Preventing Massive Gas Embolism During Cardiopulmonary Bypass: A Review of Safety Devices

Earle W. Christman, B.S. and Mark Kurusz, B.A., C.C.P.
The Department of Surgery
Division of Cardiovascular
and Thoracic Surgery
The University of Texas Medical Branch
Galveston, Texas 77550

Introduction

The possibility of passing a gas embolism to the patient undergoing extracorporeal circulation (ECC) is a serious threat to the patient and is of constant concern to the perfusionist. As early as 1914, the dangers of arterial air embolism were made evident by experimentation.[1] Considerable documentation is available outlining the significance of air or gas emboli.[2-5] Specific evidence is also available outlining their effect on vital organs,[6] neurologic damage,[7] intellectual function,[8] or death.[9] In addition, experimental data are available describing the effects of air embolism on laboratory animal models.[10,11] Gas embolism during ECC can occur many ways,[12] and according to a recent survey the most common cause is inadvertent emptying of the oxygenator.[13]

This review arose out of an incident involving an arterial runaway pumphead,[14] during which the arterial reservoir of the oxygenator emptied and gas was passed for a short distance through the arterial extracorporeal circuit. Attentiveness plus quick action by the perfusionist prevented a massive gas embolism from reaching the patient. The fact that, "It can happen to me," was made clearly evident by this accident. A search for currently available anti-gas embolism devices was, therefore, made and is presented in this paper.

Address correspondence to: Earle W. Christman, C.C.P., 10101 Tuxford Road, Richmond, Virginia 23235.

Discussion

The possibility of gas embolism during ECC was a concern to those who designed some of the early heart-lung machines.[15] Nearly all of the units included fail-safe mechanisms of varied types. The most popular concept used for film and disc oxygenators was that of maintaining a constant blood volume by ingenious feedback mechanisms. Basically, these feedback devices maintained the output of either the arterial or the venous pump, or both, depending on the design. Sensing devices consisted of oxygenator blood level sensing electrodes,[16] level floats,[17] tubing diameter sensors,[18] or those that directly monitored oxygenator weight.[19] Recirculation pumps or shunts of various designs also served to maintain a constant volume in these oxygenators by diverting a constant amount of blood into the oxygenator.[20] These early systems were elaborate and sometimes complicated. In fact, some designers strived for complete automation of the ECC system, but such circuitry was correspondingly complex. Today's heart-lung machines are functionally simpler than the earlier systems. However, the perfusionist of today is essentially the same and, therefore, must address the same concerns as those of early perfusionists regarding the safety of the patient.

The overall safe conduct of perfusion requires that a number of basic tenets be followed. First, a line of communication among the surgeon, perfusionist and anesthesiologist is essential. The concept of working as a team should be understood. Secondly, the presence of a second perfusionist to provide assistance during the case is advisable, but not always feasible. The primary perfusionist must know the reaction time for various fluid levels and flow rates. Reaction time is defined as the amount of time required for a perfusionist to react to an acute drop in oxygenation blood volume. It is calculated by dividing the volume in the arterial reservoir by the actual flow rate per minute, the result being the fractional part of one minute during which the perfusionist may react appropriately. Availability of replacement fluid for rapid administration via a quick priming tube in the event of a low circulating volume is also essential. Lastly, the perfusionist should know what to do in the event of an emergency and be mentally prepared for it anytime during the pre-, intra-, or post-pump periods. If these basic criteria are followed, the chances of a mishap occurring are reduced considerably. However, the possibility of gas embolism can never be eliminated. For this reason, it is advisable that safety devices designed to warn of or prevent an impending gas embolism be incorporated into the ECC circuit.

Anti-gas embolism devices may be divided into four categories: 1) those that attach to oxygenators; 2) those in the arterial line proximal to the arterial pumphead; 3) those that function as blood pumps; 4) and those in the arterial line distal to the arterial pumphead.

Devices That Attach to Oxygenators

A non-invasive level sensor system is currently available[A] and has been previously described.[21] A metallized tape is placed directly on the hard-shell arterial reservoir at a blood level at which the perfusionist chooses to be alerted. A detector, capable of discerning changes in electrical capacitance, is attached to the tape and plugged into a control box that emits an audible and visual warning of low blood level. In addition, it may be adapted to simultaneously shut off the heart-lung machine should the level fall below the sensor. This system adds little cost to the ECC circuit and is adaptable to all commercially available hard-shell oxygenators. The system is available as a built-in option on one manufacturer's[B] heart-lung machine.

Also currently available are photo-cell sensors that can be clipped, taped or applied by means of suction cups to the front of hard-shell oxygenators. One heart-lung machine manufacturer[C] offers a photocell sensor system that can be positioned to alarm for both high and low blood level situations. When run in the automatic mode, the arterial pumphead will shut off automatically if the blood level falls to low. In the manual mode, this feature may be over ridden, but audible and visual alarms will continue to alert the perfusionist. Similar photo-cell systems are offered by other manufacturers[D,E,F] without the high level sensor feature. (Refer to Tables I and II for detail).

An interesting anti-gas embolism concept used by another heart-lung machine manufacturer[G] is one that measures oxygenator weight. The control utilizes a transducer-activated feedback system that automatically regulates the speed of the arterial pumphead. Maintenance of a constant oxygenator blood volume is thus attainable, and it is reportedly sensitive to level fluctuations of ±5 cc's.[22,23]

When using an anti-gas embolism system that features automatic arterial pumphead shut down, it is the perfusionist's responsibility to apply clamps to the arterial and venous lines immediately upon cessation of pumping should the system be activated. This will prevent any upward advance of gas towards the heart due to density gradients and also prevent exsanguination of the patient through the venous line. It is also the perfusionist's responsibility to make sure that all gas is purged from the arterial line and that a sufficient volume is in the oxygenator in order to reinstitute cardiopulmonary bypass.

Devices Used Proximal to the Pumphead. A mechanical device which is currently available[A] operates invasively as an arterial in-line ball valve and has been previously described.[24] It is positioned immediately distal to the oxygenator arterial outlet port providing the arterial line is vertical. It is sterile, nonpyrogenic and disposable. If the oxygenator suddenly empties, an aluminum ball firmly seats against an "O" ring preventing massive gas embolism. The sound of collapsed tubing in the pumphead and distal to the valve should alert the perfusionist to stop the pump and correct the condition. This device must be positioned within 25° of vertical, and the manufacturer offers an adapter to assure that correct positioning of the ball valve is maintained when using this device on oxygenators that have horizontal arterial outlets.

Polyvinyl chloride arterial[H] and venous[I] reservoir bags are also effective massive gas embolism traps and will collapse if all fluid is pumped from them providing appropriate ports are closed. Like the in-line ball valve, collapse of arterial pumphead tubing should alert the perfusionist to the condition so that appropriate action may be taken.

TABLE I
Anti-Gas Embolism Devices: Optional and Built-in Systems For Heart-Lung Machines

Console Mfg.	Anti-Gas Mfg.	Part Number	Type & Position	Invasive	Audible/ Visual Alarm	Auto Pump Shutoff
Advanced Med-Science, Inc.	Advanced Med-Science, Inc.	HLM Models C3A, C4A	Automatic Level Regulation on Oxygenator	No	Yes	Yes
American Optical Inc.	American Optical, Inc.	16190-800	Photo-Cell on Oxygenator	No	Yes	Yes
Bio-Medicus, Inc.	Bio-Medicus, Inc.	600	Arterial Pump	Yes	No	No
Cardiovascular Instruments, Inc.	Cardiovascular Instruments, Inc.	450-L	Photo-Cell on Oxygenator	No	Yes	Yes
Cobe/Stockert Laboratories, Inc.	Cobe/Stockert Laboratories, Inc.	See (1),	Infra-Red Sensor on Oxygenator	No	Yes	Yes
PEMCO, Inc.	Delta Medical Industries, Inc.	5706 See (2),	Capacitance Sensor on Oxygenator	No	Yes	Yes
Sarns, Inc.	Sarns, Inc.	See (3), Below	Photo-Cell on Oxygenator	No	Yes	Yes
Sarns, Inc.	Sarns, Inc. (4),	Control: 13530 Sensor 13540	Photo-Cell on Arterial Line	No	Yes	Yes

1. Sensors customized for different oxygenators:

	Part No.
Cobe Optiflo II	43020-1
Shiley	43020-2
Harvey	43020-3
Bentley Q-100	43020-4
Rygg	43020-5

2. Special PEMCO modification of DELTA Medical Industries, Inc. Lev-L Sentry.
3. Sensors for the following oxygenators:

	Part No.
Galen Optiflo	12860
Cobe Optiflo II	14070
Bentley BOS 5 or 10	13630
Bentley Temptrol	10710
Harvey or Shiley	11942

4. Microbubble detector can be electrically coupled with same manufacturer's blood level sensor system or used separately.

A Device That Functions as a Blood Pump. One manufacturer[J] currently offers a centrifugal pump that functions as an effective gross gas emboli trap. The blood pump incorporates three rotator cones that, by nature of their geometry in relation to the blood flow, act as gas bubble traps by forcing bubbles to the pump's central axis due to centrifugal force.[25] The manufacturer, however, states that the pump should not be relied upon as a bubble trap. However, since fluid is required to prime and maintain blood pumping, a large gas embolism will effectively deprime the pump and stop blood flow.[26]

Devices Used Distal to the Pumphead. Although used primarily for particulate microemboli, several companies[K,L,M] offer arterial line filters that have been shown to be efficient as gas embolism traps, and they have been compared in their effectiveness.[27,28,29] It is recommended that a purge line connected from the arterial filter to a port vented to atmosphere on the oxygenator be left partially open during the course of the pump run. In the event of a gas embolism, this purge port will provide a low pressure route for its elimination. It is important that the purge line not be connected to the cardiotomy reservoir because of the possibility of cardiotomy pressurization. In this situation, gas generated in the cardiotomy reservoir can be forced retrograde through the purge line into the filter and possibly embolize the patient. The perfusionist

TABLE II
Anti-Gas Embolism Devices: Other Anti-Gas and Warning Systems

Manufacturer	Part Number	Type & Position	Invasive	Audible Alarm	Visual Alarm	Auto Pump Shutdown
Delta Medical Industries, Inc.	LEV-L-Sentry (No part no.)	Capacitance Sensor on Oxygenator	No	Yes	Yes	Yes Optional
Delta Medical Industries, Inc.	ASO-100	Ball-Valve in Arterial Line	Yes	Yes (1)	No	No
Pall Biomedical Products, Corp.	Ultipor 3840,1440	Arterial Line Filter	Yes	No	No	No
Pioneer Filters, Inc.	Swank 45-711	Arterial Line Filter	Yes	No	No	No
Sarns, Inc.	6301, 6302	Bubble-Trap in Arterial Line	Yes	No	No	No
Sarns, Inc.	13824010	Handcrank, Ratcheted	No	N/A	N/A	N/A
Sci-Med Life Systems, Inc.	RV-500-1 RV-1300-1	Venous Reservoir	Yes	Yes (1)	No	No
Surgikos, Div. of Johnson & Johnson Company	Intersept 1330	Arterial Line Filter	Yes	No	No	No
Artificial Organs Div. Travenol Laboratories, Inc.	5M 0314 5M 0317 5M 0318	Oxygenator Arterial Reservoir	Yes	Yes (1)	No	No

1. Collapse of tubing in pumphead causes thumping noise.

must close the purge line at the end of bypass to prevent arterial exsanguination retrograde from the aortic cannulation site. It is encouraging that microemboli filters are effective in removing solid as well as gaseous emboli from the blood.

Bubble traps take advantage of the buoyancy of gas bubbles in a liquid.[30] They are constructed of stainless steel and glass, and must be cleaned and autoclaved before and after each case. Similar devices have been classically described as upflow defoamers[31] and are limited to the amount of gas which they can remove from the system.[32]

Historically, microbubble detectors have been used in both clinical and experimental situations.[33,34] One manufacturer[C] has recently introduced a similar system that uses photocell detection of air bubbles and is reportedly accurate in detection of bubbles one milliliter in volume or greater.[36] The probe is designed for placement on the arterial line and fits 3/8″ (Internal Diameter) × 3/32″ (Wall Thickness) polyvinyl chloride tubing only. It will also shut off the arterial pumphead and can be used in series with their blood level detector system.

Additional Safety Devices. There are a number of safety features inherent in heart-lung machine designs that also bear mentioning.

Voltage surge compensators serve to prevent any alteration in electrical flow that may accompany a sudden transient increase in line voltage. In addition, the electrical reverse control on heart-lung machines can be a possible source for operation error if not adequately designed to prevent accidental depression. Reverse of the arterial pumphead can lead to exsanguination of the patient. Reversal of the vent pumphead can introduce air into the left ventricle or left atrium.

Hand cranks made to crank in one direction[C] provide a safety feature[36] that also insures the patient will not be accidentally exsanguinated or, in the case of the vent pump, injured or killed by gas emboli pumped through the vent in the reverse direction.

Summary

The need for incorporating effective anti-gas embolism devices into the ECC circuit is evident. This would ultimately reduce the risk to patients from receiving gas emboli as a result of a mishap during cardiopulmonary bypass. A review of safety devices currently available for preventing massive gas embolism has been made. Two tables are provided that summarize these devices in a convenient form. Table I reviews standard built-in and optional systems available in

heart-lung machines. Table II reviews other anti-gas embolism and warning systems currently available.

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