Original Article

Comparative Study of Five Blood Cardioplegia Systems

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ABSTRACT

Five blood cardioplegia delivery systems (Gish Straight Shot, Sorin BCD Advanced, A vecor MYOtherm, Baxter-Bentley HE-30, and Baxter-Bentley HE-30 Gold) were evaluated with respect to ease of rapid priming, coefficient of heat exchange, pressure drop, bubble trap capacity, and priming volume. Each system was placed in a roller pump circuit consisting of source and collection reservoirs, cardioplegia solution, and pre-post system pressure and temperature monitoring sites. A trial was performed on four units of each brand by first priming the circuit with 0.9% NaCl at 200 ml/min. Bovine blood (hematocrit 22%) was then introduced simulating use during bypass. Pressure drops across the heat exchanger were measured at flows of 200, 300, and 400 ml/min and at temperatures of 37°, 19°, and 4°C. Coefficient of heat exchange was determined at 300 ml/min flow. Air was infused into the system to quantify the bubble trap capacity of the heat exchanger module. Priming volume of the entire system and of the heat exchanger module were determined by draining each into a graduated cylinder.

The Sorin system had significantly less priming volume when compared to all others. The HE-30 units had significantly higher heat exchange coefficients compared to all other systems. Variability was noted in pressure drop at the highest flows and lowest temperatures.

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INTRODUCTION

The delivery of blood cardioplegia has become an important adjunct to the successful application of cardiopulmonary bypass to the cardiac surgical patient. Adequate myocardial protection as accomplished by efficient delivery systems is crucial to the post-operative course of the patient (1-3). While some of the advantages of blood cardioplegia remain theoretical and/or controversial, many experimental and clinical studies indicate a superiority in myocardial protection when compared to crystalloid cardioplegia (4-8). Myocardial preservation may be enhanced by blood cardioplegia’s increased capacity to carry oxygen, natural buffers, osmotic constituents, and antioxidants (9-13). Perfusion of myocardial tissue beyond critical coronary lesions may also be enhanced as a result of the rheology associated with blood cardioplegia (14, 15) and excessive hemodilution is also avoided.

To meet the technical requirements of the single pass delivery of blood cardioplegia, many systems have been developed and introduced for use during cardiopulmonary bypass. The specific requirements include a device which can be efficiently primed, a heat exchanger which can effectively cool the perfusate, a low system priming volume and flow resistance (pressure drop), and a design which effectively traps air and limits the potential for air embolism. Components which allow easy and accurate monitoring of infusion pressure and solution temperature are also desired. The purpose of this study was to perform a laboratory evaluation and comparison of five blood cardioplegia systems with single pass heat exchangers with respect to rapid priming efficiency, coefficient of heat exchange, priming volume, pressure drop, and capacity to trap gross air challenges.

MATERIALS AND METHODS

The five blood cardioplegia systems evaluated included the Sorin BCD Advanced®, Avecor MyOtherm®, Gish Straight Shot®, Baxter-Bentley HE-30 Gold® (heparin coated), and Baxter-Bentley HE-30® (non-heparin coated). Four units of each type were tested. All systems included the following: 1) an inlet blood line and cardioplegia solution line; 2) pump tubings which utilized a 4:1 mixing ratio of blood to cardioplegia solution; 3) an assembly to accomplish heat exchange; 4) access for temperature monitoring and infusion pressure monitoring; 5) a bubble trap and; 6) a patient delivery line. Only the heat exchange/monitoring assembly are described in the following paragraphs.

SORIN BCD ADVANCED (SORIN)

The Sorin system consists of an inverted “U” shaped anodized aluminum heat exchanger housed in a polycarbonate assembly. The surface area of the heat exchanger is 169 cm² with water flow running countercurrent to the cardioplegia solution flow. A unique priming valve is included in the assembly to allow the air to be displaced to a vent port at the top of the heat exchanger housing. Once primed, the solution passes over the heat exchanger and exits into a bubble trap/monitoring chamber which includes a 105 micron filter screen. A pressure monitoring line and temperature probe port are located in this chamber.

AVECOR MYOTHERM (AVECOR)

The Avecor system consists of a stainless steel bellows heat exchanger (surface area of 187 cm²) housed in a polycarbonate assembly. The cardioplegia is directed from an inlet found at the bottom of this housing to an exit chamber which includes a pressure monitoring line and temperature probe port. Water flow is directed countercurrent to cardioplegia solution flow. A small line connects the heat exchanger/monitoring assembly to a second chamber which acts as a bubble trap and “air eliminator.” The inlet (top) of this chamber includes a hydrophobic membrane with a one-way valve for air elimination and the cardioplegia solution must pass through a 170 micron filter screen to exit (bottom) into the patient line.

GISCH STRAIGHT SHOT (GISH)

The Gish system consists of a straight anodized aluminum heat exchanger with a surface area of 285 cm². The cardioplegia solution is directed from a bottom inlet to a top outlet with water flow moving in countercurrent fashion. At the outlet of the heat exchanger housing, a 30 ml bubble trap/monitoring vortex chamber directs air to a venting/pressure monitoring port. Blood is directed through a 160 micron conical filter screen to the outlet of the chamber at which point a temperature probe port is located.

BAXTER-BENTLEY HE-30 (BENTLEY COATED AND NONHEPARIN COATED)

The Bentley system consists of a 636 cm² stainless steel bellows heat exchanger housed in a polycarbonate assembly. The housing is designed to allow cardioplegia to flow from top to bottom while water flow is directed in countercurrent fashion. A bubble trap chamber and pressure monitoring site are provided at the heat exchanger housing inlet. A temperature probe port is provided at the outlet. The heparin coated system has a Duraflo II treatment applied to all blood contact surfaces.

CIRCUIT DESIGN, SET-UP AND PRIMING

The basic test circuit used to prime and evaluate each blood cardioplegia delivery system is shown in Figure 1. Before incorporating the system into the test circuit, each device was inspected carefully for defects. A pressure monitoring site was installed just distal to the blood/crystalloid mixing point to determine the pressure drop from the roller pump to the end of the patient line. A transducer® connected at this site, calibrated with

a Sorin Biomedical, Irvine, CA 92713
b Avecor Cardiovascular, Plymouth, MN 55441
c Gish Biomedical, Santa Ana, CA 92705
d Baxter Health Care Corp., Bentley Division, Irvine, CA 92713
e Model T4812DT-R, Spectramed, Oxnard, CA 93030
Figure 1
Diagram of the basic priming and evaluation circuit. RES = reservoir; PT = pressure transducer; H/C = heater/cooler; CPDS = cardioplegia delivery system; Tbi = temperature blood in; Tbo = temperature blood out.

A mercury manometer, displayed infusion pressure on a monitor. The pressure monitoring site and patient line were maintained at a constant level to eliminate any effects of hydrostatic pressure as the cardioplegia was pumped through the system. Temperature monitoring sites were inserted four inches before and after the heat exchanger to determine the temperature of the perfusate entering and exiting the heat exchanger. Temperature probes attached to these monitoring sites were connected to a temperature meter. Each probe was checked for accuracy against a mercury thermometer and found to be within 0.2°C of the standard. The delivery system was placed into its holder and the water lines from a heater/cooler were connected to the appropriate connection ports on the heat exchanger. A temperature monitoring site similar to that inserted before and after the heat exchanger was incorporated in the water line going to the heat exchanger to determine the temperature of the water flow. The pump lines were inserted in a roller pump with the oxygenator line connected to the outlet of a polycarbonate reservoir filled with saline and the crystalloid line was connected to a bag also filled with saline. These fluid containers were used to prime the delivery system and simulate the primed cardiopulmonary bypass system and crystalloid cardioplegia solution, respectively. The end of the patient line was connected to the inlet of the saline reservoir.

Priming was accomplished per manufacturers' instructions with the exception of the recommended priming flow rate. Prior to priming, the clamp on the crystalloid line of the delivery system was opened and the occlusion of the roller pump was

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f Model M1094A, Hewlett Packard, Waltham, MA 02254
g Model 12110, Sarns, 3M Health Care, Ann Arbor, MI 43103
h Model 21-01-00, Stockert-Shiley, Sorin Biomedical, Irvine, CA 92714
adjusted to just stop the flow out of the saline bag. Priming was accomplished at a flow of 200 ml/min and was discontinued when the system was completely saline filled. The adequacy of priming without manipulation of the system was carefully noted. With the roller pump off, the presence of bubbles at various points in the system was also documented. The roller pump was then turned on and the ability to dislodge bubbles while recirculating the prime was noted.

EVALUATION PROTOCOL

Following the priming phase of evaluation, the oxygenator line was connected to the outlet of a second polycarbonate reservoir filled with bovine blood which had been adjusted to a hematocrit of 22% (16). This value was chosen to simulate the final hematocrit of blood cardioplegia. The crystalloid pump boot was removed from the roller pump to prevent additional dilution during recirculation in the system. The roller pump was briefly used to replace the saline in the system with blood. All the saline was replaced with blood, the end of the patient line was connected to the inlet port of the blood reservoir.

While recirculating, the heater/cooler was turned on and the blood was warmed to 37°C. Pressure measurements were recorded at pump flow rates of 400, 300, and 200 ml/min. The heater/cooler was adjusted to cool the blood to 19°C and pressure measurements were again recorded at three flow rates. Finally, pressure measurements were recorded at a blood temperature of 4°C.

After the blood was rewarmed to 37°C, the end of the patient line was attached to a polycarbonate collection reservoir to allow the device to simulate a single pass system. The pump flow rate was set to 300 ml/min and the heater/cooler was set to the lowest temperature. Water flow at this setting was 24 L/min. At temperature equilibrium (a time interval of 30 seconds), the temperatures of the blood entering and exiting the heat exchanger and the temperature of the water entering the heater were recorded. Coefficient of heat exchange (Che) was determined by comparing the temperature change which occurred from the inlet to the outlet of the heat exchanger with the temperature gradient provided between the water and cardioplegia entering the device expressed as:

\[
\text{Che} = \frac{(T_{b_e} - T_{b_o})}{(T_{w_i} - T_{w_f})}
\]

where:

- \( T_{b_e} \) = temperature of the blood entering the heat exchanger
- \( T_{b_o} \) = temperature of the blood exiting the heat exchanger
- \( T_{w_i} \) = temperature of the water entering the heat exchanger
- \( T_{w_f} \) = temperature of the water exiting the heat exchanger

After again filling the delivery system with saline, a syringe infusion pump was connected to the pressure monitoring site. Air from a 50 ml syringe was injected into the delivery system at a rate of 140 ml/min while the roller pump recirculated the saline at a rate of 200 ml/min. As soon as air was visibly observed exiting the heat exchanger/bubble trap assembly, the amount of air injected from the syringe was recorded as bubble trap capacity.

At the conclusion of the evaluation, the entire system was reprimed, removed from the pump and holder, and the saline drained into a graduated cylinder. The amount of saline removed was recorded as system priming volume. The volume of the heat exchanger/bubble trap assembly was also determined in a similar fashion.

All data sets were expressed as mean values with the standard deviation from the mean. Significant differences between the data sets were determined with a repeated measures analysis of variance and Tukey’s procedure for multiple comparisons. P values of less than 0.05 were considered significant.

RESULTS

PRIMING

All systems were challenged with a rapid prime protocol (200 ml/min) which exceeded manufacturers’ recommendations. The unique priming valve of the Sorin system allowed for easy air removal from the uppermost point of the heat exchanger housing. Bubbles consistently formed around the temperature probe port and inconsistently formed between the heat exchanger and heat exchanger housing. These bubbles, as well as some on the filter screen, were easily removed with device manipulation and tapping. Air bubbles formed at the inlet and outlet manifolds of the A vecor heat exchanger housing; they were easily dislodged with manipulation of the device when removed from the holder. The opaque nature of the inlet and outlet of the “air eliminator” chamber made it difficult to ensure complete de-airing. Visibility for the inspection of bubble formation was not a problem in any of the other devices tested. Bubble formation tended to consistently occur at the inlet of the heat exchanger housing and on the filter screen of the Gish system. These were easily dislodged with manipulation and tapping of the heat exchanger and bubble trap housing. The Duraflo II treatment on the Bentley system did not appear to increase the efficiency of priming at the flow rate used in this study. Bubbles tended to consistently form at the temperature probe port; they were easily removed with manipulation of the device. Small bubbles also tended to inconsistently form in the folds of the heat exchanger bellows but these also were easily removed.

FLOW RESISTANCE (PRESSURE DROP)

The pressure drop data is summarized in Table 1. As expected, pressure drop increased with increasing flow and decreasing perfusate temperature. At all flow rates and tempera-

i  Model 11160, Sarns, 3M Health Care, Ann Arbor, MI 48103
j  Model 10-00-00, Stockert-Shiley, Sorin Biomedical, Irvine, CA 92714
tures, the Sorin displayed the lowest and the Gish had the highest pressure drops. The greatest variability between devices occurred at 37°C. The Sorin versus Gish pressure drop was significantly different at 37°C and 400 ml/min. There were no other significant differences at any flows or temperatures.

COEFFICIENT OF HEAT EXCHANGE

No significant difference was found between the Bentley coated and nonheparin coated but both had significantly higher coefficients of heat exchange when compared to all other systems studied (Figure 2). The Avecor, Gish, and Sorin did not significantly differ with respect to coefficient of heat exchange.

BUBBLE TRAP CAPACITY

There was no significant difference between the bubble trap capacity of any system studied (Figure 3). When comparing the bubble trap capacity to the priming volume of the heat exchanger/bubble trap assembly (the volume available in the system design to trap air) the Avecor was found to have the lowest ratio (0.47) and the Bentley coated was found to have the highest ratio (0.91). The Gish, Sorin, and Bentley nonheparin coated were found to have ratios of 0.54, 0.59, and 0.84 respectively. The ratios of the two Bentley devices did not differ significantly from one another but did differ from all other devices tested (p<0.05). The ratios of the Avecor, Sorin, and Gish did not differ significantly.

PRIMING VOLUME

The Sorin system priming volume was significantly less than all other units tested (Figure 4). While there was no significant difference between the Bentley nonheparin coated and Bentley coated, each had a significantly lower priming volume than the Avecor or Gish. The Avecor and Gish priming volumes did not significantly differ.

DISCUSSION

All systems were primed at 200 ml/min which exceeded manufacturers' instructions for use. Recommended priming flow rates typically range between 50 and 100 ml/min. It was our impression that perfusionists often exceed this priming rate either accidentally by not monitoring specific flow rate or intentionally to more quickly prime the device. We found that, although bubbles did form at consistent points in all devices, they were easily dislodged with manipulation and tapping. Bubbles were most often trapped at temperature probe ports, filter screens, and at inlet and outlet ports. Bentley has, since this study, relocated the position of the temperature probe port in the HE-30 to eliminate the bubble formation at the site that we observed in this study. While some have suggested that heparin coating improves priming efficiency with respect to bubble formation (17-19), we did not note any distinct difference in the priming of the Bentley coated versus the Bentley nonheparin coated.

In a previous unpublished study, our group found the lower recommended flow rates to be preferable and these resulted in considerably fewer incidences of bubble formation than this report's rapid prime method. It would be our recommendation to use the manufacturers' suggested flow rate. Carbon dioxide flushing of the device, as suggested by some manufacturers, would also assist in minimizing bubble formation. However, we found the resulting prime to have an unacceptably high pCO₂ value which would likely necessitate the perfusionist having to add flushing time to the patient line with cardioplegia prior to the first administration.

A low flow resistance across the system would be preferred to avoid excessive shear forces, excessive bubble point pressure on the filter screen, and the potential for tubing or connection failure. Features which influence flow resistance would include line length and diameter, heat exchanger housing and connector design, filter screens, and inclusion of components for bubble trapping, pressure monitoring, and temperature monitoring. As was expected, flow resistance increased with increasing flow and decreasing perfusate temperature. The greatest variability in flow resistance among the systems studied occurred at the warmest temperature (37°C) which would only be used for "hot shot" or warm heart surgery applications. Significant differences between systems at the lowest temperature (4°C) were not observed.

Our methodology for the determination of coefficient of heat exchange represented a challenge for the systems studied since we chose to cool 37°C blood at a moderate to high flow rate. The 30 second time interval used for temperature equilibration prior to data collection appeared to be sufficient for our purposes. Although using a lower perfusate temperature, Hill et al (20) found this time interval to be sufficient to observe a plateau in temperature change. The Bentley systems showed impressively high coefficients of heat exchange which were significantly different in value from the others systems studied. While blood flow, water flow, and countercurrent flow design were controlled.

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<th>Flow (ml/min)</th>
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<th>Bentley(C) Mean</th>
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variables, others such as heat exchanger surface area, material, and water/blood path flow design were not (21-23). It is likely that a combination of these design features accounted for the observations. It is certain that the large surface area of the Bentley systems proved to be important in the resulting high coefficient of heat exchange values that we report.

Evaluation of the bubble trap capacity was designed to represent a continued gross air infusion. We elected to use visible air as our endpoint determination. Micro-air detection may have resulted in a different data profile. While the Gish system had the highest bubble trap capacity, it also had the largest priming volume (or capacity) to hold the air challenge. The ratio between the bubble trap capacity and the heat exchanger/bubble trap assembly priming volume would suggest that the Bentley systems had the best ability to trap air for the volume available; this in spite of the fact that the Bentley system has no screen filter included in its assembly. Design differences would suggest that air challenges can be shunted toward the outlet of the device without being trapped in the system. It was not true that systems operated with the flow “inlet bottom/outlet top” principle trapped air less efficiently than those operated “inlet top/outlet bottom”. Other design features such as bubble chambers and one-way air valves seem to play a part. Small differences in line length from the air injection point used in this study and the heat exchanger may also account for some of these observations.

The priming volume of the system has an influence on the amount of hemodilution and the extent of volume shifts and additions which may occur during a given cardiopulmonary bypass procedure. While small in comparison to the priming volume of the entire cardiopulmonary bypass apparatus, blood volumes held in the cardioplegia system between infusions are obviously unusable by the patient. The priming volume of the delivery system is a function of the design of the heat exchanger housing, the safety features added for bubble trapping and air elimination, the adaptations for pressure and temperature monitoring, and the line length provided from the blood and crystalloid source to the end of the patient line.

**Figure 2**
Coefficient of heat exchange (Che) data for each system studied. Pump flow rate = 300 ml/min; water flow rate = 24 L/min; blood inlet temperature = 37°C; water inlet temperature = 4°C. Numbers above each column are mean and (standard deviation) values. BENT(C) = Bentley coated; BENT(NHC) = Bentley nonheparin coated. Both Bentley devices differed significantly from Gish, A vecor, and Sorin (p<0.05).

**Figure 3**
Bubble trap capacity (BTC) data for each system studied. Pump flow = 200 ml/min; air infusion rate = 140 ml/min. Numbers above each column are mean and (standard deviation) ml values. BENT(C) = Bentley coated; BENT(NHC) = Bentley nonheparin coated. Bubble trap capacity did not differ significantly between devices.

**Figure 4**
Priming volume (PV) data for each system studied. Numbers above each column are mean and (standard deviation) ml values. BENT(C) = Bentley coated; BENT(NHC) = Bentley nonheparin coated. The Sorin had a significantly lower PV than all other devices tested (p<0.05) and the Gish and A vecor had a significantly higher PV than all other devices tested (p<0.05).
It was not our intention to “rate” the devices evaluated. The results of our study would suggest that no single system yielded the best data in each category. For example, while the Sorin system primed well and had the lowest pressure drop and priming volume (positive features), it also had the lowest coefficient of heat exchange and bubble trap capacity (negative features). The perfusionist must weigh these features carefully and choose the system which best meets the needs of the patient and institution.

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