Original Article

Extracorporeal Circuit Sterility after 168 Hours

William V. Young, BS, CCT, CCP; Christopher H. Heemsoth, BS, CCP; George Georgiafandis, BS; Daryl C. Mitchell, CCP; Dennis K. Hackett, BS, CCP; and Donald G. Bahna, BS, CCP

Baptist Hospital of East Tennessee, Department of Perfusion, Knoxville, Tennessee

Keywords: cardiopulmonary bypass; extracorporeal circuit; sterility; minimally invasive direct coronary artery bypass

ABSTRACT

One of the most important tasks of the perfusionist is the proper assembly of the extracorporeal circuit (ECC) prior to the initiation of cardiopulmonary bypass (CPB). The ECC is usually assembled, primed and debubbled 30 minutes to one hour prior to the patient entering the operating room. But there are occasions when the ECC may have been set up and the previously scheduled procedure cancelled. Perfusionists in this situation have found themselves in a quandary; dispose of the ECC because of required nursing compliance and the sterility question, or keep it and use it later because of the economic impact on the "bottom line". Some hospitals may have satisfactorily answered the question of ECC sterility after 24 hours without observation, but the few reported papers regarding this issue, and our desire to save these circuits, inspired us to find out if they were in fact sterile after having been open for a long period of time.

The purpose of this study was to evaluate ECC sterility using an open reservoir oxygenator, over a time period of seven days. After obtaining 792 bacterial cultures from three sites within the ECC, the study was terminated. There were no positive bacterial cultures during the study period. Assuming there is no deliberate contamination, pump circuits assembled in an unused operating room can be maintained sterile for a period of seven days.

Address correspondence to:
William V. Young, BS, CCT, CCP
Perfusion Department
Baptist Hospital of East Tennessee
137 Blount Avenue
Knoxville, TN 37920

INTRODUCTION

Cardiac surgery has undergone a tremendous evolution since the earliest attempts to repair cardiac defects. The single most important step in this evolution was the development and refinement of extracorporeal circulation (1). The past forty years of development has created a technology which has been very effective at maintaining life. After millions of total body perfusions world wide, the use of cardiopulmonary bypass (CPB) has enabled cardiac surgeons to perfect their cardiac surgical skills, such that open heart surgery is now an every day experience, with mortality rates approaching 1% (2). Yet, despite the dramatic advances of extracorporeal technology, it still remains an imperfect solution for cardiac surgical patients.

Unfortunately, extracorporeal circulatory support results in far too many complications, from stimulation of the complement system (3, 4) and its subsequent total body inflammatory response, to deficient cerebral perfusion resulting in neuropsychological impairment (5, 6), all of which add to the significant cost associated with cardiac surgery. In an attempt to eliminate the complications associated with CPB, and to minimize its costs, surgeons have recently revived coronary revascularization without the use of CPB (7-9). This procedure is now known as minimally invasive direct coronary artery bypass (MIDCAB™) (9).

MIDCAB presents the heart surgery program with a paradox. On one hand, the concept of MIDCAB is to minimize the overall cost of the procedure by minimizing the morbidity rate and the disposable cost associated with CPB (8), while at the same time maintaining the safety and security of the currently performed standard procedure. Because of MIDCAB's technical difficulty and the potential for problems, we have found that many heart surgery programs performing MIDCAB require the extracorporeal circuit (ECC) be set up with a perfusionist on stand-by for the duration of the procedure (9). Other heart surgery programs, in an effort to optimize cost savings, have opted to perform MIDCAB without perfusion availability (8).

In anticipation of performing MIDCAB at Baptist Hospital of East Tennessee, we have undertaken the following study to determine the safety and efficacy of keeping ECCs set up for a prolonged period of time. The primary goal of this study was to determine how long our current ECC would remain sterile and therefore usable, once it was assembled.

MATERIALS AND METHODS

Twelve extracorporeal circuits, consisting of a flat sheet open system membrane blood oxygenator with an integral cardiotomy filter[a] and a custom heart lung tubing pack[a] were assembled in standard sterile fashion. The oxygenators were manufactured and shipped with the lid of each reservoir unlatched for access to sampling the inside of the reservoir. The assembled circuits were identical to the standard perfusion circuits used by our group for each CPB procedure. The twelve circuits were divided into two groups; Group A consisted of six dry circuits and Group B consisted of six wet circuits. The wet circuits were primed with 2 liters of Plasma-Lyte A 7.4[b] standard I.V. solution. After assembly, each extracorporeal circuit was removed from the heart lung machine and placed on a standard stainless steel table for the duration of the study. These assemblies were kept in an unused operating room for a seven day period. During that seven day period, operating room personnel were permitted to travel through this area with and without masks. They were also permitted to procure equipment from this area, but were cautioned not to touch the assembled ECCs.

Each assembled ECC was cultured at three different locations; the three sample locations were as follows:

1. Just inside the lid of the reservoir and on the defoaming sock.
2. Inside the venous connector.
3. Inside the membrane outlet.

Sampling occurred at the time of assembly for control and then every eight hours for 7 days. As part of the study protocol, if any of the control samples were positive for microbial growth, the study was to be aborted.

Extreme care was taken to prevent contamination of the circuit during the sampling process since tubing had to be removed and then reattached for every sample taken. To prevent the emptying of the wet circuits during sampling, opening of the arterial sampling port at the membrane outlet allowed for a controlled amount of fluid to be drained and therefore sampled. Sterile cotton swabs were used to take samples from the three locations. Each swab was then used to innoculate a labeled petri dish containing commercially prepared agar of Trypticase Soy Agar with 5% Sheep Blood[c]. Sterile agar plates were stored at 5°C until innoculated and then were incubated at 30°C. Incubation of each plate was for a period of at least 72 hours, unless microbial or fungal growth was detected. Analysis of growth was made by a qualified microbiology technologist. Plates were analyzed for growth every 24 hours up to 72 hours, unless the technologist determined additional incubation was required.

The operating room temperature was maintained between 16.0 and 18.7°C with a mean temperature of 17.0°C. The relative humidity was maintained between 29.6% and 47.0% with a mean relative humidity of 30.7%.

RESULTS

The twelve ECCs were maintained within this controlled environment for a period of 168 hours or seven days. Agar plates were evaluated for microbial growth, according to our institutional protocol.

Each plate was analyzed for bacterial, fungal and yeast

a COBE Cardiovascular, Inc., Arvada, CO. Catalog #050-222-000
b Baxter Healthcare Corp., Deerfield, IL 60015
c Becton Dickenson Microbiology Systems, Cockeysville, MD

growth. For the controlled period of seven days, 792 cultures were taken, yet no microbiological growth could be detected in Group A, Group B, or the control samples.

DISCUSSION

For many years there has been debate among nurses and other health care workers over the concept of what constitutes a sterile field, as well as the life of a sterile field. Historically, institutions have relied upon one or more resources for infection control guidance – the Center for Disease Control in Atlanta, institutional Infection Control Department procedures, or historical nursing tenets – to resolve this issue. Techniques for maintaining sterile fields have included covering the sterile field with sterile drapes, using time indicators to limit the period of time a sterile field would be considered safe for use after set up, and using event oriented determination of sterility. Event oriented determination of sterility requires the presence of a qualified observer. Event oriented contamination is the most accurate determination of sterility because an individual is immediately available to identify and report any break in the sterile environment. Most hospitals utilize event determination of sterility, which is the current AORN standard used to define the sterile environment. However, it is not uncommon for perfusionists within these same institutions to utilize an entirely different standard with respect to the ECC. Within many institutions perfusionists often have described these circuits as being a "closed system" which can be maintained sterile, and therefore, used after having been set up for 24 hours or more. For many years perfusionists have set up pump circuits in advance of scheduled procedures or in case of emergency. There are descriptions of pumps being assembled and kept sterile for up to 60 hours (11) after initial set up. Furthermore, pumps have been set up in offices, pump rooms, hallways, and operating rooms and then used when needed to prevent the loss of equipment due to cancellation of a procedure (11). It is important to understand that there are truly "closed systems" as well as "open systems". "Closed systems" refer specifically to ECCs where the blood path is sealed from exposure to the atmosphere and any airborne microbes. "Open systems" refer specifically to any ECC consisting of a non sealed reservoir capable of allowing air to enter and exit passively to the surrounding environment. It is clear that true "closed systems", assembled properly, would have a sterile blood path for the duration of our study period. They were therefore excluded from this study. Conversation with manufacturer representatives indicate that "open systems" comprise about 70% of the ECC market. "Open systems" are the type of circuits utilized at our institution and are the most vulnerable to passive contamination, which is why they were the target of this study.

ECCs are usually assembled, primed, and debubbled just prior to the patient being brought into the operating room. But, because of the time associated with the assembly process and the time associated with obtaining a perfusionist who might not be standing by, a preassembled ECC would allow a safer procedure by eliminating the risks associated with the emergent assembly process. In an emergency a perfusionist strives to save as much time during the assembly as possible. This is to insure the patient is placed on CPB as quickly as possible. In the case of MIDCAB, emergent assembly might be the result of cardiovascular compromise or it might be required because the surgeon has had to abort a previously planned procedure due to technical difficulty.

This study has shown that either primed or unprimed, the ECCs used at Baptist Hospital of East Tennessee could be maintained sterile for at least seven days. These circuits were maintained in an unused operating arena with uncontrolled access by operating room personnel. Although not part of the original study, at the end of the seven day study period, these perfusion circuits were placed in a general hallway used for equipment storage and patient transport. At the end of 84 hours an additional set of 36 cultures were obtained and incubated. Still, no microbiological activity was found on these cultures. After this final sample was taken each ECC was purposely contaminated by placing a hand inside each reservoir. Forty-eight hours later, all of the wet circuits contained turbid priming solution indicating possible microbiological contamination.

REFERENCES

1. Galletti PM, Brecher GA. Heart Lung Bypass Principles and Techniques of Extracorporeal Circulation. New York, Grunne & Stratton. 1962.
2. Boylan MJ, Lytle BW, Taylor PC, Loop FD, Proudfit W, Borsh JA, Cosgrove DM, III. Have PTCA failures requiring emergent bypass operation changed? Ann Thorac Surg. 1995; 59: 283-286.
3. Kirklin JK, George JF, Holman W. The Inflammatory Response to Cardiopulmonary Bypass. In: Cardiopulmonary Bypass Principles and Practice. Baltimore: Williams & Wilkins. 1993; 233-248.
4. Beckley PD, Holt DW, Tallman RDJr. Oxygenators for Extracorporeal Circulation. In: Cardiopulmonary Bypass Principles and Techniques of Extracorporeal Circulation. New York: Springer-Verlag. 1995: 213-214.
5. Rogers AT, Newman S P, Stump DA, Prough DS. Neurologic Effects of Cardiopulmonary Bypass. In: Cardiopulmonary Bypass Principles and Practice. Baltimore: Williams & Wilkins. 1993; 542-576.
6. Mora CT, Murkin JM. The Central Nervous System: Responses to Cardiopulmonary Bypass. In: Cardiopulmonary Bypass Principles and Techniques of Extracorporeal Circulation. New York: Springer-Verlag. 1995: 126-135.
7. Ullyot DT. Look ma, no hands! [Editorial]; Ann Thorac Surg. 1996; 61: 1-5.
8. Buffolo E, Silva de Andrade JC, Rodriques Branco JN, Teles CA, Aguiar LC, Gromes WJ. Coronary artery bypass

grafting without cardiopulmonary bypass. Ann Thorac Surg. 1996; 61: 63-66.
9. Acuff TE, Landreneau RJ, Griffith BP, Mack MJ. Minimally invasive coronary artery bypass grafting. Ann Thorac Surg. 1996; 61: 135-137.
10. Homishak M, Widmer S, Klementovich M, Cunningham J, Oblack D. Sterility of previously assembled cardiopulmonary bypass circuits. J Extra-Corpor Technol. 1993; 25(3): 84-86.
11. Chorak J, Leader I, Patterson M, Kumar A. Sterility of assembled heart-lung pump beyond 48 hours. Am J Infec. 1990; 5: 328-331.