.03**</td>
</tr>
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</table>

All values are expressed as mean ± standard error of the mean

**P <.01

mation on about 20% of the connector/tubing and connector/cannula joints. In general these clots were loosely adherent to both the connector and tubing and could be easily dislodged. None of the BP-80 pumps had any clots on the struts, however, two pumps had thrombus present around the center shaft. At autopsy, all organs were grossly normal with the exception of two animals which revealed rare, small renal infarctions.

Discussion

Possibly the most significant characteristic of this study was the smooth, uneventful course of each experiment. There were no mechanical problems or failures with the Bio-Pump 80 or the Bio-Pump console. All of the animals completed the 24 hour run and were electively sacrificed. Chest tube drainage was minimal. There was no cavitation or air entrained in the assist circuit. The only statistically significant difference detected in any parameter was the reduction in the level of creatinine which we feel was probably due to hemodilution and/or improved renal blood flow on bypass as a result of femoral artery cannulation.

The serum hemoglobin level average of 0.00 mg%, after twenty-four hours of assist for all dogs, indicates that the BP-80 is a very atraumatic blood pump. Of the sixty determinations of serum hemoglobin levels performed on all of the animals, only four detected any serum hemoglobin. We previously reported an average serum hemoglobin level of 0.12 mg% in dogs which had been on the same type assist circuit for 24 hours utilizing the Bio-Pump 600. Therefore, there is no question that the BP-80 can gently pump blood in an assist system for extended periods of time.

This experimental preparation is a very demanding test for any assist system, in that we use no heparin, no anti-thrombogenic surface coatings, and no platelet function inhibitors. Almost invariably, assist systems which are not anti-coagulated show some degree of thrombus formation. In this circuit there was clot formation at the connector/tubing joints and a very slight amount was seen around the center shaft of two of the Bio-Pump 80s. There was no evidence of thrombus formation on, or around, the struts of any of the pumps evaluated.

Our laboratory experience with other centrifugal pump designs (unpublished data) and our clinical experience leads us to postulate that the clots found in the Bio-Pump 80 around the center shaft are being generated proximal to the pump in the cannulae, connectors and tubing. When these thrombi build up to a sufficient size, they break off and travel to the pump, where due to the centrifugal nature and internal flow characteristics of the BP-80, they are trapped around the center shaft. Any thrombi which form distal to the BP-80 and break free, travel to the femoral artery cannula and subsequently into the animals circulation.

Anti-coagulation of patients during left and/or right ventricular assist regardless of the type of assist pump has always been a difficult issue to address, especially in light of the extremely dynamic nature of the patient on assist due, in part to the effects of an extended period on cardiopulmonary bypass. Anti-coagulation during long term perfusion for ventricular support should be based on the clinical situation and the laboratory data available at any given moment and adjusted as circumstances dictate.

References


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Questions from the Audience

Question—Marty Vanew: When you did the autopsy on the dog, did you do a microscopic examination of the brain?

Answer: No, we did a gross examination of the brain.

Question: What were the results?

Answer: There was no influx at all. The brain was normal. Grossly.

Question—Lanier Allen: What RPMs were you running the BioPump during all these procedures?

Answer: The BioPump RPMs averaged about 2,100, and the flow rates averaged 2.2 liters per minute. It ranged from the smallest animal, when the best flow we could get was 1.4 liters per minute, to the largest animal at 2.8 liters per minute.

Question: As you came down in flow rate when you were terminating the bypass, did you change the RPMs of the BioPump at all?

Answer: Well, actually, we maintained maximum flow rate we could at the minimum RPMs that would give us that flow rate. At the end of that experiment, we heparinized the animal and just sacrificed it and clamped the system while it was still on the assist. The idea was to get this system out of the animal as quickly as possible and rinse it in saline, so we could get a look at the clot situation in the pump.

Question—Tom Utsey: Could you describe how, upon initiating bypass, you would determine what your maximum flow rate—in terms of what made you stop? You mentioned no cavitation.

Answer: What we did was to turn the RPMs off until we could see the cavitation begin. Then I would keep repositioning the cannula until we could get the maximum flow rate with the minimum RPMs before cavitation would begin. Then we would back off, just below that level, and stay there for the rest of the 24-hour period.

Question—David Westbrook: You stated that you had some rare small renal infarcts. Were you able to document whether or not those were from thrombus?

Answer: No, we weren’t able to. We have another experiment planned, where we expect to use Indio 111 to label the platelets in a sequential fashion and try to determine whether they’re coming from the cannula connectors. It does not appear that they’re coming from the BioPump. The shear forces in the BioPump are so high that I think it is very difficult for a thrombosis to form in the BioPump. We’ve done some experiments on the bench, and it does appear that there is a whirlpool effect around the shaft—and that the clots come down into the pump, get caught around that whirlpool, and get trapped around the shaft.

Question—Bruce Bartel: Have you found an improvement in the BioPump 80 over the 600 series?

Answer: It runs with fewer RPMs to produce the same flow. That means it’s a little more efficient. In the paper I mentioned earlier, we presented the exact same assist system with the same cannulas. The only difference in that system was we used the reusable flow meter. Obviously, it’s five years later, but the serum hemoglobin in those animals averaged 0.12 milligrams percent for 24 hours. In these animals, we actually thought we were doing something wrong for a while and kept questioning the lab, because we couldn’t get any serum hemoglobin. So I think the pump is more efficient and handles the blood in a more gentle fashion.