
Inspection and Preventive Maintenance of Cardiopulmonary Perfusion Equipment and an Overview of Problems

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Preface

ECRI (Emergency Care Research Institute) is an independent, nonprofit organization dedicated to improving patient care through applied research and development, technology assessment, health services research, and teaching.

One of ECRI's major activities is the Health Devices Program; its objectives are to improve the reliability, safety, efficacy, and cost-effectiveness of health care technology. The program includes a monthly journal, *Health Devices*, which provides brand name comparative evaluations of medical devices, detailed reports of medical device hazards and problems related to their use.

With permission, we have excerpted a portion of the recently published *Health Devices* report on perfusion equipment. For the complete article, including useful forms, detailed procedures and a discussion of leakage current from bypass equipment, readers should contact ECRI. Copies of this issue of *Health Devices* (Vol. 9, No. 3) are available for \$45.

Overview of Perfusion Problems

Cardiopulmonary perfusion requires careful preparation and performance. We have recently investigated a number of incidents involving air embolism and heart-lung machines. We believe that the problems uncovered are common to many perfusion procedures and have based the following recommendations on the

results of our investigations. Perfusion teams may have valid reasons for deviating from some of our recommendations, but all of these points should be considered carefully. This discussion is by no means exhaustive, and perfusion teams should review all aspects of their perfusion procedures at regular intervals.

Extracorporeal Blood Circuit

The extracorporeal blood circuit should be as simple as possible. Hang all lines in an uncomplicated manner, and keep them off the floor and visible, if possible. Double-clamp a short piece of tubing and connect it to any unused ports (if not factory-plugged) on the oxygenator to assure sealing. The extracorporeal circuit should have as few connections as possible. Each junction increases blood trauma and increases the risk of disconnection, thereby increasing the risk of blood loss or air entrance.

Any defective or improper connections made in the negative pressure area between the oxygenator and the arterial pump may introduce air into the arterial line. A leak of any kind will suck air into the arterial line, introducing bubbles into the blood that may be too small to be seen, especially at high flow rates. Therefore, connections in this area should be kept at a minimum. Ideally, one continuous tubing length should extend from the arterial port of the oxygenator through the blood pump. Straps to secure the tubing onto the arterial port of the oxygenator should be considered.

Before beginning bypass, check the integrity and functioning of all components of the bypass circuit. When bypass is terminated, clamp the arterial and venous lines as close to the patient as possible. This will

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reduce the possibility that air from the perfusion equipment will enter the patient.

Scavenging (Suction) System

Blood returned from the surgical site via intra- or extracardiac suction or vent lines should not be returned directly to the oxygenator. The scavenging system is indiscriminate in what it returns from the surgical site, and all suction should be returned to a cardiomy reservoir for filtration and defoaming before returning to the oxygenator. Particulate matter and ambient air may be returned directly to the oxygenator if a cardiomy reservoir is not used. Return of blood and air directly to the oxygenator can increase the risk of emboli (particulate or gaseous).

The internal atmosphere of the oxygenator is normally a mixture of oxygen and carbon dioxide. Both gases are absorbed relatively rapidly by the blood, should small bubbles be pumped inadvertently into the arterial line. By returning the suction lines directly to the oxygenator, it is possible to move ambient air into the oxygenator. Ambient air contains approximately 79% nitrogen, which is not readily absorbed by the blood.

Because blood from the surgical site may contain a variety of particulates (fat, fibrin, tissue), this blood must be filtered before it is returned to the oxygenator. Particulate matter from the surgical site returned directly to the oxygenator can clog the sparger (oxygen diffuser plate) and prevent proper gas exchange.

Due to the high flow rates and negative pressures in the suction lines, as well as to the propensity for air to mix with the blood in these lines, the suction system can be quite traumatic to blood. For these reasons, the perfusionist should keep suction flow rates at a minimum and should allow adequate time for suctioned blood to be filtered and defoamed before being returned to the oxygenator. If suction pumps are used for ventricular venting, their direction must be checked. Reversal of the pump will cause not only air embolism, but also damaging distention of the ventricle.

In some cases perfusionists find it necessary to place a positive pressure on the cardiomy reservoir to return blood rapidly to the oxygenator during bypass. If the arterial blood filter purge line is vented to the reservoir, air might be moved into the arterial line through this purge line. For this reason, the purge line should be vented to the oxygenator. In addition, because suction pumps feed directly into the cardiomy reservoir, high

positive pressures can develop very rapidly in the reservoir if the drain line is partially occluded. Under such pressures, air may be pushed through the reservoir into the oxygenator, or air could flow retrograde through an unocclusive vent line into the patient.

If higher flow rates from the cardiomy reservoir to the oxygenator are desired, elevate the reservoir with respect to the oxygenator at the beginning of bypass. Alternately, pumping of the reservoir blood circuit into the oxygenator can be considered. In any event, excessive pressures should not be allowed to develop in the reservoir. High flow rates can be obtained by pumping or elevation, creating fewer risks than positive pressure in the reservoir. If pressures must be developed in the reservoir, they should be of short duration and constantly monitored by the perfusionist.

If cardiomy suction is required when the patient is off bypass, return the cardiomy reservoir to ambient pressure. Pressurizing the cardiomy reservoir at this time is unnecessary and may allow air to enter the oxygenator or arterial line.

Extracorporeal Filtration

In our opinion, extracorporeal filtration via blood line filters should always be used in the arterial line, especially when blood is used to prime the oxygenator. Arterial blood filters should be used during bypass to trap both gaseous and particulate emboli from extracorporeal components and the surgical site, as well as emboli caused by the procedure itself.

The hazards of unfiltered suction were discussed previously. The oxygenator is not intended to filter blood; its main purpose is to oxygenate and defoam. Emboli have been implicated as the cause of gross pathologic changes of downstream organs. Embolic sources may be fat, platelets, foreign materials, gas, silicone, anti-foam compounds, fibrin, silica, or other aggregates. The literature contains numerous reports of disorders linked to particulate matter from extracorporeal circulation. Changes in the blood due to extracorporeal circulation and particulate matter from tubing sets (spallation, i.e., the breaking off of small bits of tubing from repeated blood pump stress) and oxygenators have been reported. Although some controversy exists in the literature concerning extracorporeal filtration, it is safer, at this time, to filter than not to filter. The extracorporeal blood circuit should incorporate at least one filter (arterial line) in addition to the filtration provided by the cardiomy reservoir. An

additional blood filter may be required, depending on the level of filtration provided by the cardiomy reservoir. Particulate matter in oxygenators and tubing sets has led some perfusionists to perform pre-bypass filtration.

Equipment

The perfusionist must have access to the perfusion setup and to information on blood pressure and blood chemistry throughout the perfusion. The perfusion setup and pressure monitoring equipment must be in the direct view of the perfusionist. The perfusionist should be able to view the mean arterial and left atrial pressures (value and waveform) while simultaneously viewing the oxygenator, cardiomy reservoir, arterial blood filter, and extracorporeal tubing. Team perfusion may help prevent or minimize the severity of perfusion problems. Information on blood chemistry (clotting time and electrolytes) with blood gases should be available on a "stat" basis (within 5 minutes). If this cannot be achieved using the hospital lab, consider purchasing blood gas equipment.

Documentation

A perfusion record which is complete and provides all relevant information should be kept for each procedure. Of course, general information should be included regarding date, patient, medical record, diagnosis, surgical team (surgeon, anesthesiologist, perfusionist), and procedure. Specific information should be listed concerning starting and stopping of bypass, priming volumes, partial bypass time, and fluids and drugs administered. [If blood products are given, serial numbers should be recorded.] Flow rates (blood and gas), pressures, temperatures, blood chemistry data, heparin status (Activated Coagulation Time), and urine output should be charted at regular intervals throughout the procedure (every 10-15 minutes), or when parameters change. Disposition of blood volume remaining in the oxygenator and any other comments pertinent to the perfusion should be noted. The lot and

serial numbers of all disposable components used in the procedure should be recorded, including the tubing set, filters, and oxygen electrodes. If a prosthesis is involved, its type, model, and serial number should be listed. (A sample perfusion record is included in the complete article.)

In addition to the perfusion record, a protocol and checklist should be developed. The protocol should describe the steps necessary to prepare for the perfusion. The checklist should be used to verify that all components and systems have been checked prior to perfusion.

Inspection and Preventive Maintenance of Equipment

Periodic inspection and preventive maintenance of all perfusion equipment should begin immediately if it is not already done. Requirements for equipment control are outlined in *Health Devices*, Vol. 8, p. 225.

We recommend that heart-lung machines and attendant accessories be inspected after every 100 hours of use or quarterly, whichever comes first, barring specific hospital circumstances or manufacturer recommendations to the contrary. This procedure is intended as a supplement to manufacturer's maintenance procedures; the requirements detailed are presented in the absence of specific manufacturer information. Manufacturer recommendations for specific components or equipment should be included in the hospital's procedure. Pump occlusion should be checked by the perfusionist before each procedure.

The following inspection procedure should be performed by personnel who fully understand the technical characteristics and clinical applications of the units tested. If equipment is not routinely inspected by the perfusion team, maintenance personnel should work closely with users to familiarize themselves with the equipment and its use environment. A detailed, step-by-step procedure for inspecting heart-lung bypass units is included with the complete article.