Clinical Evaluation of a New Pump Interface Module (PIM) Safety Device

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Abstract

The Pump Interface Module (PIM) is a new safety device intended to be used in conjunction with a Cobe Air Emboli Protection System (AEPS) and a roller or centrifugal pump. The PIM is a relay device that upon receiving an alarm signal from the AEPS, interrupts line voltage, thus stopping the arterial pump. The purpose of this clinical trial was to verify the utility and user advantages of the PIM when employed with a variety of pumps. The study first involved *ex vivo* tests using the bovine model. These tests looked at different AEPS positioning, different blood flows, and simulation of a variety of clinical conditions. The clinical study evaluated the PIM using five different types of pumps during 160 open heart procedures. The pumps used were a Cinco (n = 28), Sarns 5000 (n = 47), Sarns 7000 (n = 33), Biomedicus 520 (n = 27), and Biomedicus 540 (n = 25). In all instances the PIM immediately stopped the arterial pump when an alarm signal was received from the AEPS system. The PIM is an effective and practical safety device for use with the tested pumps.

Introduction

Patient safety has been a major concern since the first open heart procedure involving cardiopulmonary bypass. From the earliest days of cardiopulmonary bypass there were many unknowns and more attention was paid to patient survival than to preventing safety related complications. As experience was gained in the field, a realization of the inherent danger and the potential for a life threatening catastrophe has become apparent. As a result, surgeons, perfusionists, hospital risk management departments, and equipment manufacturers have become concerned with the issue of safety.

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In a study published in 1980 by Stoney and colleagues,[1] a pump related accident occurred once every 300 open heart procedures. A total of 264 deaths occurred as a direct result of an accident. One of the most common problems was arterial air embolism. A later survey of perfusionists published in 1986 by Kurusz also included questions that dealt with an arterial gas embolism.[2] In Kurusz's study, an arterial line gas embolism during cardiopulmonary bypass serious enough to be life threatening was observed by 21.5% of perfusionists in 200 cases. Permanent injury or death was the patient outcome in 33 of the cases. Inattention to reservoir level was the cause of this accident in 104 cases.

Both Stoney and Kurusz addressed the issue of safety devices used by perfusionists. In the Kurusz survey, low level alarms were used by 69.9% of perfusionists.[2] Air bubble detectors were used by 47%. For those who use a low level alarm, it is used routinely in the manual mode by 64% and in the automatic shut-off mode by 36%.

Today low level and air bubble detection systems are made to be used exclusively with the manufacturer's pump oxygenator system and cannot be used with any other system. The purpose of this study was to evaluate a new safety device, the Pump Interface Module (PIM)[a], used in conjunction with the COBE Air Emboli Protection System (AEPS)[a]. The PIM is a special relay device that, upon receiving an alarm signal from the AEPS, interrupts line voltage and stops the arterial pump. This clinical evaluation and *ex vivo* study was performed to verify the utility and advantages of the PIM when used with a number of commonly available roller or centrifugal pumps.

Materials and Methods

Ex vivo Study

The purpose of the *ex vivo* study was to look at different AEPS positioning, different blood flows, and

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

to simulate a variety of clinical conditions using a roller pump or a centrifugal pump.

The Cinco[b] and Biomedicus 520[c] pumps were set-up in series using a Cobe CML[d] membrane oxygenator and a Bentley BEN 10[e] also in series. A Cobe arterial filter[f] was also utilized. The pump tubing size was 3/8" × 3/32" PVC. A Cobe Air Emboli Protection System (AEPS), which incorporates an air bubble detector, located on the arterial line in various positions, and a level sensor, attached to the CML reservoir was connected according to manufacturer's recommendations. The Cinco pump was plugged into the PIM and the PIM was connected to the AEPS.

In the Cinco pump trials, the Bentley BEN 10 and the Biomedicus pump were primed and clamped out of the circuit, while the Cobe CML was primed with 2500 cc of crystalloid solution and 10,000 units of porcine heparin.

A 70 kg. cow was anesthetized using 20 mg/kg of Biotal, intubated, and placed on an Ohio 560[g] ventilator. The animal was heparinized with 30,000 units of procine heparin. The carotid artery was exposed, and cannulated using a 24 french cannula. The internal jugular was exposed and cannulated with a 40 french cannula. Cardiopulmonary bypass was initiated and adequate blood flows were achieved.

During the first series of tests using the Cobe CML oxygenator and Cinco pump, (Figure 1) the PIM was tested by injecting air into the circuit at blood flows of 6 LPM, 4 LPM, and 2 LPM. The air bubble detector was placed 20 centimeters before the the roller pump and air was injected three separate times at each of the flow rates. The fluid level in the oxygenator was decreased below the level sensor at each flow rate to test the PIM. The air bubble detector was then placed 50 centimeters after the roller pump and the tests were repeated at flow rates of 6 LPM, 4 LPM, and 2 LPM. The above tests were repeated using the Bentley Ben 10 and Cinco pump. (Figure 2) The Cinco pump was clamped out of the circuit and the above tests were repeated using the Biomedicus 520, Cobe CML oxygenator and Bentley BEN 10. (Figure 1 and 2)

Clinical Evaluation

The purpose of the clinical evaluation was to verify the safety, efficacy, and user advantages of the PIM in the clinical setting.

[a] Cardiovascular Instruments, Inc., Wakefield, MA 53701
[c] Biomedicus, Minnetonka, MN 55343
[d] Cobe Laboratories, Inc., Lakewood, CO 80215
[e] Baxter Bentley Laboratories Inc., Irvine, CA 92714
[f] Cobe Laboratories, Inc., Lakewood, CO 80215
[g] Ohio Medical Products, Madison, WS 53701

EX-VIVO CIRCUIT WITH MEMBRANE OXYGENATOR

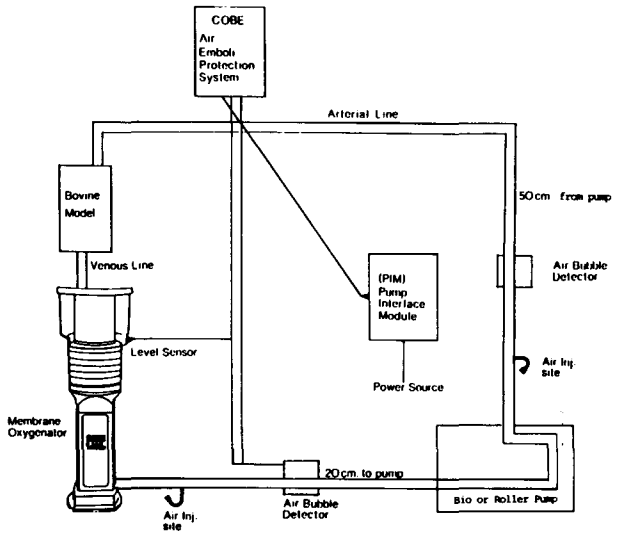

Figure 1. Ex vivo circuit with membrane oxygenator

The clinical evaluation of the PIM was a multi-center study lasting about four weeks. There were five different types of pumps evaluated on 160 open heart procedures. Each hospital was supplied with a PIM and an AEPS to be used on the hospital's unmodified heart lung machines.

The different pumps and the number of procedures are as follows: Cinco (n=28), Sarns 5000 (n=47),[h] Sarns 7000 (n=33),[i] Biomedicus 520 (n=27), and Biomedicus 540 (n=25).[j]

The PIM and AEPS were tested before each case and after termination of bypass on every case.

Results

Ex-Vivo

The PIM immediately shut off the arterial pump at each of the flow rates tested, when either the level sensor or bubble detector was tested. The placement of the air bubble detector 20 centimeters before and 50 centimeters after the pump did not affect the performance of the PIM. The PIM immediately shut off after air injection regardless of the type/brand of pump or oxygenator tested.

Clinical Evaluation

The PIM proved to be an effective and practical safety device when used with the tested pumps. When

[h] Sarns Inc. / 3M, Ann Arbor, MI 48103
[i] Sarns Inc. / 3M, Ann Arbor, MI 48103
[j] Biomedicus, Minnetonka, MN 55343

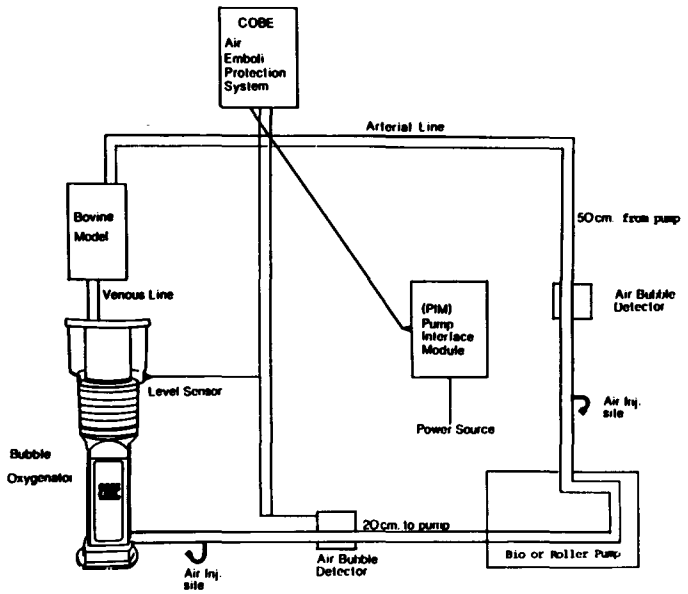

Figure 2. Ex vivo circuit with bubble oxygenator

the PIM received an alarm signal from the AEPS, the arterial pump stopped immediately on all cases with all clinical pumps.

Discussion

In this study the PIM proved to be an effective, practical, easy to use safety device. One of the chief advantages of the PIM is that it can be used with an off-the-shelf Air Emboli Protection System (bubble detector and level sensor). One disadvantage of the PIM is that the holder is not universal or easy to mount on all pumps. Also, when using the PIM with the Biomedicus 540, (which has an internal battery for power failure), the battery must be turned off during bypass for the PIM to shut off the arterial pump. Some users found the low level sensor of the AEPS not easily adaptable to softshell reservoirs, while others had no problems.

Suggestions we have made to improve the PIM are to design a universal, easy to mount holder for all pumps, and a battery back up for the PIM/AEPS if a power failure occurs. Other suggestions are to design the PIM/AEPS smaller and more compact, and design the low level sensor to be more easily adaptable for both hardshell and softshell reservoirs.

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References

1. Stoney, W, Alford, W, Burrus, G: Air embolism and other accidents using pump oxygenators. *Ann. Thorac. Surg.* 29 (4)p:336–340, 1980.
2. Kurusz, M, Conti, V, Arens, J, et. al: Perfusion accident survey. *Proceedings of the American Academy of Cardiovascular Perfusion.* 7:57–65, 1986.

Questions from the Audience

Tom Utsey, Charleston, SC: Question: Did you make an attempt to look at how small the air bubble could be if you tried a lower volume?
Answer: Yes, we started with as little as .5cc of air. With the injection site being where it was, it was hard using our 1cc syringe. We would inject .5,.7,1.5cc, and up to 2ccs. The air bubbles had to exceed .7cc to shut the unit off.
Frank Hurley, Chicago, IL: Question: Are there any other modifications necessary to install this equipment?
Answer: If you're using a Cobe system, there is a small adaptor that must be installed. Using the centrifugal pump, if the PIM shuts off, you are going to get retrograde flow. You need to be aware of that.